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

# FORM 10-K

**(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, 2024**

**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**

# Humacyte, Inc.
**(Exact name of registrant as specified in its charter)**

| **Delaware** | **85-1763759** |
|---|---|
| (State or other jurisdiction of incorporation or organization) | (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, a smaller reporting company or an emerging growth 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 | ☐ | Accelerated filer | ☐ |
| Non-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. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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, 2024, 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 $453.2 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 March 27, 2025, 155,118,816 shares of common stock, par value $0.0001, were issued and outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the Registrant's Proxy Statement relative to the 2025 Annual Meeting of Shareholders are incorporated by reference in Part III hereof.

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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 plans and ability to commercialize Symvess™ (acellular tissue engineered vessel-tyod or "ATEV™") and, if approved by regulatory authorities, our product candidates, successfully and on our anticipated timelines;
- the degree of market acceptance of and the availability of third-party coverage and reimbursement for Symvess and, if approved by regulatory authorities, our product candidates;
- our ability to manufacture Symvess and, if approved by regulatory authorities, our product candidates in sufficient quantities to satisfy our clinical trial and commercial needs;
- the expected size of the target populations for Symvess and, if approved by regulatory authorities, our product candidates;
- the anticipated benefits of our ATEVs relative to existing alternatives;
- our assessment of the competitive landscape;
- our plans and ability to execute product development, process development and preclinical development efforts successfully and on our anticipated timelines;
- our plans, anticipated timeline and ability to file applications for, and obtain marketing approvals from the United States ("U.S.") Food and Drug Administration ("FDA") and other regulatory authorities, including the European Medicines Agency ("EMA"), for our ATEVs and 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 V007 and V012 Phase 3 clinical trials;
- the outcome of our ongoing discussions with the FDA concerning the design of our clinical trials;
- our anticipated growth rate and market opportunities;
- our ability to use our proprietary scientific technology platform to build a pipeline of additional product candidates;
- the characteristics and performance of our ATEVs;
- our expectations regarding our strategic partnership with Fresenius Medical Care Holdings, Inc. ("Fresenius Medical Care") to sell, market and distribute our 6 millimeter ATEV for certain specified indications and in specified markets, if approved by regulatory authorities;
- 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 involvement in existing or potential claims and legal proceedings, and the merits, potential outcomes and effects of both existing and potential claims and legal proceedings, as well as regulatory determinations, on our business, prospects, financial condition and results of operations;
- our ability to attract, retain and motivate qualified personnel and to manage our growth effectively;
- our estimates regarding how long our existing cash and cash equivalents will be sufficient to fund our anticipated operating expenses, capital expenditures and debt service obligations;
- our future financial performance and capital requirements, including our ability to raise additional capital in the future;
- our ability to implement and maintain effective internal controls;
- the potential liquidity and trading of our securities; and
- the impact of the overall global economy and increasing interest rates and inflation on our business.

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 statements are based on information current as of the date of this Annual Report on Form 10-K and speak only as of the date on which such statements are 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 of this Annual Report on Form 10-K titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations." 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 a commercial-stage biotechnology platform company developing universally implantable, bioengineered human tissues at commercial scale, and in the first quarter of 2025 commenced the United States commercial launch of our first FDA-approved product. We are pioneering the development and manufacture of off-the-shelf, universally implantable, bioengineered human tissues, advanced tissue constructs and organ systems with the goal of improving the lives of patients and transforming the practice of medicine. We believe our regenerative medicine 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 acellular tissue engineered vessels, or ATEVs™. On December 19, 2024, the FDA granted full approval for the ATEV under the brand name Symvess™ for use in adults as a vascular conduit for extremity arterial injury when urgent revascularization is needed to avoid imminent limb loss, and autologous vein graft is not feasible. Our ATEVs 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 ATEVs with varying diameters and lengths. The ATEV cabinet is initially targeting the vascular repair, reconstruction and replacement market, including vascular trauma, arteriovenous ("AV") access for hemodialysis, and peripheral artery disease ("PAD"). We are also developing the ATEV for coronary artery bypass grafting ("CABG") and pediatric heart surgery. Over the longer term, we are developing our ATEV for the delivery of cellular therapies, including pancreatic islet cell transplantation to treat Type 1 diabetes (our BioVascular Pancreas™ or "BVP"). 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.

For the ATEV, 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 complications such as amputation and reperfusion injury. In addition, in many instances of vascular trauma the patient may not have adequate vein available, or the time between injury and treatment is too long to make autologous graft repair feasible. Synthetic grafts are often contraindicated in the setting of vascular trauma due to wound contamination that contributes to higher infection risk that can lead to prolonged hospitalization and limb loss. Given the competitive advantages our ATEVs are designed to have over existing vascular substitutes, we believe that ATEVs have the potential to become the standard of care and lead to improved patient outcomes and lower healthcare costs.

As of December 31, 2024, our ATEVs have been implanted in approximately 601 patients. In addition to vascular trauma, we and our collaborators are currently conducting Phase 3 and Phase 2 trials of our 6 millimeter ATEV in AV access for hemodialysis and PAD. We were granted Fast Track designation by the FDA for our 6 millimeter ATEV 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 May 2023, we were granted the RMAT designation for the ATEV for urgent arterial repair following extremity vascular trauma, and in June 2024, we were granted the RMAT designation for the ATEV for patients with advanced PAD. In addition, in 2018 our ATEV 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. In September 2023, we announced positive topline results from our V005 Phase 2/3 trial in vascular trauma, and in December 2023 we filed a Biologics License Application ("BLA") for urgent arterial repair following extremity vascular trauma when synthetic graft is not indicated, and autologous vein use is not feasible. In February 2024, the FDA accepted the BLA filing, granted Priority Review and set a Prescription Drug User Fee

Act ("PDUFA") date, the FDA action date for its regulatory decision regarding the BLA, of August 10, 2024. On August 9, 2024, the FDA informed us that it required additional time to complete its review of the BLA for the vascular trauma indication. On December 19, 2024, the FDA granted full approval for Symvess (acellular tissue engineered vessel-tyod) for use in adults as a vascular conduit for extremity arterial injury when urgent revascularization is needed to avoid imminent limb loss, and autologous vein graft is not feasible.

In April 2023, we announced completion of enrollment of our V007 Phase 3 trial of the ATEV for use in AV access for hemodialysis. In July 2024, we announced positive topline results from our V007 Phase 3 trial, where the ATEV met the co-primary endpoints in the study. Dependent upon interim results from our ongoing V012 Phase 3 trial of the ATEV for use in AV access for hemodialysis in women, we plan to submit a supplemental BLA for the ATEV to the FDA for an indication in AV access for hemodialysis in the second half of 2026.

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 ATEVs 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 Symvess and our product candidates, the composition of Symvess and our product candidates and systems and methods of manufacturing Symvess and our product candidates. 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 Chair 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" and collectively with the other transactions described in the Merger Agreement, the "Reverse Recapitalization"). 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:

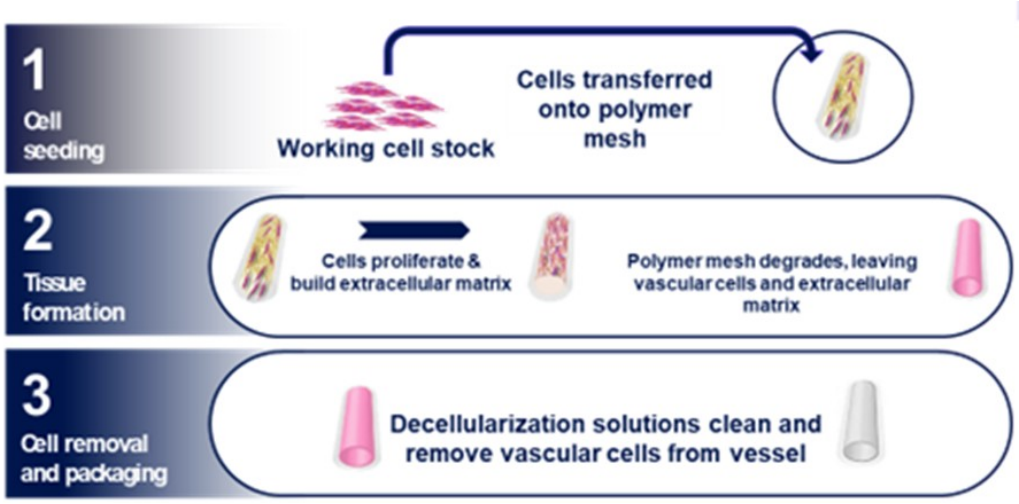
- our proprietary scientific and engineering technology platform allows us to grow human tissues, which are ultimately decellularized and therefore expected to be non-immunogenic and universally implantable; and
- our novel, scalable manufacturing paradigm is designed to allow us to produce thousands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

Over time, we intend to develop a readily available "cabinet" of ATEVs of varying diameters and lengths to address the significant unmet needs across multiple potential indications in 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 that have been 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 ATEV 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 ATEV to be grown, decellularized and ultimately shipped within the same flexible bioreactor bag. Our ATEVs are designed to be shipped to hospitals, trauma centers and outpatient surgical settings, where they can then be refrigerated for immediate use by removing each ATEV 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 ATEVs in smaller batches for clinical trials and scale out to larger batches for commercial manufacturing. In 2021 we commenced supplying our ongoing clinical trials with ATEVs produced in our current, commercial-scale LUNA200™ system, which consists of 20 growth drawers per production unit for a total of 200 ATEVs per batch. Each growth drawer is capable of producing ten 42cm ATEVs, each of which is contained within an individual bioreactor bag. Inside a LUNA200, a tubing network connects all ATEVs, allowing the entire system to share nutritive media. In this way, a single LUNA200 can produce up to 200 ATEVs (42cm in length) per batch while maintaining the critical operating parameters, such as biomechanical pulsing, that affect growth. The FDA inspected our manufacturing facility in April 2024 as part of its review and approval of our BLA in extremity vascular trauma, and we are using this facility to provide product for the United States commercial launch in that indication which commenced in the first quarter of 2025.

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 ATEVs 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 currently intend to introduce a 13cm-long ATEV line extension after the commercial launch of the 42cm ATEV, for surgeries that require shorter segments of ATEV 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 ATEVs (13cm in length) or 200 ATEVs (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 highly automated, which allows us to control and maximize ATEV production.

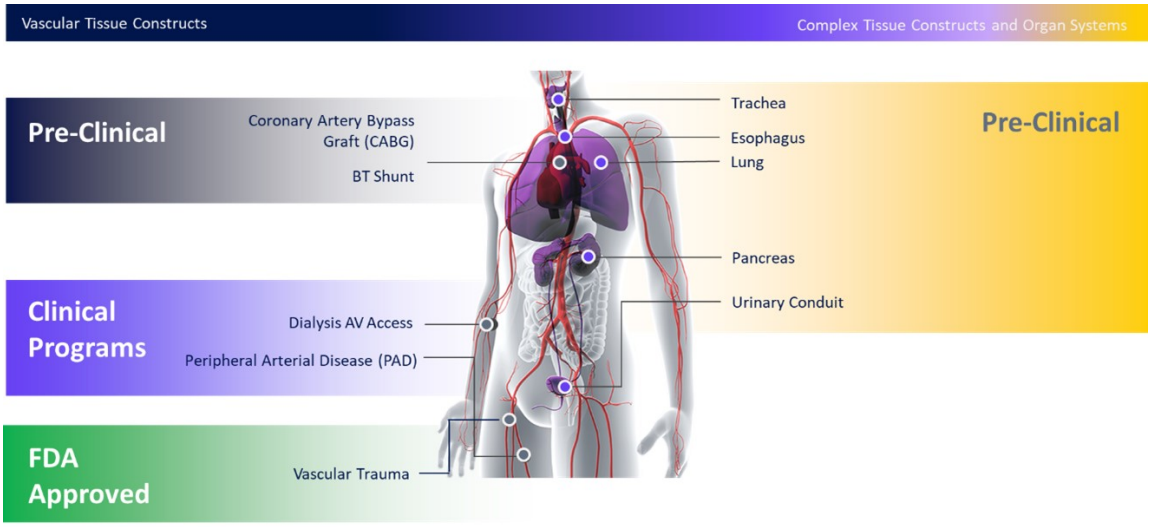
Based on observations to date, the ATEV has withstood maximal pressures that are comparable to those reported for native arteries. For example, the human aorta is reported to have rupture strengths around 1,400 mmHg, while human cerebral arteries rupture around 1,800 mmHg. We have observed ATEVs withstanding 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 that has commenced the U.S. commercial launch of one FDA-approved product, with Phase 3 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 ATEV in life and limb saving surgeries as demonstrated by their requests to the FDA to use our ATEV in multiple expanded access (compassionate use) cases where no alternative was available, as well as requests from Ukrainian surgeons that led to a humanitarian program conducted during the conflict in that country.

*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, PAD, and adult cardiac surgery. To treat these diseases and conditions, patients often require invasive vascular and 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, workplace and sporting accidents, gun violence, mass casualty terrorist attacks, stabbings, blunt trauma, and iatrogenic injuries (injuries caused by medical treatment or examination). 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 80,000 of all injuries reported in trauma patients in the United States, inclusive of urgent and iatrogenic vascular trauma injuries, and account for greater than 20% of all trauma-related deaths. Based on an analysis of the Definitive Healthcare Claims (DHC) Database 2023, we estimate that approximately 26,000 patients per year will be eligible for the ATEV within the United States (analysis was based on inclusion of patients with major repairs to injuries of the extremities, and the exclusion of patients with vein injuries, injuries to the torso, head, neck, wrist, hand, ankle or foot, or who received ligation or endovascular repair).

We believe our ATEVs are a promising alternative that can address critical gaps in existing treatment options for acute vascular injuries due to trauma. We have developed our ATEVs with the goal of providing an effective solution in all time-constrained surgical environments and in resource-limited, infection prone civilian and battlefield conditions. The ability to provide immediately available, non-immunogenic, universally implantable human vessels that have low rates of infection represents a clinically significant advantage over existing treatment options. In addition, the Budget Impact Model for the ATEV, published in the *Journal of Medical Economics* in March 2025, reported that the ATEV was projected to be cost saving for both trauma centers and third-party payors, primarily due to reductions in the costs related to amputations and conduit infections.

AV 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 2024, over 555,000 patients received 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 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. For hemodialysis patients, an infected access site can lead to sepsis, a life-threatening complication that is the most expensive cause for hospitalization in the United States and carries at least a 10% overall mortality rate.

We believe that our ATEVs, 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 in the second half of 2026 seeking approval for the use of ATEV 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, such as women and male patients with two risk factors, such as obesity and diabetes.

Peripheral Artery Disease: PAD is a cardiovascular disease of blood vessels located outside the brain and heart. Atherosclerosis, which is the buildup of plaque along the artery walls, usually affects arteries in the legs, but it can also affect arteries that carry blood from the heart to the head, arms, kidneys, and intestines. We believe our ATEVs can be used as a bypass conduit in patients suffering from PAD in the legs. Peripheral arterial bypass procedures are common with over 230,000 PAD-related procedures reported annually in the U.S. There are over 200,000 peripheral bypass procedures per year in Europe, and approximately 220,000 per year in Asia.

While endovascular techniques have become more 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 had limited success and durability as compared to conventional surgical bypass. Both angioplasty and stenting procedures provide near term success, however long-term durability has remained a question, as highlighted in the results of the recent BEST-CLI clinical trial published in the *New England Journal of Medicine* demonstrating that patients treated with surgical bypass had fewer major amputations and less need for repeat procedures than those treated with endovascular therapy.

Type I 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 1.7 million people in the United States, and costing at least $10 billion to $14 billion annually. In the EU4 (France, Germany, Italy and Spain) and the UK, the number of patients suffering with Type 1 diabetes is estimated at approximately 1.5 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 a 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 ATEVs 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 ATEV and may be implanted as an AV graft, analogous to the outpatient procedure done for hemodialysis access. After implantation, the islets may have the potential to sense blood glucose and then respond by secreting appropriate levels of insulin to maintain proper glucose levels in the blood. We have termed this new paradigm for pancreatic islet cell delivery the BioVascular Pancreas or “BVP™.”

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.

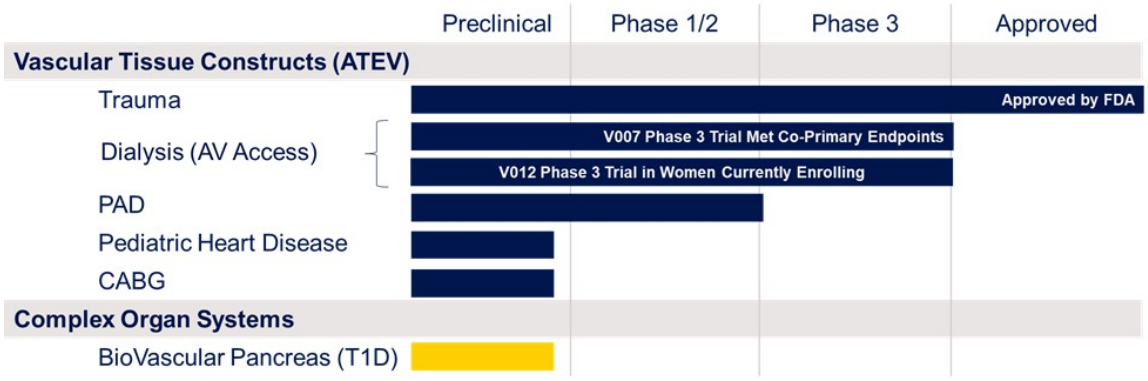
Coronary Artery Bypass Graft: CABG is a surgery used to treat a blockage or narrowing of one or more of the coronary arteries to restore the blood supply to the heart muscle. We believe our ATEVs can replace existing vascular substitutes and improve patient outcomes, particularly in obese patients or those suffering from diabetes, in whom the risks of saphenous vein harvesting are more substantial. CABG procedures are common, with more than 200,000 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. In preclinical testing, we have evaluated a small diameter ATEV ("sdATEV") which is 3.5mm in diameter and 20cm in length for use as a CABG conduit. Testing has been performed in non-human primates, pigs and sheep. We plan to utilize the collective preclinical data on the sdATEV to support an Investigational New Drug ("IND") application to the FDA for CABG during 2025.

Pediatric Heart Surgery: We have evaluated in preclinical testing a smaller diameter ATEV 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 2024, there were approximately 1,800 babies born in the United States 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 ATEV 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 Product Pipeline***

The following table highlights key information about the most active programs within our current product pipeline:




We began clinical evaluations of our ATEVs in December 2012, with the enrollment of the first Phase 2 patient in our V001 hemodialysis access trial in Europe. Since then, we have completed two pivotal and one Phase 2 trials in the United States, and currently have one pivotal trial actively enrolling and two trials in long-term follow-up. In clinical trials and in expanded access cases, ATEVs have been implanted in approximately 85 clinical centers in seven countries around the world, and by more than 100 practicing surgeons.

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

| Clinical Trial Number | Indication | Begin Enrollment | Design/Phase | Number of Subjects | Status | Outcomes** |
|---|---|---|---|---|---|---|
| **Vascular Trauma** | | | | | | |
| V005 | Vascular Trauma | 2018 | Phase 2/3 Single-arm Historical Comparator Unblinded | 72 total. Primary analysis based on a total of 51 patients with injuries of extremities | BLA approved by FDA December 19, 2024 | 30-day PP: 84.3%<br>30-day SP: 90.2%<br>Infection Rate: 2.0%<br>Amputation Rate: 9.8% |

| Clinical Trial Number | Indication | Begin Enrollment | Design/Phase | Number of Subjects | Status | Outcomes** |
|---|---|---|---|---|---|---|
| V017 | Vascular Trauma | 2022 | Retrospective observational study to evaluate the ATEV in real-world setting of humanitarian program conducted during wartime in Ukraine | 19 total treated under humanitarian program. 17 consented for inclusion in study, 16 of whom had injuries of extremities and were included in primary analysis | Included in BLA submission approved by FDA December 19, 2024 | 30-day PP: 93.8%<br>30-day SP: 93.8%<br>Infection Rate: 0%<br>Amputation Rate: 0% |
| **Dialysis Access** | | | | | | |
| V001 | Dialysis Access | 2012 | Phase 2 Single-arm | 40 | Completed | 30-day PP: 95%<br>6-month SP: 100%<br>12-month SP: 97%<br>60-month SP: 58%<br>Infection Rate/yr: 0%<br>Number of Rejections: 0 |
| V003 | Dialysis Access | 2013 | Phase 2 Single-arm | 20 | Completed | 30-day PP: 95%<br>6-month SP: 89%<br>12-month SP: 81%<br>Infection Rate/yr: 4% (1 event)<br>Number of Rejections: 0 |
| V006 | Dialysis Access | 2016 | Phase 3 Prospective Randomized Blinded | 355 total; 177 received ATEV, 178 received ePTFE | Completed | 30-day PP ATEV: 93%<br>12-month SP ATEV: 82%<br>24-month SP ATEV: 67%<br>12-month SP ePTFE: 80%<br>24-month SP ePTFE: 74% Infection Rate ATEV/yr: 0.93%<br>Infection Rate ePTFE/yr: 4.5%<br>Number of ATEV Rejections: 0 |
| V007 | Dialysis Access | 2017 | Phase 3 Prospective Randomized Blinded | 242 total; 123 received ATEV, 119 received AVF | Topline results reported August 2024, two-year follow-up in process | 6-month SP ATEV: 81%<br>12-month SP ATEV: 68%<br>6-month SP AVF: 66%<br>12-month SP AVF: 62% |
| V011 | Dialysis Access | 2019 | Phase 2 (LUNA200 Manufacturing System Bridging Study) | 30 | Completed | 30-day PP: 97%<br>30-day SP: 100%<br>12-month SP: 83%<br>Infection Rate ATEV/yr: 0%<br>Number of ATEV Rejections: 0 |
| V012 | Dialysis Access | 2023 | Phase 3 Prospective Randomized Blinded | Target 150 women total, 76 currently enrolled | Enrollment ongoing | Trial is currently enrolling, interim analysis planned on first 80 patients after one-year of follow up |
| **Peripheral Artery Disease** | | | | | | |
| V002 | PAD | 2013 | Phase 2 Single-arm | 20 | 10-year follow-up ongoing | 30-day PP: 100%<br>6-month SP: 84%<br>12-month SP: 84%<br>72-month SP: 60%<br>Infection Rate/yr: 0%<br>Number of Rejections: 0 |
| V004 | PAD | 2016 | Phase 2 Single-arm | 15 | Completed | 30-day PP: 100%<br>6-month SP: 86%<br>12-month SP: 64%<br>Infection Rate/yr: 0%<br>Number of Rejections: 0<br>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, 2024, approximately 601 patients worldwide have received our ATEVs in clinical trials, and expanded access and humanitarian programs, for the treatment of vascular trauma, AV access for hemodialysis, PAD, and in expanded access cases resulting in approximately 1,277 subject-years of exposure to the ATEV. Our cumulative ATEV exposure is approximately 993 subject-years in the hemodialysis access population, 168 subject-years in the PAD population, and 115 subject-years in the arterial trauma population. The longest our ATEV has been in a patient and used for dialysis is more than ten years and there have been more than 117,000 estimated dialysis sessions using our ATEVs. A total of 29 expanded access/compassionate use cases have been granted by the FDA, and another 28 patients with severe PAD have been treated with the ATEV under an investigator IND at the Mayo Clinic. Lastly, 19 patients suffering vascular injuries during the conflict in Ukraine have been treated with the ATEV under a humanitarian program. Throughout all of these trials and other programs, we have observed that our ATEVs 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 ATEVs, supporting the potential use of our ATEVs as off-the-shelf, universally implantable, bioengineered human tissues.

Overall, the ATEV has functioned well and as intended, across ten different clinical trials in three clinical indications. The ATEV has been implanted in approximately 601 patients, across more than 85 clinical sites in seven countries, over more than ten years as of December 31, 2024. We have observed zero instances of clinical rejection of the ATEV in any clinical trial over the past ten years, suggesting that the ATEV was not immunologically rejected after implantation.

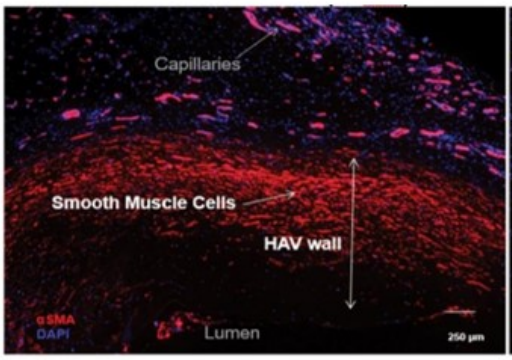
Based on clinical trial results to date, we have observed that the ATEVs have a low infection rate, with an infection rate averaging approximately 1.0% or less per patient-year in our AV access trials, and low infection rates in our trauma and PAD trials (ranging from 0% to approximately 2%, depending on the trial and indication). 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.

*ATEVs Remodel with Host Cells After Implantation*

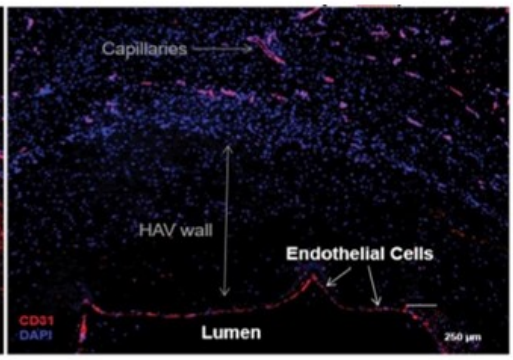
Additionally, based on clinical samples obtained during our Phase 2 AV access trials and published in three peer reviewed journals, *The Lancet* in 2016, *Science Translational Medicine* in 2019, and in the *Journal of Vascular Surgery* in 2020, we observed that the ATEV became populated with healthy, vascular cells from the patient. As described in these publications, over time the patient's cells have been observed to transform the ATEV into a multi-layered living tissue similar to native blood vessels. In these trials we have also observed ongoing cellular repair of ATEV tissues that had been previously injured during cannulation with dialysis needles, which suggests that the recellularized ATEV may be capable of self-healing. The image below shows an ATEV 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 ATEV (line of red endothelial cells indicated in the right-hand panel).

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

**Smooth Muscle Cells (Red)**
**Prominent in ATEV Wall (44 weeks)**




**Endothelial Cells (Red)**
**Line the ATEV Lumen (44 weeks)**



*ATEVs Low Rate of Infection*

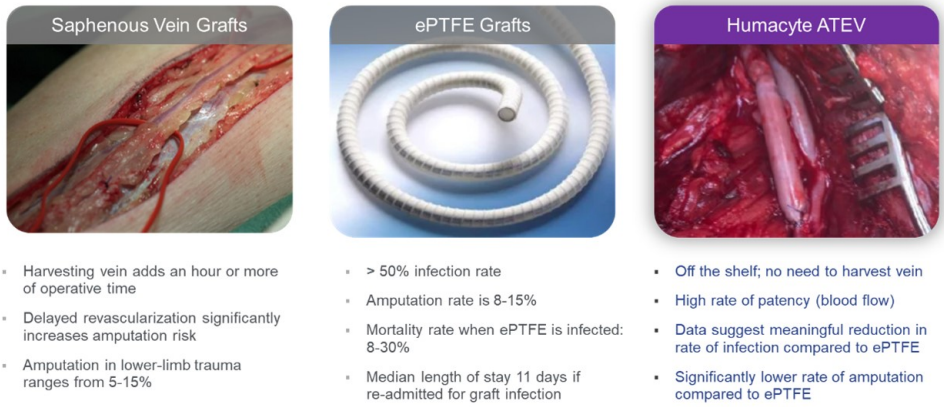
In July 2023, a preclinical study that supported a possible scientific basis for the low rates of infection that have been observed in clinical trials of the ATEV was published in the *Journal of Vascular Surgery – Vascular Science*. This work compared the infection resistance of the ATEV to ePTFE grafts, which are made of plastic. The laboratory results suggest that the bioengineered human tissue of the ATEV may have superior compatibility with the body's own neutrophils (white blood cells that combat bacterial infections) as compared to ePTFE. Histology and laboratory analyses performed in the preclinical study suggests that while human white blood cells die when they come in contact with ePTFE, the cells survive and function in contact with the ATEV, which may improve the ability of the ATEV to fight dangerous infections once implanted in the body.

***Indication #1: Use of ATEV to Repair Extremity 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, workplace and sporting accidents, gun violence, mass casualty terrorist attacks, stabbings, blunt trauma and iatrogenic injuries (injuries caused by medical treatment or examination). 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*




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.

*The ATEV as a Solution for Vascular Trauma*

We believe our ATEVs are a promising alternative that can address critical gaps in existing treatment options for acute vascular injuries due to trauma. We have developed our ATEVs with the goal of providing an effective solution in all time-constrained surgical environments and in resource-limited, infection prone civilian and battlefield environments. The ability to create immediately available, non-immunogenic, universally implantable material that has a low infection rate 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 ATEVs. As a result of this collaboration and partnership with the DoD, we anticipate Humacyte would supply ATEVs for use in military hospitals to treat injured soldiers and veterans. The DoD assigned a priority designation to the ATEV 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 $6.8 million grant from the DoD for the development of our ATEVs for vascular reconstruction and repair.

*FDA Approval of ATEV for Extremity Vascular Trauma*

In May 2023, the FDA granted RMAT designation for use of the ATEV in urgent arterial repair following extremity vascular trauma. In December 2023, the Company filed a BLA with the FDA for urgent arterial repair following extremity vascular trauma when synthetic graft is not indicated, and autologous vein use is not feasible. The BLA submission was supported by results from the V005 Phase 2/3 clinical trial, and real-world outcomes from the treatment of wartime injuries in Ukraine, both of which are described below. In February 2024, the FDA accepted the BLA filing and granted Priority Review, setting a PDUFA date of August 10, 2024. On August 9, 2024, the FDA informed us that it required additional time to complete its review of the BLA for the vascular trauma indication. On December 19, 2024, the FDA granted full approval for Symvess™ (acellular tissue engineered vessel-tyod) for use in adults as a vascular conduit for extremity arterial injury when urgent revascularization is needed to avoid imminent limb loss, and autologous vein graft is not feasible.

*V005 Phase 2/3 Civilian Trial for Vascular Trauma*

**Trial Design:** Our V005 civilian trial was a single-arm, multi-center, non-randomized clinical trial to evaluate the efficacy, safety and tolerability of our 6 millimeter ATEV in replacement or reconstruction of vascular tissues in patients with life or limb-threatening vascular trauma for whom the standard of care, saphenous vein, was not feasible or available for vascular repair. As a single-arm study, the comparators for the ATEV results were derived from a systematic literature review and meta-analysis of studies evaluating synthetic grafts in vascular injury repair. A total of 72 patients were enrolled in the V005 trial, of which 51 had vascular injury of the extremities and comprised the primary evaluation group for the study. The primary efficacy endpoint was patency of the ATEV at 30 days, with 30-day rates of infection and amputation comprising the secondary endpoints.

**V005 Trial Results:**

For the primary analysis group of 51 patients with extremity injury, the range of trauma injuries in V005 were broad, including penetrating trauma cases and blunt injury cases. Mechanisms of injury included motor vehicle accidents, gunshot wounds, industrial accidents, and falls in the V005 trial. The ATEVs were placed throughout the body, including in the lower limbs and upper limbs and were used to repair the axillary artery, femoral artery, popliteal artery and vein, and the brachial artery. Many of the injuries treated in the V005 trial were contaminated injuries that are at elevated risk of graft infection.

The most common reasons reported by clinicians for using the ATEV in the V005 trial instead of the standard of care, saphenous vein, was the need to avoid the time required to harvest saphenous vein (32.3%), the quality of the patient's vein (25.8%), and concomitant injuries to the vein (16.1%), suggesting that the ready, off-the-shelf feature of the ATEV has the potential to save valuable time for surgeons in the restoration of blood flow.

The V005 trial met its objectives. V005 results included in the BLA submission to the FDA and published in *JAMA Surgery*, an American Medical Association peer-reviewed journal, in November 2024, are summarized in the following table.

*V005 Phase 2/3 ATEV Results in Vascular Trauma Compared to Synthetic Graft Benchmark*

| 30-Day Endpoint | V005 Trial ATEV Extremity Group (n=51) (%) | Synthetic Graft Benchmark (%) |
|---|---|---|
| Primary Patency | 84.3% | 78.9% |
| Secondary Patency | 90.2% | 78.9% |
| Conduit Infections | 2.0% | 8.4% |
| Amputations | 9.8% | 24.3% |

In the package insert for Symvess, the FDA applied a different imputing methodology for V005 Symvess patients who did not have a day 30 assessment. For patients who missed day 30 follow-up due to unrelated death or loss of follow-up, patients were imputed as treatment failures (i.e., loss of patency, and failure of limb salvage). The FDA also added three more patients enrolled after data cutoff.

*V005 Phase 2/3 ATEV Results in Vascular Trauma in Package Insert*

| 30-Day Endpoint | V005 Trial ATEV Extremity Group (n=54) (%)* |
|---|---|
| Primary Patency | 66.7% |
| Secondary Patency | 72.2% |
| Conduit Infections | 1.9% |
| Limb Salvage | 75.9% |

* Nine patients not available for Day 30 assessment were imputed as failures for patency and limb salvage estimation.

This imputing methodology used in the package insert was different than that used in the synthetic graft benchmark publications. The FDA elected to exclude the synthetic graft comparator from the package insert.

The safety profile of the ATEV in the V005 trial was consistent with previous studies and there were no cases of clinical rejection of the ATEV. A summary of adverse events (“AEs”) for the duration of the study (mean duration of follow up is 295 days) is included in the table below.

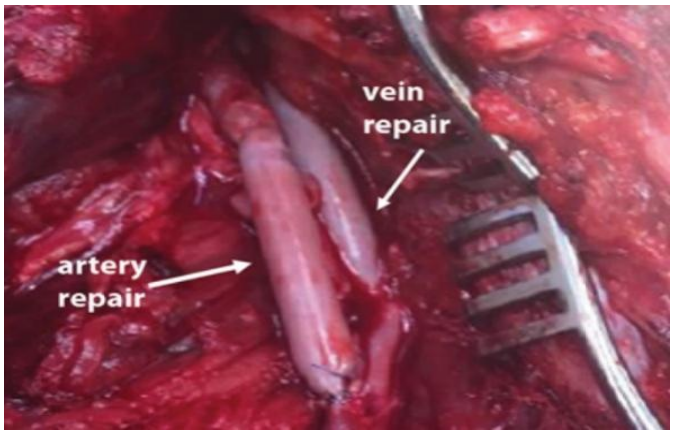
*V005 Phase 2/3 ATEV Adverse Events*

| Adverse Event | V005 Trial - ATEV Extremity Group (n=51) Number of Patients (%) |
|---|---|
| Total Adverse Events | 50 (98.0%) |
| Non-Fatal Serious Adverse Events | 28 (54.9%) |
| Deaths: | |
| At Day 30 | 3 (5.9%) |
| Over Duration of Study | 4 (7.8%) |
| ATEV Infections | 2 (3.9%) |
| ATEV Rupture | 1 (2.0%) |
| ATEV Occlusion/Thrombosis | 15 (29.4%) |
| Pseudoaneurysm | 1 (2.0%) |
| Aneurysm | 1 (2.0%) |
| Other | 2 (3.9%) |

There were no unexpected safety signals for the ATEV in the V005 trial. The most common AEs were thrombosis, anemia, pyrexia, thrombocytopenia, constipation, nausea, peripheral edema, and tachycardia. The most common non-fatal Serious Adverse Events ("SAEs") were thrombosis, anastomotic stenosis, wound infection, muscle necrosis, wound infection, hemorrhage shock, and cardiac arrest. Deaths occurring prior to day 30 were adjudicated as not casually related to the ATEV by an Independent Adjudication Committee.

We believe the V005 trial results indicate that for patients in need of extremity arterial repair, when use of autologous vein was not suitable, and who were at high-risk level for wound infection, the ATEV may offer an effective option for revascularization. A case study from the trial is shown in the figure below, a photograph of an ATEV 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 ATEV repair of popliteal artery (left) and vein (right) in V005 subject.*




*Ukraine Humanitarian Program, - V017 Trial*

**V017 Background and Results:**

In the second quarter of 2022, Humacyte launched a humanitarian initiative to provide its ATEVs to hospitals in Ukraine for the treatment of wounded civilians and soldiers with vascular trauma injuries. Ukrainian surgeons presented patient outcomes from the use of the ATEV to treat wartime vascular trauma at two vascular conferences in December 2022, the VI Congress of Vascular Surgeons, Phlebologists, and Angiologists of Ukraine in Kyiv, Ukraine, and the 11th Munich Vascular Conference (MAC) 2022. The surgeons described long-standing limitations in vascular tissue repair and replacement as well as the injuries that they have observed during the Russian-Ukrainian conflict. Surgeons utilized the ATEV to treat patients with wartime injuries including blast trauma, shrapnel injuries, and gunshot wounds. The surgeons observed that access to the ATEV, a biologic conduit, has improved their ability to perform vascular reconstructions by eliminating the need to harvest a venous conduit. A total of 19 vascular patients were treated under this humanitarian program, and results from 16 of these patients were published in *JAMA Surgery* in November 2024, along with results from the V005 trial.

The FDA advised Humacyte to include in the BLA submission patient outcomes from the Ukraine humanitarian program. We refer to the results for the 16 patients from Ukraine with extremity vascular trauma who provided consent for use of their results in the BLA filing as the V017 trial. A high success rate for the 16 extremity patients in the V017 trial was observed, despite the presence of contaminated wound beds, as summarized in the table below.

*V017 Ukraine Humanitarian ATEV Results in Vascular Trauma*

| 30-Day Endpoint | V017 Trial ATEV Extremity Group (%) |
|---|---|
| Primary Patency | 93.8% |
| Secondary Patency | 93.8% |
| Conduit Infections | 0.0% |
| Amputations | 0.0% |

The safety profile of the ATEV in the V017 trial was consistent with previous studies and there were no cases of clinical rejection of the ATEV. A summary of AEs for the duration of the study (mean duration of follow up is 139 days) is included in the table below.

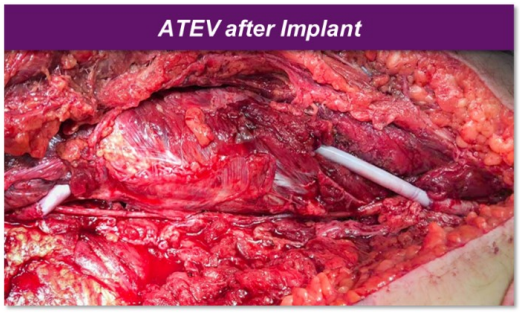
*V017 Ukraine Humanitarian ATEV Adverse Events*

| Adverse Event | V017 Trial - ATEV Extremity Group (n=16) Number of Patients (%) |
|---|---|
| Total Adverse Events | 4 (25.0%) |
| Non-Fatal Serious Adverse Events | 1 (6.3%) |
| Deaths: | |
| At Day 30 | 0 (0.0%) |
| Over Duration of Study | 0 (0.0%) |
| ATEV Infections | 0 (0.0%) |
| ATEV Rupture* | 1 (6.3%) |
| ATEV Occlusion/Thrombosis | 1 (6.3%) |
| Pseudoaneurysm | 0 (0.0%) |
| Aneurysm | 0 (0.0%) |

*One ATEV rupture associated with extensive shrapnel remnants in the wound that caused bleeding.

In the figure below, photographs are shown of the first patient treated under the humanitarian program in Ukraine. The patient was a 42-year-old male who suffered a gunshot wound in the leg which damaged his femoral artery. The patient was initially treated using synthetic graft which became infected, and the patient experienced critical right lower extremity ischemia. The ATEV was implanted as a right superficial femoral artery reconstruction to achieve wound healing and limb salvage. After three months, the ATEV was reported to have retained primary patency with no evidence of ATEV infection.

*Intra-operative photographs of attempted synthetic graft repair of femoral artery (left) and subsequent repair with ATEV (right) in patient from Ukraine humanitarian program.*

*Combined V005 and V017 Results of ATEV for Vascular Trauma*

The BLA submission was supported by the combined results from the V005 (civilian) Phase 2/3 clinical trial and real-world outcomes from the treatment of wartime injuries in Ukraine in the V017 (military) trial. Combined results included in the BLA submission to the FDA and published in *JAMA Surgery* in November 2024 are summarized in the following table. The Synthetic Graft Benchmark publications included a combination of civilian and military injuries.

*Combined V005 Phase 2/3 ATEV and V017 Ukraine Real-World Results in Vascular Trauma Compared to Synthetic Graft Benchmark*

| Outcome Day 30 | ATEV V005 (n=51) | ATEV V017 (n=16) | Combined ATEV (n=67) | Synthetic Graft Benchmark |
|---|---|---|---|---|
| Primary Patency | 84.3% | 93.8% | 87.1% | 78.9% |
| Secondary Patency | 90.2% | 93.8% | 91.5% | 78.9% |
| Conduit Infection Rate | 2.0% | 0.0% | 0.9% | 8.4% |
| Amputation Rate | 9.8% | 0.0% | 4.5% | 24.3% |
| Death Rate (all causes) | 5.9% | 0.0% | 3.5% | 3.4% |

The ATEV demonstrated a higher 30-day secondary patency rate, and patients treated with the ATEV were only 40% as likely to lose blood flow through their conduit after one month compared to the rate historically reported for synthetic grafts, which is a key period for recovery after traumatic injury. In addition, patients treated with the ATEV had approximately 1/5$^{th}$ the amputation rate, and approximately 1/9$^{th}$ rate of infection compared to that historically reported for synthetic grafts.

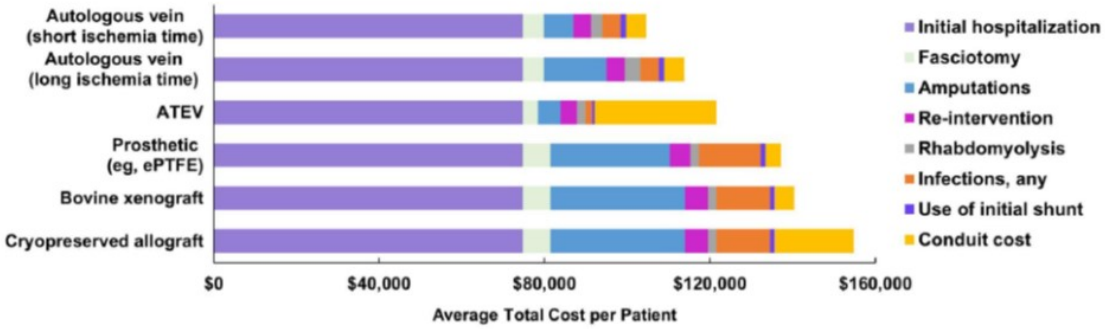
*BLA Approval and Indication*

On December 19, 2024, the FDA granted full approval for the ATEV for use in adults with extremity vascular trauma. The granted indication language was: “for use in adults as a vascular conduit for extremity arterial injury when urgent revascularization is needed to avoid imminent limb loss, and when autologous vein graft is not feasible.” Although Humacyte had originally filed for an indication of use that included when “autologous vein was not feasible and synthetic graft was not indicated,” the FDA granted an indication for when “autologous vein is not feasible,” a broader indication of use without the restriction of “when synthetic graft was not indicated.”

*Budget Impact Model*

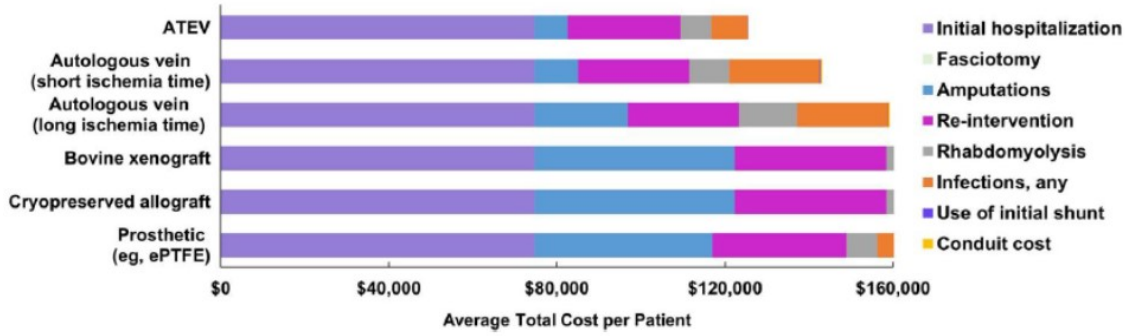
In March 2025, the Budget Impact Model for Symvess was published in the *Journal of Medical Economics*. The publication reported that Symvess was projected to be cost saving for both trauma centers and third-party payers, primarily due to reductions in the costs related to amputations and conduit infections. This publication used inputs from the PROOVIT vascular trauma registry, databases of hospital charges and insurance claims, published literature, and expert opinion to evaluate the economic impact from the perspective of Level I trauma centers and third-party commercial, Medicare and Medicaid payors. The publication was developed in collaboration with health economists and vascular surgeons to ensure that current practices in extremity arterial trauma practices were reflected, and that current health economic modeling standards were followed. Based on the model, the per-patient cost for trauma centers of treating patients with Symvess is estimated to be less than the cost of treating trauma patients with synthetic and other non-autologous grafts as shown in the graph below.

*Symvess (ATEV) Budget Impact Model*
*Estimated Per-Patient Cost for Trauma Centers*




The model also showed greater savings for third-party payors (compared to trauma centers) due to the avoidance of late complications occurring after patients' release from the hospital as shown in the graph below.

*Symvess (ATEV) Budget Impact Model*
*Estimated Per-Patient Cost for Third-Party Payors*



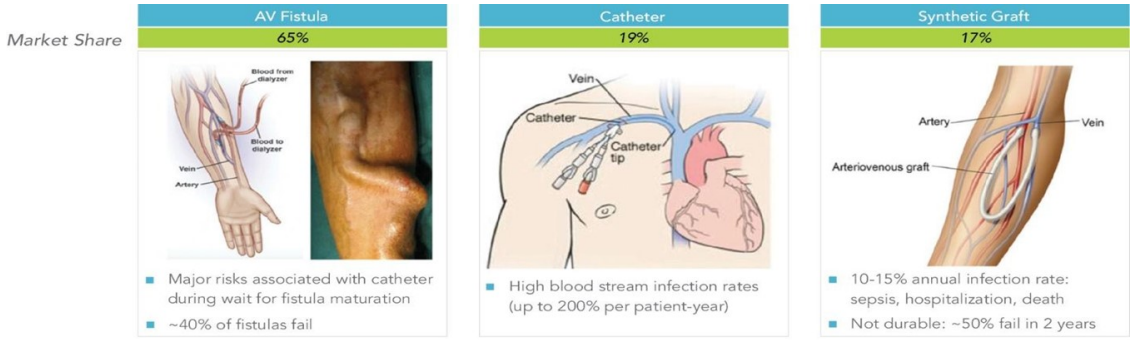

The major drivers of cost savings in the Budget Impact Model associated with Symvess across all stakeholders were attributed to reductions in the rate of vascular conduit infection and amputation.

***Proposed Indication #2: Use of the ATEV for AV Access for Hemodialysis***

*Overview of Hemodialysis and Existing Methods of AV 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, including women and patients with small vessel anatomy, advanced age, obesity, diabetes 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.

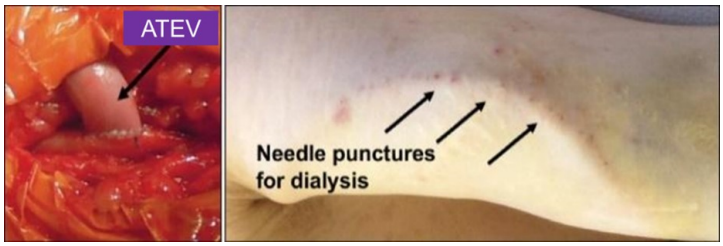
Synthetic graft. A synthetic graft, typically made from ePTFE and sewn between an artery and vein in the patient's arm, is generally used in patients who are not candidates for fistulae. The drawbacks of synthetic grafts include higher infection rates, which can be as high as 10% – 15% per patient-year, 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 % |

**Overview of ATEV Experience in Hemodialysis Access:** A table listing our clinical trials of the ATEV in hemodialysis access is included below. We have implanted the ATEV into approximately 418 total patients for hemodialysis access, for a total of more than 993 patient-years of exposure, as of December 31, 2024. Throughout these trials, we have observed consistent and sustained high primary and secondary patency rates. We have observed zero instances of clinical rejection of any ATEV in any hemodialysis access trial.

*Implantation of ATEV for Hemodialysis*




We have also observed in multiple clinical trials that our ATEVs 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 ATEVs may be a result of the ATEV'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 ATEV 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 ATEV after needle puncture for hemodialysis. In examining ATEV explanted segments we have observed healed needle cannulation tracts with cells expressing smooth muscle markers. This self-healing indicates that the ATEV 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 2 and Phase 3 Trials of the ATEV in Hemodialysis Access*

| Clinical Trial Number | Indication | Begin Enrollment | Design/Phase | Number of Subjects | Status | Outcomes** |
|---|---|---|---|---|---|---|
| V001 | Dialysis Access | 2012 | Phase 2 Single-arm | 40 | Completed | 30-day PP: 95%<br>6-month SP: 100%<br>12-month SP: 97%<br>60-month SP: 58%<br>Infection Rate/yr: 0%<br>Number of Rejections: 0 |
| V003 | Dialysis Access | 2013 | Phase 2 Single-arm | 20 | Completed | 30-day PP: 95%<br>6-month SP: 89%<br>12-month SP: 81%<br>Infection Rate/yr: 4% (1 event)<br>Number of Rejections: 0 |
| V006 | Dialysis Access | 2016 | Phase 3 Prospective Randomized Blinded | 355 total; 177 received ATEV 178 received ePTFE | Completed | 30-day PP ATEV: 93%<br>12-month SP ATEV: 82%<br>24-month SP ATEV: 67%<br>12-month SP ePTFE: 80%<br>24-month SP ePTFE: 74%<br>Infection Rate ATEV/yr: 0.93%<br>Infection Rate ePTFE/yr: 4.5%<br>Number of ATEV Rejections: 0 |
| V007 | Dialysis Access | 2017 | Phase 3 Prospective Randomized Blinded | 242 total; 123 received ATEV, 119 received AVF | Topline results reported August 2024, two-year follow-up in process | 6-month SP ATEV: 81%<br>12-month SP ATEV: 68%<br>6-month SP AVF: 66%<br>12-month SP AVF: 62% |

| Clinical Trial Number | Indication | Begin Enrollment | Design/Phase | Number of Subjects | Status | Outcomes** |
|---|---|---|---|---|---|---|
| V011 | Dialysis Access | 2019 | Phase 2 (LUNA200 Manufacturing System Bridging Study) | 30 | Completed | 30-day PP: 97%<br>30-day SP: 100%<br>12-month SP: 83%<br>Infection Rate ATEV/yr: 0%<br>Number of ATEV Rejections: 0 |
| V012 | Dialysis Access | 2023 | Phase 3 Prospective Randomized Blinded | Target 150 women total, 76 currently enrolled | Enrollment ongoing | Trial is currently enrolling, interim analysis planned on first 80 patients after one-year of follow up |

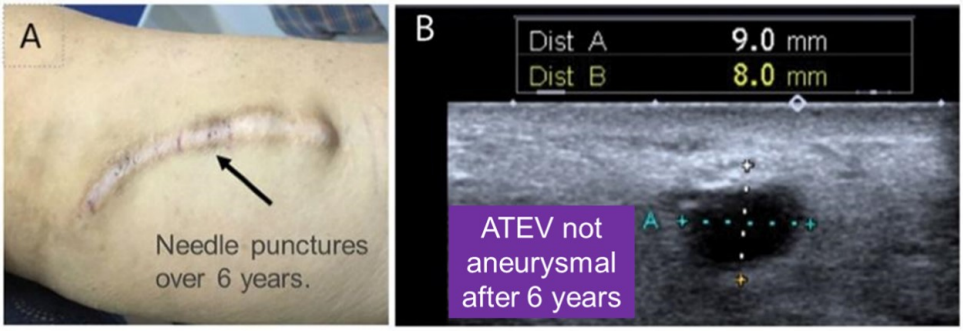
** PP: Primary Patency, which is the interval of time of access placement until any intervention designed to maintain or reestablish patency, access thrombosis, or the time of measurement of patency, i.e. patent without interventions.

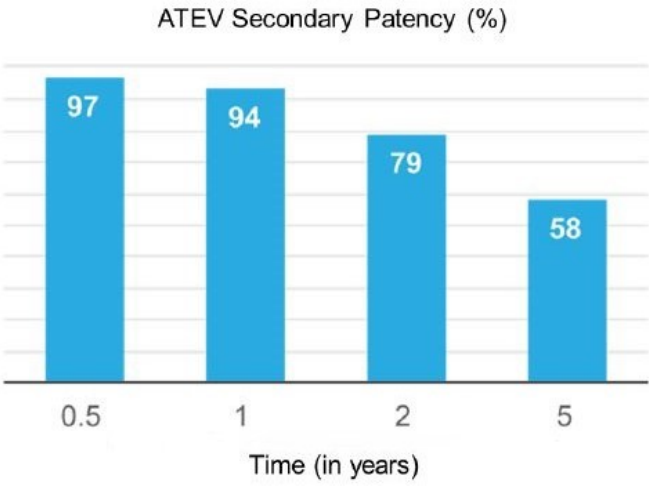
SP: Secondary Patency, which is the interval from the time of access placement until abandonment, i.e. patent with or without interventions.

*Long-Term Data from Early Phase 2 Trials in Hemodialysis: V001 and V003*

**Phase 2 Trial Design and Current Outcomes:** We have completed or are in long-term follow-up on two open-label Phase 2 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 ATEV 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 ATEVs 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 ATEV in AV Access*






*Phase 3 V006 AV Access Study*

**Trial Design:** Our V006 HUMANITY study was a prospective, multi-center, multinational, open-label, randomized, two-arm, comparative study. Eligible study subjects were randomized to receive either a ATEV 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. ATEV 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) | ATEV (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 |

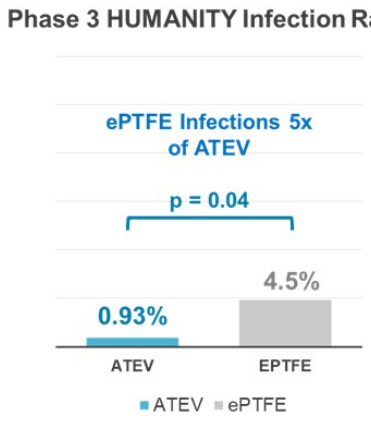
The secondary patency of the ATEV was greater than that of ePTFE at six and 12 months but lower at 18 and 24 months, an outcome that had not been modelled in the V006 trial design. As per the pre-specified Cox Proportional Hazards test, the ATEV did not achieve its primary efficacy endpoint regarding secondary patency. In terms of safety, the ATEV 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 ATEV. The safety advantage of the ATEV over ePTFE may be clinically important as infection and sepsis are the second most common cause of death in dialysis patients.

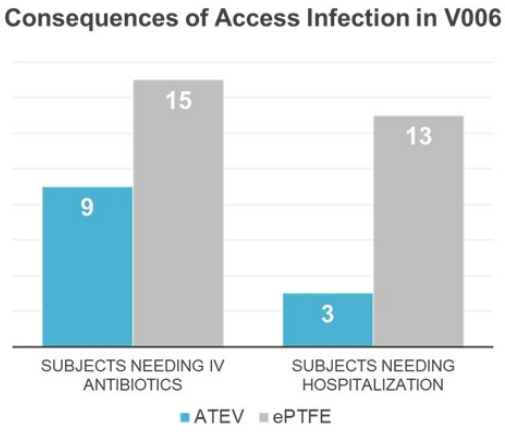
*Phase 3 V006 HUMANITY trial secondary patency results*

| Secondary Patency | 6 months | 12 months | 18 months | 24 months |
|---|---|---|---|---|
| ATEV **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 (ATEV 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*



The reported SAEs related to the ATEV 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 3 Clinical Study in AV Access*

| Description of SAE | Number of SAEs (% of total subjects) | |
|---|---|---|
| | ATEV | 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(5.1)% |

Overall, although the primary efficacy endpoint concerning secondary patency was not met, the ATEV performed in the V006 trial as was expected, based upon ATEV performance in previous Phase 2 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 ATEV subjects in V006 was somewhat worse than for ePTFE subjects.

In the V006 trial, the ATEV displayed significantly fewer infections than did the ePTFE grafts. This was associated with fewer instances of immune sensitization in ATEV subjects as compared to ePTFE subjects, which could translate to easier kidney transplantation at future times. Similar to prior studies, we observed that the ATEV 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 3 V007 AV Access Study

**Trial Design:** In April 2023 we completed enrollment of a Phase 3 trial, called V007, in 242 patients with ESRD. V007 is a Phase 3, 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 ATEV 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 ATEV for vascular access or an autogenous AV fistula. The objective of V007 is to compare the safety and efficacy of our 6 millimeter ATEV to autogenous AV fistula for functional hemodialysis access.

Eligible study subjects in V007 are randomized to receive either an ATEV or an autogenous fistula and followed to 24 months post-implantation by routine study visits. 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 ATEV and fistula subjects.

**One-Year Results:** As of December 31, 2024, there were 242 patients enrolled in the V007 trial, and enrollment was completed in April 2023. Demographics of the patients enrolled in V007 are summarized in the following table.

*Phase 3 V007 trial subject demographics*

| | **ATEV (N=123)** | **AVF (N=119)** |
|---|---|---|
| ITT Set | 123 | 119 |
| Safety Set* | 121 (98%) | 121 (102%) |
| Females | 37 (30%) | 33 (28%) |
| Whites | 73 (59%) | 86 (72%) |
| Age, mean (min, max) | 57.1 (24, 82) | 60.1 (21, 87) |
| Age ≥ 65 | 43 (35%) | 44 (37%) |
| BMI ≥ 30 | 52 (42%) | 42 (35%) |
| BMI mean value (min, max) | 30.2 (19, 49) | 29.1(17, 49) |
| History of Diabetes | 82 (67%) | 83 (70%) |

*Two patients randomized to ATEV received an arteriovenous fistula ("AVF") and were analyzed as AVF in the Safety Set
ITT = Treatment group assignment based on randomization.
Safety Set = Treatment group assignment based on actual treatment.

Topline results were reported in August 2024 and expanded results, including subgroup analyses, were presented at the American Society of Nephrology's (ASN) Kidney Week 2024, the premier nephrology meeting, in October 2024. In the V007 trial, the ATEV demonstrated superior function and patency at six and 12 months (co-primary endpoints) compared to AVF, the current standard of care for hemodialysis, as summarized in the following table.

*Phase 3 V007 trial 12-month results (all patients)*

| **Co-Primary Endpoints** | **ATEV (n=123)** | **AVF (n=119)** | **p-value** | |
|---|---|---|---|---|
| Functional Patency at Month 6 | 81.3% | 66.4% | 0.0071 | |
| Secondary Patency at Month 12 | 68.3% | 62.2% | | |
| | | | **Difference** | **p-value** |
| Duration of Use Over First 12 Months | 7.5 months | 6.1 months | 1.4 months | 0.0162 |

Safety events per year of usability in the V007 Phase 3 trial are summarized in the following table.

*Phase 3 V007 trial safety results (all patients)*

| **12-Month Safety Summary** | **ATEV** | | **AVF** | |
|---|---|---|---|---|
| | Subjects (%) n=121 | Events Per Patient Year | Subjects (%) n=121 | Events Per Patient Year |
| Treatment Emergent Adverse Events | 98.3% | 16.0 | 96.7% | 13.5 |
| Serious Adverse Events | 81.8% | 5.1 | 61.2% | 3.5 |
| Adverse events of special interest: | | | | |
| Study access (SA)-related infections | 5.8% | 0.1 | 4.1% | 0.1 |
| Thrombosis | 52.9% | 1.7 | 9.1% | 0.2 |
| Stenosis | 66.1% | 3.0 | 47.9% | 1.9 |
| Clinically significant Steal Syndrome | 0.8% | 0.0 | 5.8% | 0.1 |
| Rupture of SA | 0.0% | 0.0 | 1.7% | 0.0 |
| Leading to SA revision or ligation | 11.6% | 0.3 | 24.0% | 0.7 |
| Leading to SA excision | 4.1% | 0.1 | 1.7% | 0.0 |

The largest area of difference in AEs was in thrombosis. The majority of ATEV patients with thrombosis, 94%, were successfully treated.

Sub-group analysis was also performed in patient groups that historically have poor outcomes with AV fistula procedures. In female patients, subjects implanted with the ATEV had significantly higher six-month and one-year patency rates than female patients receiving an AV fistula as summarized in the table below.

*Phase 3 V007 trial 12-month results (female patients)*

| **Co-Primary Endpoints** | **ATEV (n=37)** | **AVF (n=33)** | **p-value** | |
|---|---|---|---|---|
| Functional Patency at Month 6 | 89.2% | 54.5% | <0.0001 | |
| Secondary Patency at Month 12 | 81.1% | 48.5% | | |
| | | | **Difference** | **p-value** |
| Duration of Use Over First 12 Months | 8.3 months | 5.0 months | 3.3 months | 0.0011 |

It was also noted in the V007 trial that obese patients (BMI of at least 30) (n=93) implanted with the ATEV had significantly higher six-month and one-year patency rates than obese patients receiving an AV fistula. In addition, diabetic patients implanted with the ATEV had significantly higher six-month and one-year patency rates than diabetic patients receiving an AV fistula. Based on these results, we consider the subgroup of females and males with obesity and diabetes (a subgroup that combined represents over half of dialysis patients), to be a target population that could benefit from the ATEV. Results through 12 months of follow up from the V007 trial in females and males with obesity and diabetes are summarized in the following table.

*Phase 3 V007 trial 12-month results – target population*
*(female patients and males with obesity and diabetes)*

| **Co-Primary Endpoints** | **ATEV (n=56)** | **AVF (n=54)** | **p-value** | |
|---|---|---|---|---|
| Functional Patency at Month 6 | 85.7% | 51.9% | <0.0001 | |
| Secondary Patency at Month 12 | 76.8% | 46.3% | | |
| | | | **Difference** | **p-value** |
| Duration of Use Over First 12 Months | 8.0 months | 4.5 months | 3.5 months | 0.0002 |

The ATEV showed no increased in overall safety events per year of usability in the expected target population (all females and males with obesity and diabetes) as summarized in the following table.

*Phase 3 V007 trial safety results – target population*
*(female patients and males with obesity and diabetes)*

| **12-Month Safety Summary** | **ATEV** | | **AVF** | |
|---|---|---|---|---|
| | Subjects (%) n=54 | Events Per Patient Year | Subjects (%) n=56 | Events Per Patient Year |
| Treatment Emergent Adverse Events | 96.3% | 14.8 | 98.2% | 21.8 |
| Serious Adverse Events | 77.8% | 4.2 | 67.9% | 6.1 |
| Adverse events of special interest: | | | | |
| Study access (SA)-related infections | 7.4% | 0.1 | 5.5% | 0.1 |
| Thrombosis | 51.9% | 1.2 | 12.5% | 0.3 |
| Stenosis | 64.8% | 3.0 | 51.8% | 2.9 |
| Clinically significant Steal Syndrome | 1.9% | 0.0 | 3.6% | 0.1 |
| Rupture of SA | 0.0% | 0.0 | 3.6% | 0.1 |
| Leading to SA revision or ligation | 11.1% | 0.2 | 28.6% | 1.2 |
| Leading to SA excision | 5.6% | 0.2 | 3.6% | 0.1 |

Phase 3 V012 AV Access Study in Women

In collaboration with our corporate partner Fresenius Medical Care and its subsidiary Frenova Renal Research, we conducted a study to review the outcomes of 178,575 adult patients who received in-center dialysis at Fresenius Kidney Care dialysis centers. Among the areas of study were the complications and cost of treatment by patient demographic. The objective of the study was to further define patient subgroups who could most benefit from the ATEV. The study showed that women, particularly obese and diabetic women, have higher complication rates, including infections and access failures, and higher treatment costs.

Based on the results of the results of this research, we have commenced a clinical study designed to demonstrate the clinical and health economic benefits of the ATEV in women dialysis patients, a high-unmet-need population. We have commenced a Phase 3 trial, which we refer to as the V012 trial, in up to 150 patients with ESRD. V012 is a Phase 3, prospective, multi-center, open label, randomized, two-arm comparative study conducted in the United States. The V012 trial is designed to assess the usability of the ATEV for dialysis in comparison to autogenous fistulas, in female patients currently receiving hemodialysis via catheter. The primary measure of efficacy will be total days free from in-dwelling catheter (“catheter-free days”) until 365 days, or until access abandonment, whichever occurs first. The primary measure of safety will be the number and severity of infections related to all accesses (including catheters) from access creation until 365 days. An interim analysis is planned on the first 80 patients after one-year of follow up, and 76 patients have currently been enrolled in the study.

Planned Supplemental BLA Filing in AV Access

Based on discussions with the FDA, our current plan is to submit a supplemental BLA after interim analysis of V012 study, subject to the results of that interim analysis. This plan would support a supplemental BLA submission in the second half of 2026 dependent upon the rate of enrollment in the V012 study and on the timeline for interim data analysis. Our current expectation is that the supplemental BLA submission would target the subgroups in which the ATEV has showed the best results to date, which are all females and males with risk factors for fistula non-maturation.

***Proposed Indication #3: PAD***

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.

We have observed strong patency rates and no reported cases of infection for the ATEV in PAD in clinical studies to date. We are developing our 6 millimeter ATEV for use as a bypass conduit for patients with PAD. We have conducted two Phase 2 trials to evaluate the safety and efficacy of our 6 millimeter ATEV for use as a bypass conduit with PAD, which we refer to as our V002 and V004 trials. For both of these Phase 2 trials, the ATEV was implanted as a femoral popliteal bypass graft in patients with PAD.

*Our Current Phase 2 Trials of the ATEV in PAD*

| Clinical Trial Number | Indication | Begin Enrollment | Design/ Phase | Number of Subjects | Status | Outcomes** |
|---|---|---|---|---|---|---|
| V002 | Peripheral | 2013 | Phase 2 | 20 | 10-year | 30-day PP: 100% |
| | Artery Disease | | Single-arm | | follow-up | 6-month SP: 84% |
| | | | | | ongoing | 12-month SP: 84% |
| | | | | | | 72-month SP: 60% |
| | | | | | | Infection Rate/yr: 0% |
| | | | | | | Number of Rejections: 0 |
| V004 | Peripheral | 2016 | Phase 2 | 15 | Completed | 30-day PP: 100% |
| | Artery Disease | | Single-arm | | | 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.

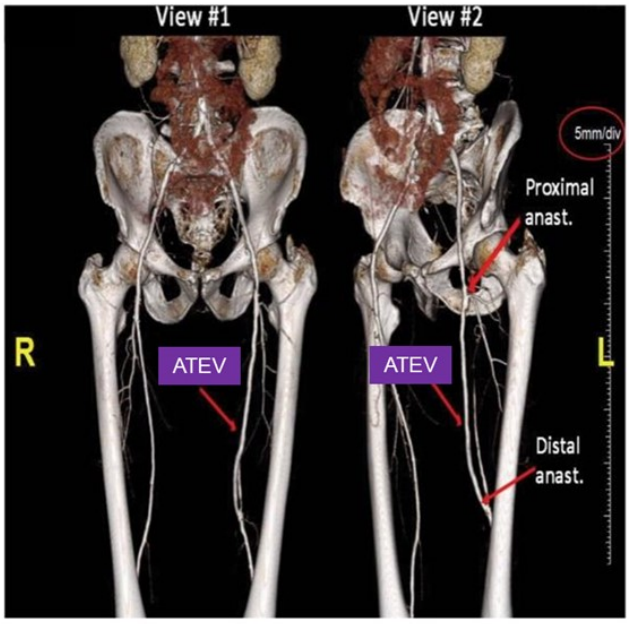
SP: Secondary Patency, which is the interval from the time of access placement until abandonment, i.e. patent with or without interventions.

**Trial Design:** Both our V004 and V002 trials were 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 had the primary objectives of evaluating the safety of the ATEV 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 ATEV 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 ATEVs 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 ATEV and there was no infection or signs of immunological reaction to the graft.

There have been no ATEV-related infections reported during the V002 trial as of December 31, 2024, 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 ATEV implantation. In all cases, the ATEV maintained normal architecture and function. A representative image is shown below, taken 50 months post-implantation. Proximal and distal anastomoses of ATEV 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 ATEV diameter along the length of the implant.

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




Patients in the V002 trial are currently in long-term follow-up out to ten years. In 2022, six-year results from V002 were published in *Journal of Vascular Surgery – Vascular Science*. The article, entitled "6-Year Outcomes of a Phase 2 Study of Human-Tissue Engineered Blood Vessels for Peripheral Arterial Bypass," reported overall secondary patency rate of 60% at 72 months, including all patients originally enrolled, as estimated by Kaplan Meier analysis. There was no evidence of graft rejection or infection, and no patients underwent amputation of the affected limb out to six years.

*Long-term results from V002 Phase 2 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% | **60%** | — |
| Ankle-Brachial Index (median) | 0.64 | 0.90 | 0.96 | — | 1.07 | 0.98 | 0.94 (n=2) | 0.97 (post-op) |
| ATEV Infection Rate | — | 0% | 0% | 0% | 0% | 0% | **0%** | 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 2 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, ATEV 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 ATEV 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 ATEV rejection. Lastly, there were zero reported amputations of any operative limb in the first 12 months of follow-up.

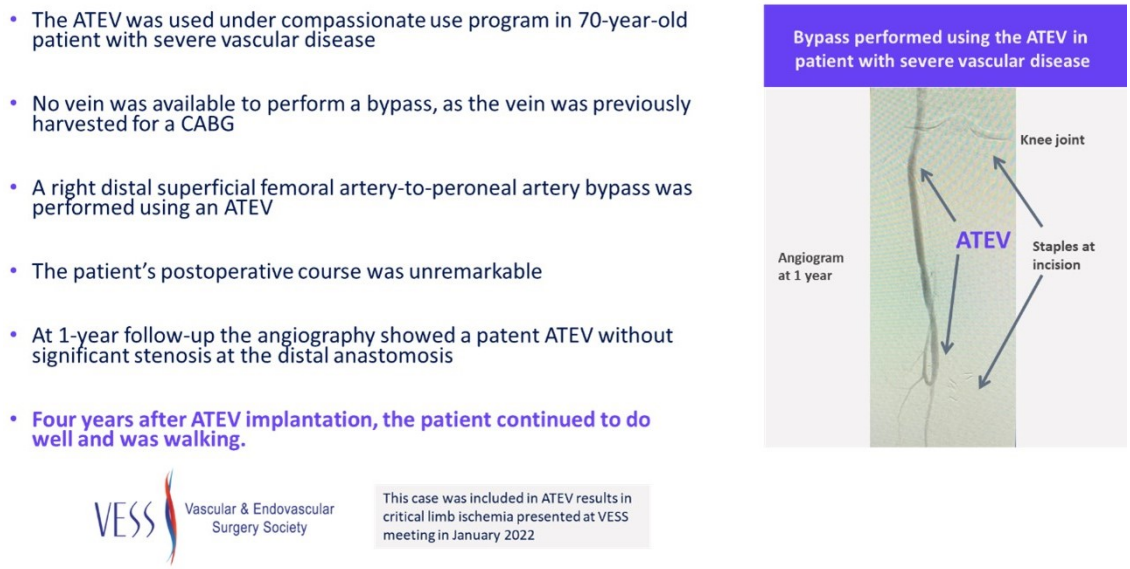
Published literature reports of patients with Rutherford stage 4 and 5 PAD and no autologous vein available for revascularization show that outcomes can include amputation. For Rutherford 4 and 5 patients with no vein and no revascularization procedure, amputation rates at 6 months are reported at 31%.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

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

The FDA has granted use of the ATEV in 29 special expanded access cases through December 31, 2024, the majority of which were patients with chronic limb-threatening ischemia ("CLTI"), the end stage of PAD. Each of these compassionate use cases was conducted under an individual, investigator-initiated IND application 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 ATEV. Imaging at one year demonstrated a patent graft as illustrated below.




*42-year-old with Infected Dacron Graft*

An ATEV 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 ATEV. The patient was seen at one, three, six, nine, and 12 months after ATEV implantation. At all visits, the ATEV 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 ATEV was patent and appeared remarkably similar to the patient's native blood vessels. The patient had no signs of infection in the ATEV and continues to have no limitations or complications during normal activity or exercise.

*Mayo Clinic Study in Severe PAD*

The Mayo Clinic, Rochester, MN, is conducting a study in patients with CLTI under an investigator-initiated IND filed with the FDA. In February 2024, researchers published interim results in the *Journal of Vascular Surgery*, including their conclusion that in the clinical study the ATEV was a safe, resilient, and effective conduit for arterial bypass and limb salvage. This is an important result since approximately 40% of patients requiring lower extremity bypass do not have saphenous vein available, which is the standard of care for treating this challenging disease state. The presentation reported the outcomes of 29 patients, with a mean age of 71 and having no available vein to use as a bypass graft, who underwent ATEV implantation. Of these 29 patients, 28 (97%) had previously experienced unsuccessful revascularization procedures on the extremity and 21 (72%) had tissue loss or gangrene. Based on the state of this disease, this patient group had a 30-50% one-year risk of amputation. Notably, performing bypass surgery in 24 (83%) of the patients necessitated the fusion of two 42 cm long ATEVs to achieve the required bypass length. Surgeons reported that the operations to implant the ATEV achieved a 100% technical success rate, without any ATEV-related major adverse events reported. At a median follow-up of nine months, the secondary patency rate for patients implanted with the ATEV was 71%. The limb salvage rate was 86%, corresponding to only a 14% amputation rate.

***Preclinical Pipeline***

*Pancreatic Islet Transplantation for Type 1 Diabetes (BioVascular Pancreas)*

The BVP is a modification of Humacyte's ATEV product, leveraging the ATEV to deliver therapeutic cells within close proximity of the patient's bloodstream. We believe that the ATEV 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 ATEV in vivo. These attributes mean that the ATEV 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 ATEV 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 ATEV could maintain viability of a therapeutic number of islets after implantation of the ATEV 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.

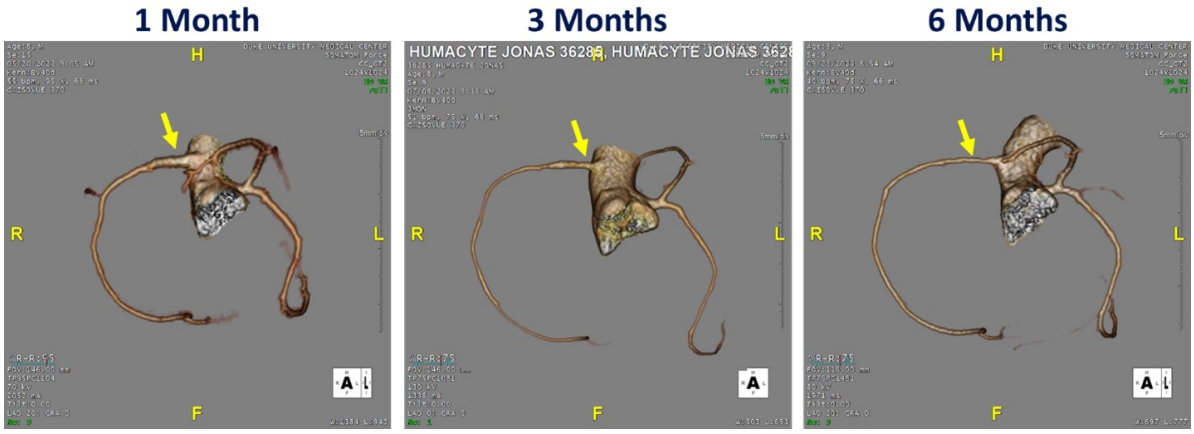

In April 2023, Humacyte and Breakthrough T1D (f/k/a JDRF International) ("JDRF"), the leading global organization funding type 1 diabetes research, announced a collaboration to advance the development of the BVP product candidate. During 2023 and 2024, we performed testing the BVP in primates. In these experiments, researchers observed that insulin-producing cells in the BVP survive for months after implantation into the animal and continue to make insulin after implantation that is measurable in the bloodstream. We consider these results to be extremely encouraging as they support the potential ability of the BVP to deliver a curative number of insulin-producing islets into diabetic subjects. Additional work in large animals is currently ongoing, including using the BVP in diabetic large animals.

*Coronary Artery Bypass Graft*

Evaluation of 3.5-4mm diameter ATEVs for CABG has been performed over the last four years at Humacyte. We performed a preclinical study at Duke University to evaluate the use of our small diameter ATEV for CABG in adult primates (baboons), and we have also performed studies of the sdATEV in sheep and pig models of CABG surgery, with follow-up times ranging from 1-3 months. The goal of the primate and other large animal studies is to assess patency and function of the small diameter ATEV, as well as host responses and cellular remodeling. ATEVs are followed by ultrasound imaging of the heart, and angiographic imaging of the conduits. In November 2024, researchers presented preclinical results of the sdATEV in a baboon model of CABG at The American Heart Association's Scientific Sessions 2024 meeting. In the six-month preclinical CABG model, the sdATEV was observed to sustain patency (blood flow), recellularized with the animals' host cells, and remodeled to effectively reduce the initial size mismatch between the sdATEV and the animals' native artery. In the preclinical study, the sdATEV was implanted between the aorta and right coronary artery ("RCA") in five baboons to simulate a CABG procedure. Animals were followed for six months after sdATEV implantation and all sdATEVs maintained patency throughout the study. The baboon study provided an effective model for demonstrating the feasibility, mechanical durability and capacity for host-cell remodeling of the sdATEV for CABG. After implantation, the sdATEV was observed to recellularize with host cells and remodel to effectively reduce the initial size mismatch with the RCA.

Based on discussions with the FDA, we plan to file an IND with the FDA seeking authorization to commence human clinical testing of the sdATEV in CABG.

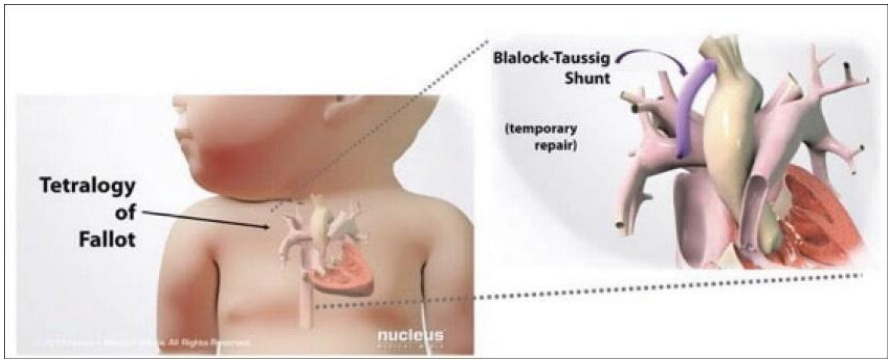
*Angiography showing adaptive remodeling*
*of ATEV after implant in baboon CABG model*




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

Tetrology 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 ATEV 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*



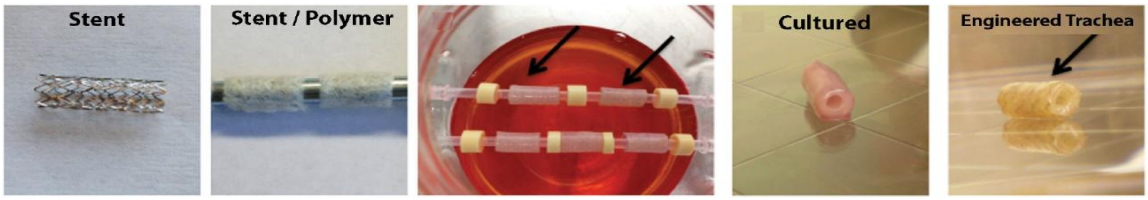

In October 2023, results of the preclinical study were published in the open-access *Journal of Thoracic and Cardiovascular Surgery (JTCVS Open)*. In the study, researchers implanted 3.5mm diameter ATEVs into a juvenile large-animal model of pediatric heart disease. The 3.5mm ATEV was implanted between the subclavian and pulmonary arteries, to mimic a commonly-performed surgical procedure used to treat babies born with Tetralogy of Fallot, one of the most common pediatric heart conditions. The study assessed the ATEV's patency, structure, and blood flow from one week to six months after the implant. The 3.5mm diameter ATEV has smaller product dimensions but is manufactured using a similar process as Humacyte's 6mm ATEV 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 ATEV is indicative of the potentially broad application of our proprietary bioengineered tissue platform and manufacturing processes.

*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.

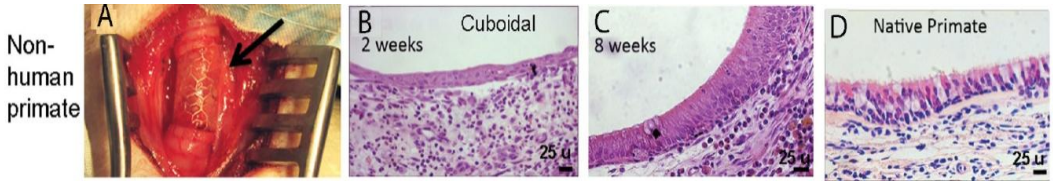
We have modified the ATEV production process to enable the embedding of a biocompatible medical-grade stent within the wall of the engineered vessel. Combining a non-degradable stent with the degradable polymer scaffold used for ATEV production results in a composite scaffold that can be seeded with smooth muscle cells and grown in culture. After decellularization, the engineered trachea consists of the extracellular matrix contained in the ATEV, 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***

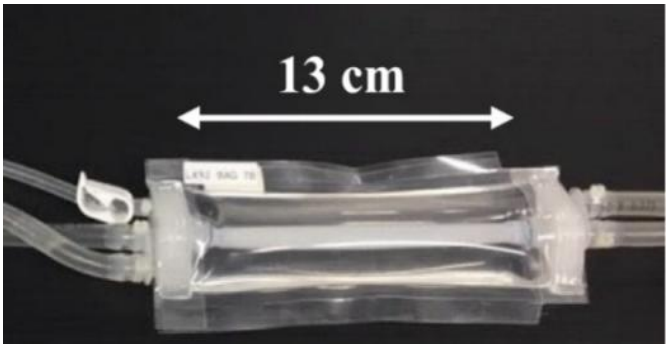
We have developed a novel paradigm for manufacturing human tissues that mimics key aspects of human physiology. Recognizing that commercial scale production capacity of bioengineered tissue has been non-existent, we prioritized the development of a scalable, reproduceable, commercial biomanufacturing 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 ATEVs in commercial quantities in a system designed for cGMP compliance.

Our proprietary manufacturing process was designed with a modular approach allowing us to produce ATEVs in smaller batches for clinical trials and scale out to larger batches for commercial manufacturing. The current, commercial-scale LUNA200 system utilizes 20 growth drawers holding ten ATEVs each for a total of 200 ATEVs per batch. Since 2021 this system has been utilized to produce clinical product for use in our ongoing Phase 3 trials. The FDA inspected our manufacturing facility in April 2024 as part of its review and approval of our BLA in extremity vascular trauma, and we are using this facility to provide product for the United States commercial launch in that indication which commenced in the first quarter of 2025.

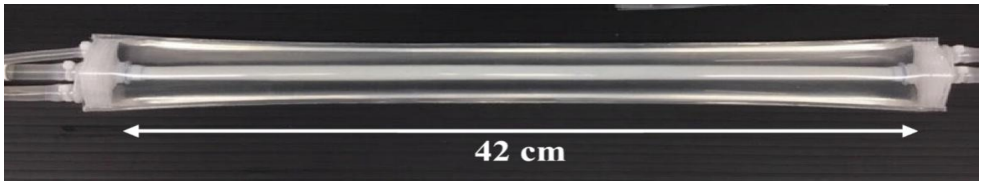
Our manufacturing process utilizes our LUNA200 system, consisting of 20 “growth drawers.” Each growth drawer is capable of producing ten 42cm ATEVs and each ATEV remains contained within an individual bioreactor bag. Inside a LUNA200, a closed tubing network connects all 20 growth drawers as well as 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 ATEVs per batch while maintaining the critical operating parameters that direct growth, creating a gross capacity of approximately 900 ATEVs per system annually.

We have designed the LUNA200 to have the ability to produce ATEVs 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 ATEV line extension after commercial launch of the 42cm ATEV. Using our existing LUNA manufacturing equipment, we can generate 400 13cm ATEVs per batch. Our modular manufacturing platform can be scaled without impacting the operating parameters that support the ATEV 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 ATEV capacity of approximately 7,200 ATEVs. 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 ATEV 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 ATEV manufacturing utilizing biochemical and gene expression assays. Each qualified primary isolation can produce approximately 500,000 to one million ATEVs.

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 ATEV 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 ATEVs 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 ATEV 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 continue to explore the development 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 (as amended, 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 expired 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"). 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*

Following the December 2024 FDA approval of Symvess in extremity vascular trauma, we commenced the United States commercial launch in that indication in the first quarter of 2025. For our vascular repair and replacement applications of our technology, including vascular trauma, AV access for dialysis, and the treatment of PAD, we have retained the right to commercialize our ATEV within the United States. In the United States we are commercializing the ATEV through our own direct sales and marketing team and expect to do so also for any additional ATEV indications that may be approved. We own end-to-end commercialization and are pursuing collaborations with appropriate strategic partners who have established distribution channels for specialized markets.

Our first market launch of Symvess for the treatment of extremity vascular trauma in the United States involves a highly concentrated market of approximately 200 Level I Trauma Centers that may be reached with a small field sales forces. Many of the major trauma centers already have familiarity with our ATEVs through their participation in our clinical trials. Our sales launch commenced in the first quarter of 2025 and includes dual targeting of surgeons to create pull-through demand and hospital administration (trauma center Value Analysis Committees) to ensure adoption and uptake of the ATEV in vascular trauma. We have recruited and trained a highly experienced sales team for the commercial launch of Symvess. All ten sales team members are multi-year President's Club winners, representing the top 10% of achievers in their prior sales organizations. The average hospital medical device and biotech experience of our sales team members exceeds 15 years, all sales team members have experience in vascular surgery and/or trauma surgery, and 80% have previous experience selling regenerative therapies. All team members have experience selling clinically differentiated disruptive technologies and premium priced portfolios.

We have developed and published a Budget Impact Model based on the clinical results supporting the approval of Symvess, and the estimated reduction in clinical complications potentially achievable by treating specific patients with Symvess versus current standard of care. Based on the model, the per-patient cost of treating patients with Symvess is estimated to be less than the cost of treating trauma patients with synthetic grafts, cryopreserved allografts, or xenografts, as well as other patients at high risk of complications. Major drivers of cost savings associated with Symvess were attributed to reductions in the rate of amputation and vascular conduit infection.

Additionally, we submitted a New Technology Add-On Payment ("NTAP") application for Symvess to the Centers for Medicare and Medicaid Services ("CMS") in October 2024. We presented Symvess data at a public Town Hall with the CMS in December 2024. If successful, NTAP reimbursement will begin for discharges on October 1, 2025, offering hospitals additional payment to cover a portion of the costs associated with Symvess.

We expect that the large market potential of earlier-stage applications of our technology platform such as CABG and BVP 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 ATEV 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 PAD, 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 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 ATEV 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 ATEV product opportunities.

We are pursuing a dual regulatory and legislative reimbursement strategy to ensure separate Medicare payment for the ATEV 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 RMAT 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 ATEVs, there is uncertainty with respect to third-party coverage and reimbursement of our ATEVs. 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.

Containment of healthcare costs has been a priority of federal, state, and foreign governments, and the prices of drug products have been a focus of this effort. Governments have shown significant interest in implementing cost-containment programs. This interest has resulted in significant proposed and enacted reform measures affecting healthcare reimbursement and drug pricing, including the enactment in August 2022 of significant changes to potential Medicare drug product reimbursement through government negotiation of certain drug prices, as well as manufacturer discount and inflation rebate obligations under the Inflation Reduction Act (the "IRA").

***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, 2024, our patent estate is comprised of 15 families of patents. Of these families, 12 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, one is exclusively licensed to Humacyte from Duke University and one is 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) Twelve issued U.S. patents, 73 foreign patents in Austria, Australia, Belgium, Canada, China, Cyprus, Denmark, France, Germany, Greece, Hong Kong, Hungary, Ireland, Italy, Japan, Netherlands, Portugal, Spain, Sweden, Switzerland, Turkey, and the UK, seven pending U.S. non-provisional patent applications, and 12 pending foreign applications in Australia, Canada, China, Europe, Japan 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, Netherlands, Spain, Sweden, Switzerland, Turkey, and the UK, one pending U.S. non-provisional patent application, and four pending foreign patent applications in Europe and Canada, which we co-own, and

(iii) one issued U.S. patent, one issued foreign patent in Japan, one pending U.S. non-provisional patent application, and five pending foreign patent applications in Australia, Canada, Europe, Japan, and Hong Kong, which we exclusively license.

Many of these patents and patent applications generally relate to the scaffolds used to make Symvess and our product candidates, the composition of Symvess and our product candidates, and systems and methods of manufacturing Symvess and our product candidates. Excluding any patent term adjustment or patent term extension, the U.S. patent relating to the scaffold used to make Symvess and our product candidates 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 Symvess and our product candidates expires in 2032. Based on the FDA approval of the ATEV in December 2024, in February 2025 we filed with the U.S. Patent and Trademark Office an application for extension of patent term on one of our U.S. patents relating to the composition of Symvess and our product candidates under 35 U.S.C. § 156. If granted, we estimate that the expiration of the patent will be extended by approximately 50 months. The U.S. patent relating to the entangler machinery used to make tubular scaffolds expires in 2035. Included in our patent portfolio is one U.S. patent expiring in 2040, and multiple pending, Humacyte-owned non-provisional applications relating to the manufacturing of engineered tissues at commercial scale, as well as other technologies and product candidates. If these non-provisional applications are allowed, such additional patents issuing therefrom would be expected to expire around 2043.

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 Symvess™ in the United States, Europe, United Kingdom and Ukraine, 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 (as amended, 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 ATEV*

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 ATEVs, which may or may not contain a stent (the "Tubular Prothesis License Agreement"). The license granted under the Tubular Prothesis License 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 Tubular Prothesis 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 Tubular Prothesis License 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 Tubular Prothesis License 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 Tubular Prothesis 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.

*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 BVP (the "BVP License Agreement"). The license granted under the BVP License 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 BVP 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 BVP License 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 BVP License 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 BVP 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 BVP 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 ATEV 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 ATEVs 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 ATEVs multiple key characteristics will drive rapid clinical adoption amongst surgeons and the broader healthcare community:

- Off-the-Shelf: Our “cabinet” of ATEVs 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 ATEVs are available for immediate use by opening and removing the ATEV from its original flexible bioreactor bag. Since our ATEV does not need flushing, harvesting or thawing, as is common with other vascular substitute alternatives, we believe hospitals will be able to use our ATEVs for vascular surgery more quickly with smaller surgical teams, reduced logistics and decreased overall cost.

- No Surgical Harvesting: The use of our ATEVs 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 ATEVs have the potential to be universally implantable and durable across patients. Because our ATEVs 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 ATEVs as compared to synthetic materials. As a result, we believe our ATEVs 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 ATEVs to precise specifications under controlled quality standards, which will allow surgeons the flexibility to quickly and easily select an ATEV in the appropriate size and shape for each indication.

- Regenerative Potential: Our ATEVs 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.

We expect our ATEVs will 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 ATEVs 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® and Procol®, are processed animal-derived vessels, while allografts are processed allogeneic cellular vessels, such as CryoVein® and AngioGRAFT®.

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 ATEVs, including NovaHep AB, Xeltis AG, Hancock Jaffe, and Vascudyne Inc. We may face competition from these and other emerging technologies such as bioabsorbable polymetric 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 Symvess and our product candidates.

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. Symvess and our product candidates 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. Our first vessel product, Symvess, received approval of its BLA on December 19, 2024 for use as a vascular conduit for extremity arterial injury when urgent revascularization is needed to avoid imminent limb loss, and autologous vein graft is not feasible. None of our other vessel products or other investigational products have received FDA approval. 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 ("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 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 current good tissue practice ("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 further approvals for Symvess and/or our product candidates 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, though not always, conducted in three sequential phases, which may overlap or be combined. For certain of Humacyte's development of product candidates, Phase 1 and Phase 2 trials have heretofore been combined into a single trial design.

- *Phase 1*. 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 2*. 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 3*. 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 3 trials to support approval, but in some cases may approve an application on the basis of one trial. For example, FDA's approval of our BLA for Symvess for extremity arterial injury was based on a single pivotal trial with supporting evidence from humanitarian use of the product in Ukraine.

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 4 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 product candidates 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 new indications for Symvess and/or our product candidates. 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 Symvess received its initial approval for marketing via a BLA, we believe that it will be entitled to 12 years of exclusivity. 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 1, 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 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 many 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 ("HTC/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, such as Symvess, are 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. As a condition of approval of our BLA for Symvess in extremity arterial injury, we are obligated to conduct post-approval studies and trials, and report the results to the FDA. 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*

The commercial success of Symvess and our product candidates, if they are approved for marketing, 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 Symvess and our product candidates 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 1 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 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 ATEVs 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, proactively or 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 ATEVs 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 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, (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 preclinical 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 preclinical 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 ATEVs 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, 2024, we had 220 employees, of which 218 were full-time. 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.

***Additional Information***

We were incorporated in Delaware on July 1, 2020, under the name Alpha Healthcare Acquisition Corp. 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 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. 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 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 securities. 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 securities 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.
- Our near-term prospects are dependent on the success of Symvess, our sole FDA-approved product, and if we are unable to successfully commercialize it in the vascular trauma indication and obtain regulatory approval for Symvess in additional indications, our business, operating results and financial condition will be materially harmed.
- Symvess and our product candidates, if approved, 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.
- 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 Symvess or 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.
- 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 ATEVs can lead to incorrect implantation or follow-up procedures which could harm the results of our clinical trials and market acceptance of Symvess and our product candidates, 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.
- The sizes of the market opportunities for Symvess and 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 to do so, we may not be able to generate product revenue and will have to alter our development and commercialization plans.

- The manufacture of Symvess and our product candidates is complex, we have limited experience manufacturing commercial product, and we have in the past and may in the future encounter difficulties in production. If we or any third-party manufacturer encounter such difficulties, our ability to supply Symvess for commercial sale or Symvess and our product candidates for clinical trials could be delayed or halted entirely.
- The terms of the Purchase Agreement (defined below) 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 Symvess and our product candidates 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 of Symvess and Commercialization of Our Product Candidates**

***Our near-term prospects are dependent on the success of Symvess, our sole FDA-approved product, and if we are unable to successfully commercialize it in the vascular trauma indication and obtain regulatory approval for Symvess in additional indications, our business, operating results and financial condition will be materially harmed.***

Our business currently depends heavily on our ability to successfully commercialize Symvess in the United States and in other jurisdictions where we may obtain marketing approval. Symvess currently is our only product approved for sale in the US 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 Symvess. 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 Symvess, and if we are unable to successfully commercialize it in the vascular trauma indication and obtain regulatory approval for Symvess in additional indications, our business, along with our operating results and financial condition, will be materially harmed. We may never be able to successfully commercialize Symvess or our product candidates or meet our expectations with respect to revenues for a number of reasons, including:

- a lack of acceptance of Symvess by physicians, patients, third-party payors and other members of the medical community;
- our limited experience in marketing, selling and distributing Symvess or any other product;
- our limited experience in the commercial manufacturing of Symvess or any other product;
- reimbursement and coverage policies of government and private payors such as Medicare, Medicaid, group purchasing organizations, insurance companies, health maintenance organizations and other plan administrators;
- our ability to expand the current FDA-approved indications for Symvess into treatment of pediatric patients, treatment of a broader set of traumas, or indications outside of trauma;
- emergence of new AEs associated with Symvess once the product is in commercial use or data suggesting that known AEs are more frequent or severe than originally thought;
- changed or increased regulatory restrictions in the United States, EU and other foreign territories; and
- a lack of adequate financial or other resources to commercialize Symvess successfully.

For example, during its review of the Symvess BLA, the FDA identified concerns relating to mid-graft rupture or anastomotic failure of Symvess post-implantation. As a result, the FDA approved package insert for Symvess contains a boxed warning relating to mid-graft rupture or anastomotic failure, and as a condition of Symvess approval we are obliged to conduct a post-approval long-term observational study to further characterize these and other risks. If our post-approval study demonstrates that these or other risks associated with Symvess are more severe and/or more prevalent than currently understood, this may have adverse impacts on our business, including lack of market acceptance of our product, imposition of further warnings or limitations on distribution and/or use of Symvess, or revocation of our marketing authorization.

There is no guarantee that the infrastructure, systems, processes, policies, relationships, and materials we have built for the launch and commercialization of our approved product in the United States will be sufficient for us to achieve success at the levels we expect. Even our ability to generate product revenue and become profitable from Symvess depends on our assumptions regarding the relevant market opportunity and the degree of market acceptance for Symvess, and if approved, our other products, for which our estimates may prove inaccurate, and market acceptance in any approved indication, which may never occur.

***Symvess and our product candidates, if approved, 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 commercial success of Symvess and our product candidates will depend, in part, on the acceptance of physicians, patients and health care payors, as medically necessary, cost-effective and safe. Symvess and any other 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, cost 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 Symvess or any of our product candidates that receives marketing approval will depend on a number of factors, including:

- the efficacy and potential advantages of Symvess or our product candidates compared with alternative products or methods, including convenience and ease of administration;
- the prices we charge for Symvess or our other 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 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, or the emergence of new, previously unknown side effects; and
- any restrictions on the use of Symvess and our other products, if approved.

***If our clinical trials are delayed, do not produce favorable results, or otherwise fail to demonstrate safety and efficacy to the satisfaction of the FDA or similar regulatory authorities outside the United States, we may incur significant additional costs or experience significant delays in completing, or ultimately be unable to complete, the development, approval, 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, and before gaining approval for additional indications for our approved Symvess product, 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.

A number of factors may impact the timing of our preclinical and clinical programs and the development and commercialization of our product candidates. These include factors such as inability to recruit sufficient numbers of patients, delays in obtaining IRB approval for planned trials, or disagreements with regulatory agencies on clinical trial design and/or imposition of clinical holds. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all, or that they will be successful. 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.

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, Symvess has been approved in the United States in an initial indication, and none of our product candidates have been approved in the United States, Europe or in any other jurisdiction. 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. In addition, because of the nature of the ATEVs, many of our clinical trials are "open label," meaning that both the patient and the investigator know whether the patient is receiving the investigational product candidate. These studies often require the use of historical control arms consisting of patients previously treated with alternative therapies in the normal course of medical care. Use of open label study designs further complicates the clinical development process. Because of these and other factors, we may experience substantial difficulties in agreeing with FDA and other regulatory authorities on clinical trial design.

If our studies are not successful, we be delayed in obtaining marketing approval or may not receive marketing approval at all. For example, our V006 trial did not meet its primary endpoint, which has delayed development of the ATEV for the hemodialysis access indication. If we fail to achieve the primary endpoint of our other ongoing or future clinical trials, or if safety issues arise, 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 our clinical trials achieve their primary endpoints, the FDA may still determine that such trials do not adequately establish the safety and effectiveness of our products. Data obtained from preclinical and clinical studies are subject to varying interpretations, which may delay, limit, or prevent marketing approval. In such a circumstance, the FDA may require that we design and conduct new, additional clinical trials to demonstrate safety and effectiveness, or may determine not to approve our products at all.

Additionally, even though we received FDA approval for Symvess in trauma, we may face a number of difficulties if the results of our clinical trials for additional Symvess indications or for our product candidates are unfavorable, inconclusive, or only modestly favorable or if there are safety concerns, such as AEs or 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.

***Our progress in early stage clinical trials may not guarantee success in late stage clinical trials, and our progress in trials for one product candidate or the FDA's approval of Symvess 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, or the FDA's approval of, one of our product candidates also do not necessarily indicate that we will obtain positive results in clinical trials related to product candidates. The novelty of our proprietary scientific technology platform adds another layer of risk that early-stage clinical trials may not guarantee success 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.

***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. However, the final 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 final 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.

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 ATEVs we may need to delay, abandon or limit development and marketing of our product candidates.***

Our ATEVs may prove to have undesirable or unintended side effects, toxicities or other characteristics. If our ATEVs are associated with undesirable side effects in clinical trials or in commercial marketing, 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. For approved products, such as Symvess, the FDA and other regulatory authorities may limit the scope of that approval, require us to include detailed warnings and/or contraindications in product labeling, and/or implement a REMS, which may include restrictions on distribution or use of the product. If serious safety concerns emerge after product approval, FDA and other regulatory authorities may take steps to withdraw the product from the market. Any of these events could cause us to delay, abandon or limit the development and marketing of Symvess and our product candidates, if approved. For more information, see the section of this Annual Report on Form 10-K titled "Business."

***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 V012 trial, which is a Phase 3 clinical trial comparing the safety and efficacy of our 6 millimeter ATEV to AV fistula for hemodialysis access in women. 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. 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;
- 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 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 ATEVs can lead to incorrect implantation or follow-up procedures which could harm the results of our clinical trials and market acceptance of Symvess and our product candidates.***

Our ATEV product, Symvess, is FDA approved as a vascular conduit for extremity arterial injury when urgent revascularization is needed to avoid imminent limb loss, and autologous vein graft is not feasible. For other indications, our ATEVs are currently in various stages of preclinical and clinical testing. We do not have the personnel capacity to directly conduct or manage solely with our own personnel all of the clinical trials that are necessary for the development of further indications for our ATEVs. 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, with regard to Symvess, surgeons may not be, previously exposed to the implantation and follow-up procedures related to their use. As a result, our ATEVs may be, and have been in the past, incorrectly implanted and follow-up procedures may be performed incorrectly, resulting in increased interventions or failure of the ATEV, and complicating interpretation of clinical trial results. Our efforts to educate investigators, surgeons and interventionalists regarding the proper techniques for use of our ATEVs both during clinical trials and in commercial use may be costly, prove unsuccessful and could materially harm our ability to continue the clinical trials or commence marketing of Symvess. Regulatory authorities may also seek to impose

restrictive labeling or proactive communication obligations on any marketing approval granted for use of our ATEVs as a result, which could reduce market acceptance of any of our ATEVs that receive marketing approval. For example, the FDA approved package insert for Symvess contains a boxed warning relating to mid-graft rupture or anastomotic failure.

***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 ATEVs and to progress 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.

***The sizes of the market opportunities for Symvess or 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 Symvess and certain of our product candidates, if approved, 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 Symvess or our product candidates, if approved by regulatory authorities, and our total market opportunities for Symvess or 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, the approval we received for Symvess in trauma includes only adults as a vascular conduit for extremity arterial injury when urgent revascularization is needed to avoid imminent limb loss, and autologous vein graft is not feasible. Any approval that we receive for our product candidates also may be based on a narrower definition of the relevant patient population than we have estimated. These and similar limitations on future products 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 Symvess or our product candidates.***

The development and commercialization of new biological products is highly competitive and subject to rapid change and technological advancements. We expect that Symvess will, and that our product candidates would, if approved, 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 and commercializing 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 provide them with further competitive advantage.

We have obtained initial marketing approval for Symvess in the United States for vascular repair in adults with certain extremity trauma injuries. We plan to seek marketing approval for our product candidates in the United States as biologics and for Symvess and our product candidates 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 Symvess and 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 ATEV 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 ATEV 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 ATEV 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 do so, we may not be able to generate product revenue and will have to alter our development and commercialization plans.***

We recently received FDA approval to commercialize Symvess in the United States. As a company, we had no prior experience commercializing a product. 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.

***There is uncertainty with respect to third-party coverage and reimbursement of Symvess and our product candidates, if approved. 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, including Symvess. 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. 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 Symvess or our product candidates, 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 Symvess and our other products, if approved, as cost-effective, and coverage and reimbursement may not be available to our customers or may not be sufficient to allow our products to be marketed on a competitive basis. Cost control initiatives could also cause us to decrease any price we might establish for our products, which could result in lower than anticipated product revenue. Moreover, eligibility for reimbursement does not imply that any such 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 Symvess or our other products, if approved, 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.

On August 16, 2022, President Biden signed the IRA into law, which sets forth meaningful changes to drug product reimbursement by Medicare. Among other actions, the IRA permits HHS to engage in price-capped negotiation to set the price of certain drugs and biologics reimbursed under Medicare Part B and Part D. The IRA contains statutory exclusions to the negotiation program, including for certain orphan designated drugs for which the only approved indication (or indications) is for the orphan disease or condition. Should Symvess or our other products, if approved, be covered by Medicare Part B or Part D, and fail to fall within a statutory exclusion, such as that for an orphan drug, Symvess or our other products could, after a period of time, be selected for negotiation and become subject to prices representing a significant discount from average prices to wholesalers and direct purchasers. The IRA also establishes a rebate obligation for drug manufacturers that increase prices of Medicare Part B and Part D covered drugs at a rate greater than the rate of inflation. The inflation rebates may require us to pay rebates if we increase the cost of a product covered by Medicare Part B or Part D faster than the rate of inflation. In addition, the law eliminates the “donut hole” under Medicare Part D beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and requiring manufacturers to subsidize, through a newly established manufacturer discount program, 10% of Part D enrollees’ prescription costs for brand drugs below the out-of-pocket maximum and 20% once the out-of-pocket maximum has been reached. Our cost-sharing responsibility for any approved product covered by Medicare Part D could be significantly greater under the newly designed Part D benefit structure compared to the pre-IRA benefit design. Additionally, manufacturers that fail to comply with certain provisions of the IRA may be subject to penalties, including civil monetary penalties. The IRA is anticipated to have significant effects on the pharmaceutical industry and may reduce the prices we can charge and reimbursement we can receive for our products, among other effects.

Any reduction in reimbursement from Medicare resulting from the IRA or other legislative or policy changes, or from other government programs may result in a similar reduction in payments from private payers. These healthcare reforms and the implementation of any future cost containment measures or other reforms may prevent us from being able to generate sufficient revenue, attain and/or maintain profitability or commercialize our drug candidates. We cannot be sure whether additional legislative changes will be enacted, or the effect of forthcoming guidance implementing the IRA, or whether FDA regulations, guidance or interpretations will be changed, or what the impact of such changes on our product candidates or the marketing approvals of our product candidates, if any, may be.

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 the development, approval and commercialization of Symvess and any product candidates that we develop in the future.***

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

- decreased demand for Symvess or any product candidates 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 Symvess or 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.

**Risks Related to Manufacturing Symvess and Our Product Candidates**

***The manufacture of Symvess and our product candidates is complex, we have limited experience manufacturing commercial product, and we have in the past and may in the future encounter batch failures and difficulties in production. If we or any third-party supplier encounter such difficulties, our ability to supply Symvess for commercial sale or our product candidates for clinical trials could be delayed or halted entirely.***

The process of manufacturing our ATEVs, including Symvess, is complex, highly regulated and subject to multiple risks. The manufacture of biologics such as our ATEVs has been, and continues to be, susceptible to product loss and batch failures due to a range of factors including raw material and other component deficiencies, contamination, equipment failure, temporary power outages, improper installation or operation of equipment, damage to facilities, vendor or operator error, inconsistency in yields, variability in product and raw material characteristics and difficulties in scaling the production process. Even minor deviations from normal manufacturing processes has resulted, and could in the future result, in reduced production yields, batch failures, product defects and other supply disruptions. For example, from time to time we have had multiple batch failures in succession. We believe we have identified the root cause of those failures and have implemented appropriate corrective actions. However, if our corrective actions are not successful, or if the FDA disagrees with our root cause analysis or our corrective actions, it may delay or disrupt our manufacturing operations or delay or prevent the filing or approval of marketing applications for our ATEVs. If microbial, viral or other contaminations are discovered in Symvess or our product candidates, or in the manufacturing facilities in which our products are made, manufacturing may be delayed or disrupted 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 depend on cell banks in our manufacturing process, and the loss or alteration of our master cell banks would result in significant disruptions to that process.

We currently manufacture Symvess for initial commercial distribution and our 6 millimeter ATEVs 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 Symvess in commercial quantities in compliance with 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. We have limited years of experience manufacturing our ATEVs in-house with the LUNA200 system, and no experience manufacturing the volume of Symvess and our ATEV product candidates that we anticipate will be required to achieve planned levels of commercial sales and to supply all of our clinical trials. 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. We also have experienced interruptions in the supply of the raw materials required to manufacture our products, and increased costs due to supply chain disruptions or inflation in the cost of goods, services or other operating inputs. Likewise, supply chain interruptions could affect the transport of Symvess or our clinical trial materials, such as our investigational ATEVs and other supplies, which would negatively impact our ability to conduct our clinical trials or commercialize our product. In addition, we may not be able to develop and implement efficient manufacturing capabilities and processes to manufacture our ATEVs in sufficient volumes that also satisfy the legal, regulatory, quality, price, durability, engineering, design and production standards required to commercialize our ATEVs, including Symvess, successfully.

If we are unable to produce sufficient quantities of Symvess for commercialization or our investigational ATEVs for our clinical trial needs, 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 ATEVs, including Symvess, 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 Symvess for commercial sale or 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, (iii) require significant modifications to our manufacturing facility, personnel, and procedures, (iv) delay or prevent filing or approval of marketing applications for our product candidates, (v) result in temporary or permanent closures of our manufacturing facilities, and/or (vi) result in other civil or criminal penalties.

**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 ATEVs 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, and could result in civil or criminal penalties. 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, GCPs, and generally accepted research standards.

The performance of the sites for our clinical trials may also be adversely affected by various other issues, including the lack of familiarity with the properties of our ATEVs, 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 Symvess or our product candidates, if approved by regulatory authorities.

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

We currently rely, and expect to continue to rely, on third parties for the supply of certain components necessary for Symvess and our product candidates, such as donor tissue, other biologically derived substances, human serum, the PGA polymer mesh and the bioreactor bags in which our ATEVs 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 ATEVs 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, pandemics or otherwise, or to source or manufacture such components in accordance with cGMPs and cGTPs, as applicable, could delay our ability to commercialize Symvess, which would reduce revenue from our sole approved product, or to complete our clinical trials, obtain marketing approval for 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. We incurred net losses of $148.7 million and $110.8 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024 and 2023, we had an accumulated deficit of $686.0 million and $537.3 million, respectively. We have historically financed our operations primarily through the sale of equity securities and convertible debt, proceeds from our going public transaction, borrowings under loan facilities, the Purchase Agreement 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.

To become and remain profitable, we must succeed in commercializing Symvess, obtaining marketing approval for Symvess outside of the United States, obtaining marketing approval for our product candidates, 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, 2024, we had net operating loss carryforwards for federal and state tax purposes of approximately $465.0 million and $471.7 million, respectively, which begin to expire in 2025. In addition, we had tax credit carryforwards for federal and state tax purposes of approximately $27.3 million as of December 31, 2024, which begin to expire in 2025 and will expire completely in 2044. 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 for Symvess in the United States, (ii) continue our preclinical and clinical development efforts, including the ongoing clinical trials, and (iii) to commercialize Symvess in the United States and to obtain marketing approval for our 6 millimeter ATEV outside of the United States 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 Symvess outside of the United States and of our product candidates 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 Symvess in the United States, 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 Symvess and 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, 2024, we had cash and cash equivalents of $44.9 million and restricted cash of $50.4 million, and as of December 31, 2023, we had cash and cash equivalents of $80.4 million and restricted cash of $0.4 million. Subsequent to December 31, 2024, in March 2025 we completed a public offering of common stock which provided approximately $46.6 million in net proceeds. Based upon our current operating plan, we believe that our cash and cash equivalents 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 the Purchase Agreement, we may be limited in our ability to incur future debt.***

On May 12, 2023, the Company and Global entered into the Purchase Agreement with the Purchasers and another affiliate of Oberland, as agent for the Purchasers (the "Agent"), to obtain financing with respect to the further development and commercialization of the Company's ATEV, to repay the Company's credit facility with Silicon Valley Bank ("SVB"), and for other general corporate purposes. Pursuant to the terms of the Purchase Agreement, we are limited in our ability to incur additional indebtedness without the prior written consent of the Purchasers. The Purchasers have an option to terminate the Purchase Agreement and to require Global to repurchase the Revenue Interests in the event that we incur additional indebtedness in violation of the terms of the Purchase Agreement.

We cannot assure you that our business will generate sufficient cash flow from operations, that we will be able to incur future debt on favorable terms or at all, or that future financing will be available to us in amounts sufficient to fund our operations.

***To date, we have obtained marketing approval for, and begun commercializing, only one product, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability.***

We recently began commercializing Symvess, our sole approved product in the United States. 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 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 already had commercialized a product.

**Risks Related to Government Regulation**

***Even though we received marketing approval for Symvess, we continue to 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.***

Symvess and any other product candidates for which we also obtain marketing approval in the United States, will be subject to ongoing regulatory requirements from the FDA and, if approved elsewhere, from 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. For example, the FDA's approval of Symvess includes requirements to conduct an open-label study to assess the safety and efficacy of Symvess in certain patients 17 years of age or younger, as well as a long-term observational study to further characterize the risk of graft failure and infection in patients with extremity vascular injury who have received Symvess for the approved indication. 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, we are subject to extensive and ongoing post-approval regulatory requirements for Symvess by the FDA, and if approved elsewhere, by other non-U.S. regulatory authorities, with regard to the manufacturing, labelling, packaging, AE reporting, storage, advertising, distribution, promotion and recordkeeping for Symvess and any other product candidates that may receive marketing approval. If we 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 or other civil and/or criminal penalties 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 Symvess or 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 Symvess or any of our product candidates in jurisdictions outside the United States, 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 approved products. 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.

***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 ATEVs, 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. In December 2024, the FDA approved Symvess as a vascular conduit for extremity arterial injury when urgent revascularization is needed to avoid imminent limb loss, and autologous vein graft is not feasible, but there can be no assurance that we will obtain approval outside of the United States for that indication or marketing 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 approval for our product candidates. The FDA has substantial discretion in the approval process and decisions made by the FDA can be unpredictable. 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 and favorable clinical trial results are no guarantee of approval.

***Even though we obtained approval for Symvess from the FDA, we may never obtain approval for our ATEVs 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 though we received FDA approval to market Symvess 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. On December 12, 2023, we submitted our BLA for the ATEV in urgent arterial repair following extremity vascular trauma when synthetic graft is not indicated and autologous vein use is not feasible. We submitted our BLA using a "rolling review," 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 ATEV, which has received Fast Track and RMAT designations for AV access in hemodialysis, and RMAT designation for urgent arterial repair following extremity vascular trauma. In February 2024, the FDA accepted our BLA in the vascular trauma indication and granted priority review of that 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 though we have utilized a "rolling review" and we have received priority review for that BLA, it may not lead to a shorter review period. The FDA could require us to submit major amendments to the BLA, which could lead to a longer review time. 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 ATEVs 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.

In addition, if FDA approves a BLA for a biologic that has received orphan drug designation, then FDA may not approve another application for the same drug or biologic for the same disease or condition until the expiration of seven years from the date of the approval of the orphan BLA. This is known as orphan exclusivity. However, even if one of our biological product candidates receives orphan exclusivity, the FDA can still approve different drugs or biologics 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 and policy changes. 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.

***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 ATEV for use in the creation of AV access for hemodialysis, in 2017, the FDA granted RMAT designation for our 6 millimeter ATEV for the creation of vascular access for performing hemodialysis, in 2023, the FDA granted RMAT designation for our 6 millimeter ATEV for urgent arterial repair following extremity vascular trauma, and in 2024, the FDA granted RMAT designation for the ATEV for patients with advanced PAD. We have not received designations pursuant to any of the FDA's expedited programs for our other indications, although we may in the future seek such designations if such product candidates meet the criteria for that designation. 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.

In addition, in 2018, our ATEV 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 commercial success of Symvess or our product candidates.***

Our industry is highly regulated, and changes in or revisions to laws and regulations that make gaining coverage of and adequate reimbursement for Symvess or 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 Symvess or 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. At the federal level, the Inflation Reduction Act of 2022, or IRA:

- Requires manufacturers to pay rebates for a Medicare Part B or Part D drug if the price increases for the drug exceed the rate of inflation.
- Eliminates the "donut hole" under Medicare Part D beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and requiring manufacturers to subsidize 10% of Part D enrollees' prescription costs for brand drugs below the out-of-pocket maximum and 20% once the out-of-pocket maximum has been reached.
- Delays the rebate rule that would require pass through of pharmacy benefit manager rebates to beneficiaries.
- Directs the Centers for Medicare & Medicaid Services, or CMS, to engage in price-capped negotiation for certain Medicare Part B and Part D drugs and biologics. Specifically, the IRA's Price Negotiation Program applies to high-expenditure single-source drugs and biologics that have been approved for at least 7 or 11 years, respectively, among other negotiation selection criteria, beginning with ten high-cost Part D drugs starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. The negotiated prices will be capped at a statutorily determined ceiling price. There are statutory exemptions from the IRA's Price Negotiation Program, including for a drug that has only a single orphan drug designation and is approved only for an indication or indications within the scope of such designation. The IRA's Price Negotiation Program is currently the subject of legal challenges.

Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties or a potential excise tax. The IRA permits the Secretary of Health and Human Services, or HHS Secretary, to implement many of the IRA's provisions through guidance, as opposed to regulation, for the initial years. The IRA is anticipated to have significant effects on the pharmaceutical industry and may reduce the prices pharmaceutical manufacturers can charge and the reimbursement pharmaceutical manufacturers can receive for approved products, among other effects.

Lowering prescription drug prices was a stated priority of the Biden administration. On October 14, 2022, President Biden signed an executive order to lower prescription drug costs for Americans. In response to this directive, the Center for Medicare and Medicaid Innovation developed new models intended to lower drug costs under Medicare and Medicaid. These models include designing new payment methods for drugs approved under accelerated approval to encourage timely confirmatory trial completion and improve access to post-market safety and efficacy data, with the goal of reducing Medicare spending on drugs that have no confirmed clinical benefit; creating a list of generic drugs for which the out-of-pocket Part D costs will be capped at $2 a month per drug; and establishing a new approach for administering outcomes-based agreements for cell and gene therapies. President Biden also signed an executive order on July 9, 2021, affirming the administration's policy to support legislative reforms that would lower the prices of prescription drugs, including by supporting the development and market entry of lower-cost generic drugs and biosimilars, and support the enactment of a public health insurance option. Among other things, the executive order directs the HHS Secretary to provide a report on actions to combat excessive pricing of prescription drugs, continue to clarify and improve the approval framework for generic drugs and identify and address any efforts to impede generic drug competition, enhance the domestic drug supply chain, reduce the price that the Federal government pays for drugs, and address price gouging in the industry. It is unclear whether these initiatives will be continued or expanded upon in the Trump administration.

The American Rescue Plan Act of 2021 eliminated 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, as of January 1, 2024. In addition, 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.

We cannot predict how further developments of or changes to these laws and regulations will affect our business.

The FDA also released a final rule, effective November 30, 2020, providing guidance for states to build and submit plans for importation of 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 Trump 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 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 certain health care professionals and teaching hospitals;
- 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. These risks may be compounded as our information technology hardware ages. 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 commercialization of Symvess or 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. During late 2020 and early 2021, a professional services firm providing services to the Company was the target of a cyber-attack. The Company believes that it was not materially impacted by the attack. Our third-party service providers and partners, with whom we may share data, are subject to similar risks as we are relating to cybersecurity, privacy violations, business interruption, and systems, as well as employee failures. While we have procedures in place for selecting and managing our relationships with third-party service providers and other business partners, we do not have control over their business operations or governance and compliance systems, practices and procedures, and our management of multiple third party service providers increases our operational complexity. If we fail to adequately monitor our third party service providers' and partners' performance, including for compliance with our agreements and regulatory and legal requirements, we may have to incur additional costs to correct errors, our reputation could be harmed or we could be subject to litigation, claims, legal or regulatory proceedings, inquiries or investigations. These risks may also be present if our third party service providers and partners use separate information systems that are not integrated with our systems and suffer a cybersecurity incident. As a result, we are subject to the risk that the activities associated with our third party service providers and partners will adversely affect our business, even if the cyber incident does not directly impact our systems or information.

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.

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.

Moreover, if our data management systems do not effectively collect, store, process and report relevant data for the operation of our business (whether due to equipment malfunction or constraints, software deficiencies, cybersecurity attack and/or human error), our ability to effectively plan, forecast and execute our business plan and comply with applicable laws and regulations will be impaired, perhaps materially. Any such impairment could materially and adversely affect our financial condition, results of operations, cash flows and the timeliness with which we report our internal and external operating results.

***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, including 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 separation from the EU 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 enacted the California Consumer Privacy Act ("CCPA"), which creates 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, and the CCPA was supplemented by the California Consumer Rights Act ("CPRA"). There are a number of other states that have considered similar privacy proposals, with states like Virginia and Colorado, among others, enacting their own privacy laws. Some states are also considering consumer health data privacy laws, with states like Washington and Nevada enacting such laws. In addition, the use of pixels and other website technologies increasingly are attracting attention from privacy regulators and private litigants, including under theories involving state wiretap laws. 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 Symvess or our product candidates, if approved, may be impaired if we are unable to obtain and maintain effective intellectual property rights for our proprietary scientific technology platform, Symvess and our 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 Symvess or 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. For applications filed on or after March 16, 2013 in the United States, the first to file a patent application is generally entitled to the patent, assuming the other requirements for patentability are met.

Prior to March 16, 2013, however, 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. Any such developments 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 Symvess or 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, among others, 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 Symvess and our 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 Symvess or the other affected product candidates. If we or any such licensors fail to adequately protect this intellectual property, our ability to commercialize Symvess or our product candidates, if approved, 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 Symvess or our 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 ATEVs, including Symvess, 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 Symvess or 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 or 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.

In Europe, a new unitary patent system took effect on June 1, 2023, and may significantly impact European patents, including those granted before the introduction of the new system. Under the new system, Applicants can, upon grant of a patent, opt for that patent to become a Unitary Patent which will be subject to the jurisdiction of a new Unitary Patent Court (“UPC”). Patents granted before the implementation of the new system can be opted out of UPC jurisdiction, remaining as national patents in the UPC countries. Patents that remain under the jurisdiction of the UPC may be challenged in a single UPC-based revocation proceeding that, if successful, could invalidate the patent in all countries who are signatories to the UPC. Further, because the UPC is a new court system and there is little precedent for the court’s laws, there is increased uncertainty regarding the outcome of any patent litigation. We are unable to predict what impact the new patent regime may have on our ability to exclude competitors in the European market. In addition to changes in patents laws, geopolitical dynamics, including Russia’s incursion into Ukraine, may impact our ability to obtain and enforce patents in particular jurisdictions. If we are unable to obtain and enforce patents as needed in particular markets, our ability to exclude competitors in those markets may be reduced.

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 Symvess or any of our 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, 2024, we had 220 employees. As we move forward in our efforts to commercialize Symvess and our product candidates, 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, sales and marketing 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, maintain competitive compensation packages, 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;
- publication of negative news articles or other media releases which could affect public opinion about our products or result in increased regulatory scrutiny of our product and product candidates;
- changes in government regulation;
- potential or actual military conflicts or acts of terrorism;
- announcements concerning the Company 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 our business. 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 the Company 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 the Company or fails to publish reports on the Company regularly, our stock price or trading volume could decline.

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

As of December 31, 2024, we had warrants outstanding to purchase up to an aggregate of 14,079,314 shares of our common stock and options outstanding to purchase up to an aggregate of 12,274,139 shares of our common stock. As of December 31, 2024, we had the Option outstanding to purchase up to $8,050,000 worth of 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"), as of December 31, 2024 we also have the ability to issue 5,817,353 shares and 1,030,033 shares, respectively. In addition, the aggregate number of shares under the 2021 Plan and the ESPP will automatically increase on January 1 of each year, 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. 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 the Company 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 intend to 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 on 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 our predecessor 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 assets and 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, 2024 are derivative liabilities related to the Contingent Consideration, the Private Placement Warrants, warrants issued in our October 2024 and November 2024 registered direct offerings (the "Registered Direct Offerings"), and the Purchasers' put option under the Purchase Agreement, and a derivative asset related to our Common Stock Purchase Agreement. 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, the Private Placement Warrants and the warrants issued in our Registered Direct Offerings each reporting period and that the amount of such gains or losses could be material.

***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 are and may continue to be subject to legal and other proceedings that could cause us to incur significant expenses, divert our management's attention, and materially harm our business, financial condition, and operating results.***

As disclosed in *Legal Proceedings*, we and our affiliates currently are subject to various lawsuits and demands. These proceedings, as well as any litigation, government inquiries or investigations, regulatory proceedings, as well as personal injury or class action claims and lawsuits, and securities, commercial and intellectual property infringement matters that we could face in the future, can be protracted and expensive, and have results that are difficult to predict. Determining reserves for pending litigation and other legal and regulatory matters requires significant judgment, and there can be no assurance that our expectations or estimates will prove correct. Adverse outcomes with respect to any of these legal proceedings may result in significant settlement costs or judgments, penalties and fines. Even if these proceedings are resolved in our favor, the time and resources necessary to resolve them, or public scrutiny related to them, could divert the resources of our management and require significant expenditures.

***Changes in U.S. government policies under the Trump administration, including increased tariffs and reductions in federal research funding, could adversely affect our business.***

Recent policy actions by the Trump administration, including the imposition of new tariffs on imported materials and goods from certain foreign countries, including Canada, Mexico and China, and the temporary freeze on federal grants and loans, may have an adverse impact on our business. Increased tariffs on critical raw materials, components, and finished goods could raise our production costs, disrupt our supply chain, and reduce our competitiveness in the marketplace. Additionally, the administration's halt on certain federal research grants may negatively impact our industry. Any prolonged reductions in such funding could slow innovation, delay collaborations, and limit the adoption of new technologies that contribute to our business growth. If these or similar policy changes continue or expand, we may face increased costs. Although we cannot predict the full extent of these impacts, any prolonged disruption could adversely affect our business, financial condition, and results of operations.

***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. Our entire management team and many of its other employees devotes substantial time to compliance.

These rules and regulations 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, and other factors, may make it more difficult and more expensive in the future for Humacyte to obtain director and officer liability insurance. 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.

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.

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 the 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 1C. Cybersecurity.**

**Cybersecurity Risk Management and Strategy**

We have certain processes for assessing, identifying, and managing material risks from cybersecurity threats, which are integrated into our enterprise risk management processes. Specifically, we have processes for:

- **Identifying and Managing Cybersecurity Risks** — We have implemented a cross-functional approach to assessing, identifying and managing material cybersecurity threats and incidents. We periodically review, assess, update and test our policies, standards, processes and practices in a manner intended to address cybersecurity threats and events. The results of such reviews, assessments and tests are evaluated by management and periodically reported to our Audit Committee of the Board of Directors, and our Board of Directors.

- **Technical Safeguards** — We have integrated cybersecurity into our overall information technology operations and designed our processes and systems to help protect our information assets and operations from internal and external cyber threats, protect employee and patient information from unauthorized access or attack as well as secure our networks and systems.

- **Incident Response and Recovery Planning** — To better facilitate our cybersecurity program, our cybersecurity team works collaboratively across our Company to implement programs designed to protect our information systems from cybersecurity threats and to promptly respond to any material cybersecurity incidents. We conduct regular tabletop exercises, including incident simulations to test these plans and ensure personnel are familiar with their roles and responsibilities in a response scenario.

- **Third-Party Risk Management** — We maintain a risk-based approach to identifying and overseeing material cybersecurity threats presented by third parties and the systems of third parties that could adversely impact our business in the event of a material cybersecurity incident affecting those third-party systems.

- **Education and Awareness** — We provide training regarding cybersecurity threats as a means to equip our employees, directors and consultants with tools to make employees, directors and consultants aware of and to address cybersecurity threats, and to communicate our evolving information security policies, standards, processes and practices. We also use technology-based tools to mitigate cybersecurity risks and to bolster our employee-based cybersecurity programs.

We adjust our cybersecurity policies, standards, processes, and practices as necessary based on the information provided by our assessments, audits and reviews. Such processes include (i) procedural and technical safeguards, (ii) response plans, (iii) annual tests on our systems, (iv) incident simulations and (v) routine review of our cybersecurity policies and procedures to identify risks and improve our practices. We engage certain external cybersecurity firms to enhance our cybersecurity oversight. We include confidentiality provisions in all contracts with third-party service providers, and data protection provisions in certain contracts with third-party service providers where applicable, to help protect us and our employees and patients from any related vulnerabilities.

**Governance**

Our Board of Directors is responsible for exercising oversight of management's identification and management of, and planning for, risks from cybersecurity threats. While the full Board of Directors has overall responsibility for risk oversight, the Board of Directors has delegated oversight responsibility related to risks from cybersecurity threats to the Audit Committee. The Audit Committee reports to the Board of Directors at least annually, and notifies the Board of Directors as necessary regarding significant new cybersecurity threats or incidents. The Audit Committee of our Board of Directors meets not less than annually to discuss our approach to overseeing cybersecurity threats with management, including with members of our internal cybersecurity team. Any material cybersecurity incidents are promptly reported by management to our Audit Committee.

We use an internal management committee to run our information and technology function, comprised of information technology, finance, and legal employees, and led by our Vice President – Information Technology and Automation, and Chief Financial Officer, each of whom have experience managing the information and technology functions, and cybersecurity safeguards, at multiple prior companies. Through ongoing communications with this management committee, senior management is informed about and monitors the prevention, detection, mitigation and remediation of cybersecurity threats and incidents in real-time and reports such threats and incidents to the Audit Committee, when appropriate. Management updates the Audit Committee annually with an overview of our cybersecurity threat risk management and strategy processes. Members of the Audit Committee are also encouraged to regularly engage in ad hoc conversations with management on cybersecurity-related topics and discuss any updates to our cybersecurity risk management and strategy programs. The Audit Committee is notified between such updates regarding material new cybersecurity threats or incidents that meet pre-established reporting thresholds and any ongoing updates regarding any risk, as needed.

We have not identified any risks from cybersecurity threats, including as a result of any previous cybersecurity incidents, that have materially affected or are reasonably likely to materially affect our company, including our business strategy, results of operations or financial condition. However, as discussed under "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K, cybersecurity threats could pose multiple risks to us. As cybersecurity threats become more frequent, sophisticated, and coordinated, it is reasonably likely that we will be required to expend greater resources to continue to modify and enhance our protective measures.

**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**

On November 18, 2024, James A. Cutshall filed a putative class action lawsuit, captioned *Cutshall v. Humacyte, Inc., et al*., No. 1:24-cv-00954 (the "Securities Litigation"), against the Company and certain of the Company's officers in the United States District Court for the Middle District of North Carolina. The complaint in the Securities Litigation asserts claims under Sections 10(b) and 20(a) of the Exchange Act on behalf of a putative class of persons and entities that purchased or otherwise acquired securities of the Company between May 10, 2024 and October 17, 2024, based on allegations that the defendants made or were responsible for false or misleading statements and omissions related to the BLA for the vascular trauma indication and to alleged deficiencies at the Company's Durham, North Carolina manufacturing facility. The Complaint seeks a variety of relief, including unspecified compensatory damages, attorneys fees and costs. On January 31, 2025, the court appointed co-lead plaintiffs. On February 19, 2025, the court entered a scheduling order directing the co-lead plaintiffs to file a consolidated amended complaint by April 24, 2025 and the defendants to answer or otherwise respond to the amended complaint by June 27, 2025.

On January 7 and 10, 2025, putative stockholders of the Company filed two verified stockholder derivative actions in the United States District Court for the Middle District of North Carolina, captioned *Silva v. Sebelius, et al*., No. 1:25-cv-00005 (the "*Silva* Action") and *Misko v. Niklason, et al*., No. 1:25-cv-00028 (the "*Misko* Action"). Each of these derivative actions was brought on behalf of the Company against certain of its current or former directors and officers, as well as Ayabudge LLC. The complaints in each action assert claims for violations of Section 14(a) of the Exchange Act, breach of fiduciary duty, unjust enrichment, abuse of control, gross mismanagement, and waste of corporate assets, based on a variety of allegations including claims that the defendants are responsible for any damages sustained by the Company as a result of the Securities Litigation. The *Misko* Action also includes a claim for contribution against certain defendants under Sections 10(b) and 21(d) of the Exchange Act for any liability the Company may sustain as a result of the Securities Litigation. On February 18, 2025, the court issued an order consolidating the *Silva* Action and the *Misko* Action (collectively, the "Consolidated Derivative Action") and staying the defendants' obligation to respond to any complaint in the Consolidated Derivative Action pending the submission of a proposed scheduling order. On March 11, 2025, the parties entered a joint motion to stay the Consolidated Derivative Action pending final resolution of the Securities Litigation. On March 24, 2025, the court granted the parties' joint motion to stay the Consolidated Derivative Action.

On December 19, 2024, the Company received a demand letter (the "Demand Letter") from a purported stockholder of the Company, demanding that the Board assert claims against certain of the Company's current or former officers and directors for breach of fiduciary duty, gross mismanagement, corporate waste, unjust enrichment, aiding and abetting, violations of Section 14(a) of the Exchange Act, and insider trading, based on a variety of allegations including claims that the Company's current and former officers and directors are responsible for any damages sustained by the Company as a result of the Securities Litigation. On January 24, 2025, the Board appointed a demand evaluation committee to evaluate the claims made in the Demand Letter and report back to the full Board. On February 19, 2025, the purported stockholder who sent the Demand Letter filed a stockholder derivative action in the United States District Court for the Middle District of North Carolina, captioned *Olson v. Niklason, et al.*, No. 1:25-cv-00123 (the "*Olson* Action"), alleging that the Company had refused his demand. The complaint in the *Olson* Action asserts substantive claims and allegations that are substantially similar to those asserted in the Consolidated Derivative Action.

The Company disputes all claims asserted against it in the Securities Litigation and disputes that the plaintiffs in the Consolidated Derivative Action and *Olson* Action have standing to assert claims derivatively on its behalf. The Company is currently unable to estimate the potential loss or range of loss, if any, associated with these lawsuits, which could be material.

See the section "Legal Matters" contained in Note 13 — Commitments and Contingencies 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.

**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." As of March 27, 2025, there were 181 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. 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

*The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our accompanying consolidated financial statements and 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 Merger (defined below); 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 titled "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 a commercial-stage biotechnology platform company developing universally implantable, bioengineered human tissues at commercial scale, and in the first quarter of 2025 commenced the United States commercial launch of our first FDA-approved product. We are pioneering the development and manufacture of off-the-shelf, universally implantable, bioengineered human tissues, advanced tissue constructs and organ systems with the goal of improving the lives of patients and transforming the practice of medicine. We believe our regenerative medicine 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 ATEVs. On December 19, 2024, the FDA granted full approval for the ATEV under the brand name Symvess™ for use in adults as a vascular conduit for extremity arterial injury when urgent revascularization is needed to avoid imminent limb loss, and when autologous vein graft is not feasible. Our ATEVs 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 ATEVs with varying diameters and lengths. The ATEV cabinet would initially target the vascular repair, reconstruction and replacement market, including use in vascular trauma, AV access for hemodialysis, and PAD. We are also developing the ATEV for CABG and pediatric heart surgery. Over the longer term, we are developing our ATEV for the delivery of cellular therapies, including pancreatic islet cell transplantation to treat Type 1 diabetes (our BVP). 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.

For the ATEV, 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 complications such as amputation and reperfusion injury. In addition, in many instances of vascular trauma the patient may not have adequate vein available, or the time between injury and treatment is too long to make autologous graft repair feasible. Synthetic grafts are often contraindicated in the setting of vascular trauma due to wound contamination that contributes to higher infection risk that can lead to prolonged hospitalization and limb loss. Given the competitive advantages our ATEVs are designed to have over existing vascular substitutes, we believe that ATEVs have the potential to become the standard of care and lead to improved patient outcomes and lower healthcare costs.

As of December 31, 2024, our ATEVs have been implanted in approximately 601 patients. In addition to extremity vascular trauma, we and our collaborators are currently conducting Phase 3 and Phase 2 trials of our 6 millimeter ATEV in AV access for hemodialysis and PAD. We were granted Fast Track designation by the FDA for our 6 millimeter ATEV for use in AV access for hemodialysis in 2014. We also received the first RMAT designation from the FDA, for the creation of vascular access for performing hemodialysis, in March 2017. In May 2023, we were granted the RMAT designation for the ATEV for urgent arterial repair following extremity vascular trauma, and in June 2024, we were granted the RMAT designation for the ATEV for patients with advanced PAD. In addition, in 2018 our ATEV 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.

In September 2023, we announced positive topline results from our V005 Phase 2/3 trial in vascular trauma, and in December 2023, we filed a BLA for urgent arterial repair following extremity vascular trauma when synthetic graft is not indicated, and autologous vein use is not feasible. In February 2024, the FDA accepted the BLA filing and granted priority review and set a PDUFA date of August 10, 2024. On August 9, 2024, the FDA informed us that it required additional time to complete its review of the BLA for the vascular trauma indication. On December 19, 2024, the FDA granted full approval for Symvess (acellular tissue engineered vessel-tyod) for use in adults as a vascular conduit for extremity arterial injury when urgent revascularization is needed to avoid imminent limb loss, and autologous vein graft is not feasible. In February 2025, the FDA completed its required review of commercial batch information for Symvess and has authorized us to commence commercial shipments.

In April 2023, we announced completion of enrollment of our V007 Phase 3 trial of the ATEV for use in AV access for hemodialysis. In July 2024, we announced positive topline results from our V007 Phase 3 trial, where the ATEV met the primary endpoints in the study. Dependent upon interim results from our ongoing V012 Phase 3 trial in women, we plan to submit a supplemental BLA for the ATEV to the FDA for an indication in AV access for hemodialysis in the second half of 2026.

We have generated no product revenue and incurred operating losses and negative cash flows from operations in each year since our inception in 2004. As of December 31, 2024 and 2023, we had an accumulated deficit of $686.0 million and $537.3 million, respectively, and working capital of $27.9 million and $64.8 million, respectively. Our operating losses were approximately $114.4 million and $100.0 million for the years ended December 31, 2024 and 2023, respectively. Net cash flows used in operating activities were $98.1 million and $73.3 million during the years ended December 31, 2024 and 2023, respectively. Substantially all of our operating 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 begin to commercialize Symvess and advance our product candidates.

As of December 31, 2024, we had cash and cash equivalents of $44.9 million and restricted cash of $50.4 million. Subsequent to December 31, 2024, in March 2025 we completed a public offering of common stock which provided approximately $46.6 million in net proceeds. We believe our cash and cash equivalents on hand will be sufficient to fund operations for at least 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, and the results of our commercial sales efforts. We recently received FDA approval to commercialize Symvess, but we have not generated any revenue from the sale of commercialized products to date. Our ability to generate product revenue will depend on the successful development and commercialization of Symvess and our product candidates. Until such time, if ever, we expect to finance our operations through the use of existing cash and cash equivalents, the 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:

- commercialize Symvess via U.S. market launch for indications in vascular trauma and, if approved, in AV access for hemodialysis;
- obtain marketing approval for our 6 millimeter ATEV in additional indications involving vascular repair, reconstruction and replacement, including in AV access for hemodialysis;
- scale out our manufacturing facility to the extent required to satisfy potential market demand for Symvess in the United States and our product candidates, following receipt of any regulatory 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
- continue operating as a public company, which includes higher costs associated with hiring additional personnel, director and officer insurance premiums, audit and legal 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**

On March 25, 2025, we entered into an underwriting agreement with TD Securities (USA) LLC, Barclays Capital Inc. and BTIG, LLC, as representatives of the several underwriters named therein, relating to the issuance and sale in an underwritten offering (the "Public Offering") of 25,000,000 shares of Common Stock, at a price to the public of $2.00 per share (the "Firm Shares"). The Company also granted the underwriters a 30-day option to purchase up to an additional 3,750,000 shares of Common Stock at the same price as the Firm Shares. The net proceeds to us from the Public Offering were approximately $46.6 million after deducting underwriting discounts and commissions and estimated Public Offering expenses. The Public Offering closed on March 27, 2025.

**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. From inception through December 31, 2024, we have been awarded grants, including 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 and refining 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 CROs and consultants, including in connection with our clinical trials, and other related clinical trial fees, such as for clinical site fees and investigator grants related to patient screening and treatment, conduct of clinical trials, 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 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 2 and 3 clinical trials for our 6 millimeter ATEV and other work needed to obtain marketing approval for our 6 millimeter ATEV for use for in AV access in hemodialysis in the United States. 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 2 and Phase 3 clinical trials.

Direct expenses for our vascular trauma, AV access for hemodialysis and PAD indications include costs related to our clinical trials, including fees paid to CROs, consultants, clinical sites and investigators. Costs related to development activities which broadly support multiple programs using our technology platform, including personnel, materials and supplies, external services costs, and other internal expenses, such as facilities and overhead costs, are not allocated to

individual research and development programs. Other research and development expenses include direct costs not identifiable with a specific product candidate, including costs associated with our research and development platform used across programs, process development, manufacturing analytics and preclinical research and development for prospective product candidates and new technologies.

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 and refinement 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 Symvess and our product candidates, if approved, whether alone or in collaboration with others;
- the degree of market acceptance of Symvess and any product candidates that obtain marketing approval; and
- maintaining a continued acceptable safety profile following approval of Symvess in the vascular trauma indication and in any other indications for which approval may be granted, or for any of our product candidates, if approved.

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 continue to increase for the foreseeable future to support our expanded infrastructure and increased costs of operating as a public company and as we commercialize Symvess in the United States and seek marketing approval for Symvess outside of the United States. These increases are expected to include increased employee-related expenses, increased sales and marketing expenses, and increased director and officer insurance premiums, audit and legal 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 (Expense), Net*

Total other income (expense), 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) interest income earned on our cash and cash equivalents and short-term investments, (iii) interest expense incurred on the Purchase Agreement (defined below), finance leases, and our former loan agreement with SVB during the periods each were outstanding, (iv) the change in fair value of our derivative liabilities and asset including the private placement Common Stock warrant liabilities related to the Private Placement Warrants, which we assumed in connection with the Merger; Common Stock warrant liabilities related to our Registered Direct Offerings; the contingent derivative liability related to the Purchase Agreement; a liability related to a freestanding option agreement related to the Purchase Agreement; a derivative liability related to our agreement with JDRF (defined below); and a derivative asset related to our Common Stock Purchase Agreement (defined below), all of which are subject to remeasurement to fair value at each balance sheet date resulting in a non-cash gain or loss, (v) a loss on debt extinguishment related to the prepayment of our loan agreement with Silicon Valley Bank in May 2023, and (vi) an employee retention credit we recognized in June 2023.

**Results of Operations**

*Comparison of the Years Ended December 31, 2024 and 2023*

| | Year Ended December 31, | | Change | |
|---|---|---|---|---|
| ***($ in thousands)*** | **2024** | **2023** | **$** | **%** |
| **Operating expenses:** | | | | |
| Research and development | $ 88,599 | $ 76,550 | $ 12,049 | 16 % |
| General and administrative | 25,799 | 23,497 | 2,302 | 10 % |
| Total operating expenses | 114,398 | 100,047 | 14,351 | 14 % |
| **Loss from operations** | **(114,398)** | **(100,047)** | **(14,351)** | **14 %** |
| | | | | |
| Other income (expense), net | | | | |
| Interest income | 4,104 | 5,467 | (1,363) | (25) % |
| Change in fair value of Contingent Earnout Liability | (33,045) | (10,023) | (23,022) | 230 % |
| Interest expense | (9,277) | (6,599) | (2,678) | 41 % |
| Change in fair value of derivatives | 3,915 | (260) | 4,175 | (1606) % |
| Employee retention credit | — | 3,107 | (3,107) | (100) % |
| Loss on extinguishment of debt | — | (2,421) | 2,421 | (100) % |
| Total other expense, net | (34,303) | (10,729) | (23,574) | 220 % |
| **Net loss** | **$ (148,701)** | **$ (110,776)** | **$ (37,925)** | **34 %** |

*Research and Development Expenses*

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

| ($ in thousands) | Year Ended December 31, 2024 | Year Ended December 31, 2023 | Change $ | Change % |
|---|---|---|---|---|
| **Direct Expenses** | | | | |
| Vascular Trauma | $ 2,181 | $ 3,976 | $ (1,795) | (45) % |
| AV Access | 6,620 | 8,748 | (2,128) | (24) % |
| PAD | 143 | 306 | (163) | (53) % |
| Total | 8,944 | 13,030 | (4,086) | (31) % |
| **Unallocated Expenses** | | | | |
| External services | 7,071 | 6,106 | 965 | 16 % |
| Materials and supplies | 21,765 | 13,705 | 8,060 | 59 % |
| Payroll and personnel expenses | 36,537 | 30,118 | 6,419 | 21 % |
| Other research and development expenses | 14,282 | 13,591 | 691 | 5 % |
| Total | 79,655 | 63,520 | 16,135 | 25 % |
| **Total research and development expenses** | **$ 88,599** | **$ 76,550** | **$ 12,049** | **16 %** |

Research and development expenses were $88.6 million for the year ended December 31, 2024, representing an increase of $12.0 million, or 16%, from $76.6 million for the year ended December 31, 2023. The increase was primarily driven by expenses incurred to support our expanded research and development initiatives, including increased product manufacturing and development and support of the FDA review of the BLA in vascular trauma. Expense increases were primarily comprised of a $8.1 million increase in the purchase of materials and supplies, in part due to an increased number of manufacturing production runs, and $6.4 million in additional payroll and personnel expenses.

*General and Administrative Expenses*

General and administrative expenses were $25.8 million and $23.5 million for the years ended December 31, 2024 and 2023, respectively. The increase in general and administrative expenses during the year ended December 31, 2024 of $2.3 million, or 10%, compared to the year ended December 31, 2023 was primarily driven by preparation for our planned commercial launch of the ATEV in vascular trauma. Major changes in expenses included a $2.6 million increase in salaries and benefits due to the recruitment and hiring of a sales force for Symvess and other expansion of the commercial team, and a $1.3 million increase in professional fees, partially offset by a $1.8 million decrease in non-cash stock compensation expense.

*Total Other Income (Expense), net*

Total other expense, net was $34.3 million for the year ended December 31, 2024, compared to net expense of $10.7 million for the year ended December 31, 2023. The increase in net expense of $23.6 million primarily resulted from a $23.0 million increase in the non-cash loss resulting from the remeasurement of the Contingent Earnout Liability during each year.

**Liquidity and Capital Resources**

*Sources of Liquidity*

We have historically financed our operations primarily through the sale of equity securities and convertible debt, including pursuant to the Offering (as defined below) and Registered Direct Offerings we completed in October and November 2024, proceeds from the Merger and related PIPE Financing (as defined in Note 14 to our accompanying consolidated financial statements contained in Part II, Item 8 of this Annual Report on Form 10-K), borrowings under loan facilities, the Purchase Agreement (defined below), 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, 2024 and 2023, we had an accumulated deficit of $686.0 million and $537.3 million, respectively.

As of December 31, 2024 and 2023, we had working capital of $27.9 million and $64.8 million, respectively. As of December 31, 2024 and 2023, we had cash and cash equivalents of $44.9 million and $80.4 million, respectively, and restricted cash of $50.4 million and $0.4 million, respectively. We funded the restricted cash account on August 14, 2024, in accordance with our amended Purchase Agreement (defined below), of which $50.0 million is not subject to our unilateral control.

Subsequent to December 31, 2024, in March 2025 we completed a public offering of common stock which provided approximately $46.6 million in net proceeds. As of March 31, 2025, we had $47.5 million in remaining availability for sales of Common Stock under our Common Stock Purchase Agreement with Lincoln Park and $72.6 million in remaining availability for sales of Common Stock under our ATM Facility, defined below.

Before consideration of management's plans described below, we believe our cash and cash equivalents on hand and existing capacity under our Common Stock Purchase Agreement will be sufficient to fund operations at least into March 2026. The future viability of the Company beyond that point is dependent on our ability to generate cash flows from the sale of Symvess and raise additional capital to finance our operations. 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 regarding our assessment. We believe that our longer-term working capital, planned research and development, capital expenditures and other general corporate funding requirements may be satisfied through the sale of equity, debt financings, debt refinancing or restructuring 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 of this Annual Report on Form 10-K titled "Forward-Looking Statements" and "Risk Factors." If we are unable to raise sufficient capital, we plan to implement a program that delays, reduces, suspends or ceases certain of our planned capital expenditures, research and development programs or any future commercialization efforts, which would have a negative impact on our business, prospects, operating results and financial condition. Based on our current cash and cash equivalents on hand and existing capacity under our Common Stock Purchase Agreement, and after considering management's plans, we believe we have the ability to fund operations at least into the middle of 2026.

On May 12, 2023, we entered into a Revenue Interest Purchase Agreement (the "Purchase Agreement") with two purchasers (the "Purchasers"), both affiliates of Oberland Capital Management LLC ("Oberland"), and another affiliate of Oberland, as agent for the Purchasers (the "Agent"), to obtain financing in respect to the further development and commercialization of our ATEV, to repay our then outstanding credit facility with SVB, and for other general corporate purposes. Pursuant to the Purchase Agreement, and subject to customary closing conditions, the Purchasers purchased certain revenue interests (the "Revenue Interests") from us in exchange for an aggregate investment amount of up to $150.0 million (the "Investment Amount"). Under the terms of the Purchase Agreement, $40.0 million of the Investment Amount, less certain transaction expenses, was funded on May 12, 2023, which was used to repay in full all and retire our indebtedness under our loan agreement with SVB, with the remaining proceeds funded to the Company. On March 11, 2024, $20.0 million of the Investment Amount was funded to the Company. On December 19, 2024, the FDA granted full approval for our BLA for the vascular trauma indication, and we did not elect to draw the additional $40.0 million that became available under the Purchase Agreement. As of December 31, 2024, we are not entitled to draw on any further installments under the Purchase Agreement. See Note 6 to our accompanying consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K for additional details about this financing transaction.

On February 18, 2024, we agreed with the Purchasers and the Agent, to waive certain breaches related to, and extend the deadline for certain post-closing obligations under, the Purchase Agreement, including the requirement for us to deliver a leasehold mortgage in favor of the Agent over our headquarters. On May 8, 2024, we reached an agreement with the Purchasers to amend the Purchase Agreement to remove requirements related to the leasehold mortgage. In exchange for the removal of this requirement, on August 14, 2024 we funded an account in the amount of $54.0 million, over which the Agent has certain consent and other rights to $50.0 million of the funds. See Note 6 for further information.

On February 29, 2024, we entered into an underwriting agreement with Cowen and Company, LLC and Cantor & Fitzgerald & Co., as representatives of the several underwriters named therein, relating to the issuance and sale in an underwritten offering (the "Offering") of 15,410,000 shares of our Common Stock at a price to the public of $3.00 per share. The net proceeds to us from the Offering were approximately $43.0 million, after deducting underwriting discounts and commissions and Offering expenses. The Offering closed on March 5, 2024.

On September 24, 2024, we entered into the Common Stock Purchase Agreement with Lincoln Park for an equity line financing, which provides that, subject to the terms and conditions set forth in the Common Stock Purchase Agreement, we have the sole right, but not the obligation, to sell to Lincoln Park shares of Common Stock having an aggregate value of up to $50.0 million over a 24-month period. We control the timing and amount of any sales to Lincoln Park. As of December 31, 2024, we had completed sales of shares under the Common Stock Purchase Agreement that provided $2.5 million in gross proceeds. As of March 31, 2025, we had $47.5 million in remaining availability for sales of our Common Stock under our Common Stock Purchase Agreement with Lincoln Park.

On October 4, 2024, we entered into a securities purchase agreement with an institutional investor pursuant to which the investor purchased approximately $30.0 million worth of Common Stock and warrants in the October 2024 Registered Direct Offering (as defined below). The net proceeds to us from the October 2024 Registered Direct Offering were approximately $28.0 million, after deducting placement agent's fees and offering expenses of approximately $2.0 million. The October 2024 Registered Direct Offering closed on October 7, 2024.

On November 13, 2024, we entered into a securities purchase agreement with an institutional investor pursuant to which the investor purchased approximately $15.0 million worth of Common Stock and warrants in the November 2024 Registered Direct Offering (as defined below). The net proceeds to us from the November 2024 Registered Direct Offering were approximately $14.9 million after deducting offering expenses of approximately $0.1 million. The November 2024 Registered Direct Offering closed on November 15, 2024.

On March 25, 2025, we entered into an underwriting agreement with TD Securities (USA) LLC, Barclays Capital Inc. and BTIG, LLC, as representatives of the several underwriters named therein, relating to the issuance and sale in the Public Offering of 25,000,000 shares of Common Stock, at a price to the public of $2.00 per share. We also granted the underwriters a 30-day option to purchase up to an additional 3,750,000 shares of Common Stock at the same price as the Firm Shares. The net proceeds to us from the Public Offering were approximately $46.6 million after deducting underwriting discounts and commissions and estimated Public Offering expenses. The Public Offering closed on March 27, 2025.

*ATM Facility*

On September 1, 2022, we entered into an agreement with Jefferies LLC for the sale from time to time of up to $80.0 million of shares of Common Stock pursuant to a sales agreement (the "ATM Facility"). In December 2024, we sold an aggregate of 1,333,596 shares of Common Stock under the ATM Facility at an average price of $5.26 per share for net proceeds of approximately $6.8 million after deducting sales commissions of approximately $0.2 million. From December 31, 2024 through March 31, 2025, we sold an aggregate of 75,793 shares of Common Stock under the ATM Facility at an average price of $5.04 per share for net proceeds of approximately $0.4 million.

*Material Cash Requirements*

Our known material cash requirements include: (1) the purchase of supplies and services that are primarily for research and development; (2) repayments pursuant to the Purchase Agreement (for additional information see below and Note 6 to our accompanying consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K); (3) employee wages, benefits, and incentives; (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), and (5) payments under our JDRF Agreement (for additional information see Note 13 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, for example, legal contingencies, uncertain tax positions, and other matters.

As of December 31, 2024, we had non-cancellable purchase commitments of $31.3 million for supplies and services that are primarily for research and development. We have existing license agreements with Duke University and Yale University, a distribution agreement with Fresenius Medical Care and our JDRF Agreement. 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, 2024. For additional information regarding our agreements with Duke University, Yale University, and Fresenius Medical Care, and the nature of payments that could become due thereunder, see the sections in this Annual Report on Form 10-K titled "Business — Distribution" and "Business — Intellectual Property." For additional information about our JDRF Agreement, see Note 13 — Commitments and Contingencies to our accompanying consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K.

*Revenue Interest Purchase Agreement*

On May 12, 2023, we entered into the Purchase Agreement and repaid in full all of the then-existing obligations under our loan agreement with SVB. Under the Purchase Agreement, as of December 31, 2024, we had $64.2 million recorded as a revenue interest liability on our consolidated financial statements. For additional information regarding repayment, see Note 6 — Revenue Interest Purchase Agreement to our accompanying consolidated financial statements in Part II, Item 8 of this Annual Report on Form 10-K.

*Leases*

Our finance leases relate to our headquarters facility containing our manufacturing, research and development and general and administrative functions, which was substantially completed in June 2018 and is being 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, 2024 are as follows:

| *($ in thousands)* | Total | Less than 1 year | 1 – 3 years | 3 – 5 years | More than 5 years |
|---|---|---|---|---|---|
| Finance leases | $ 21,431 | $ 4,212 | $ 7,000 | $ 4,447 | $ 5,772 |
| Operating lease | 784 | 105 | 210 | 210 | 259 |

*Future Funding Requirements*

We expect to incur significant expenses in connection with our ongoing activities as we seek to (i) commercialize Symvess and seek marketing approval for Symvess in additional indications and for our product candidates in the United States and to obtain marketing approval for our 6 millimeter ATEV outside of the United States, (ii) continue clinical development of our 6 millimeter ATEV for use in hemodialysis AV access and submit a BLA for FDA approval of an indication in hemodialysis AV access, (iii) advance our pipeline in major markets, including PAD Phase 3 trials and continue preclinical development and advance to planned clinical studies in CABG and BVP for diabetes, and (iv) scale out our manufacturing facility as required to satisfy market demand. 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 cost and timing of our future commercialization activities, including product manufacturing, marketing and distribution for Symvess in the United States, 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 Symvess and any product candidates for which we receive marketing approval;
- 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 Symvess outside of the United States and of our product candidates in the United States;

- the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our additional product candidates;
- 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, 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 commercialize Symvess and to develop and commercialize 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. 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 plan to implement a program that delays, reduces, suspends or ceases our planned capital expenditures, research and development programs or any future commercialization efforts, which would have a negative impact on our business, prospects, operating results and financial condition.

Our principal use of cash in recent periods has been primarily to fund our operations, including the clinical and preclinical development of our product candidates. Our 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:

| | Year Ended December 31, | |
|---|---|---|
| ***($ in thousands)*** | **2024** | **2023** |
| Net loss | $ (148,701) | $ (110,776) |
| Non-cash adjustments to reconcile net loss to net cash used in operating activities[(1)]: | 50,268 | 30,900 |
| Changes in operating assets and liabilities: | 311 | 6,571 |
| Net cash used in operating activities | (98,122) | (73,305) |
| Net cash used in investing activities | (1,572) | (173) |
| Net cash provided by financing activities | 114,183 | 4,507 |
| Net increase (decrease) in cash, cash equivalents and restricted cash | $ 14,489 | $ (68,971) |
| Cash, cash equivalents and restricted cash at the beginning of the period | $ 80,801 | $ 149,772 |
| Cash, cash equivalents and restricted cash at the end of the period | $ 95,290 | $ 80,801 |

(1) Primarily includes depreciation, amortization related to our leases, stock-based compensation expense, non-cash interest expense related to our revenue interest liability and our JDRF Award liability (defined below) the changes in fair value of our Contingent Earnout Liability and our derivative liabilities and asset, and an immaterial amount of loss on disposal of property and equipment, and in 2023 includes a loss on extinguishment of debt, amortization of our debt discount.

*Cash Flow from Operating Activities*

The increase in net cash used in operating activities from 2023 to 2024 was primarily due to increased spending on preclinical, clinical and pre-commercial activities as well as payroll and personnel expenses, expansion of clinical development of the ATEV for use in AV access, and preparation for the planned commercial launch of the ATEV for an indication in vascular trauma.

*Cash Flow from Investing Activities*

Net cash used in investing activities for the year ended December 31, 2024 consisted of purchases of property and equipment. Net cash used in investing activities for the year ended December 31, 2023 consisted primarily of purchases of property and equipment, which fully offset proceeds from the maturity of our short-term investments (certificates of deposit).

*Cash Flow from Financing Activities*

Net cash provided by financing activities for the year ended December 31, 2024 consisted primarily of $43.1 million of net proceeds from our Registered Direct Offerings we completed in October and November 2024, $43.0 million of net proceeds from our Offering we completed in March 2024 and $19.5 million of net proceeds from our Purchase Agreement. Net cash provided by financing activities for the year ended December 31, 2023 consisted primarily of $37.9 million of net proceeds from our Purchase Agreement, partially offset by $31.8 million of cash payments related to the repayment of our loan agreement with SVB.

*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 discussion and analysis of our financial condition and results of operations are based upon our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. 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 based on 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.

*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 income (expense), 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 valuations at December 31, 2024 and 2023.

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.

*Revenue Interest Liability*

On May 12, 2023, we entered into the Purchase Agreement to obtain financing in respect to the further development and commercialization of our ATEV, to repay our credit facility with SVB, and for other general corporate purposes. We recorded a revenue interest liability related to the Purchase Agreement on our consolidated balance sheet on the date we entered into the Purchase Agreement, which is presented net of issuance costs and a debt discount. We impute interest expense associated with this liability using the interest method. The estimated effective interest rate is calculated based on the rate that would enable the debt to be repaid in full over the anticipated life of the arrangement. Interest expense and amortization of our issuance costs and debt discount is recognized over the estimated term in our consolidated statements of operations and comprehensive loss. The interest rate on the liability may vary during the term of the agreement primarily due to the level of forecasted net sales. We evaluate the interest rate quarterly based on our current net sales forecasts utilizing the prospective method. A significant increase or decrease in net sales could materially impact the revenue interest liability, interest expense and the time period for repayment.

At December 31, 2024, the revenue interest liability is calculated using our current estimate of forecasted global net sales of our products, and impacted by a debt discount comprising the estimated fair value of a bifurcated derivative liability related to the Purchasers' put option under the Purchase Agreement, the estimated fair value of a freestanding option agreement related to the Purchase Agreement, and issuance and transaction costs incurred. As Symvess is currently our only product approved for sale in the United States and we have not yet generated product revenue, the estimated probability and timing or amounts of repayment is likely to change each reporting period.

The fair value of the contingent derivative liability is valued using a "with-and-without" method. The "with-and-without" methodology involves valuing the whole instrument on an as-is basis and then valuing the instrument without the individual embedded derivative. The difference between the entire instrument with the embedded derivative compared to the instrument without the embedded derivative was the fair value of the contingent derivative liability. The estimated probability and timing of underlying events triggering the exercisability of the contingent derivative liability bifurcated from within the Purchase Agreement, forecasted cash flows and the discount rate are significant unobservable inputs used to determine the estimated fair value of the entire instrument with the embedded derivative.

*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*. The fair value of our Common Stock has been determined based on the closing price of the shares on Nasdaq.
- *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 determined based on a blended approach using the historical share volatility of our Common Stock and that 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. 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.

*Common Stock Warrants*

*Public and Private Placement 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 (*"ASC 480") and ASC Topic 815, *Derivatives and Hedging (*"ASC 815").

We accounted for the Private Placement Warrants in accordance with the guidance contained in ASC 815, under which the warrants did not meet the criteria for equity treatment and must be recorded as liabilities. As the Private Placement Warrants met 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 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 met the criteria to be classified within stockholders' equity.

*Registered Direct Offering Warrants*

We accounted for the common stock warrants issued in the Registered Direct Offerings in accordance with the guidance contained in ASC 480 and ASC 815. The Registered Direct Offering Warrants (as defined in Note 2 to our accompanying consolidated financial statements contained in Part II, Item 8 of this Annual Report on Form 10-K) did not meet the criteria for equity treatment and must be recorded as liabilities. As the Registered Direct Offering 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 Black-Scholes valuation 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 Registered Direct Offering 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 Registered Direct Offering Warrants involves certain assumptions requiring significant judgment and actual results can differ from assumed and estimated amounts.

***Emerging Growth Company and Smaller Reporting Company Status***

We are 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 we are an emerging growth company we 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 we choose to early adopt a new or revised accounting standard. This may make it difficult or impossible to compare our financial results with the financial results of another public company because of the potential differences in accounting standards used.

Additionally, we are 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. We 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) our annual revenues in our 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 Disclosures 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 subsidiaries (the "Company") as of December 31, 2024 and 2023, and the related consolidated statements of operations and comprehensive loss, of changes in 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, 2024 and 2023, 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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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.

***Emphasis of Matter***

As discussed in Note 1 to the consolidated financial statements, the Company has incurred operating losses and negative cash flows from operations since inception. Management's evaluation of the events and conditions and management's plans to mitigate these matters are also described in Note 1.

/s/ PricewaterhouseCoopers LLP

Raleigh, North Carolina

March 31, 2025

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, | |
|---|---|---|
| | 2024 | 2023 |
| **ASSETS** | | |
| Current assets | | |
| Cash and cash equivalents | $ 44,937 | $ 80,448 |
| Prepaid expenses and other current assets | 2,922 | 2,830 |
| Total current assets | 47,859 | 83,278 |
| | | |
| Restricted cash | 50,209 | 209 |
| Property and equipment, net | 23,063 | 26,791 |
| Finance lease right-of-use assets, net | 15,490 | 17,313 |
| Other long-term assets | 1,251 | 632 |
| **Total assets** | **$ 137,872** | **$ 128,223** |
| | | |
| **LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)** | | |
| Current liabilities | | |
| Accounts payable | $ 4,490 | $ 6,490 |
| Accrued expenses | 11,424 | 9,340 |
| Finance lease obligation, current portion | 2,917 | 2,560 |
| Other current liabilities | 1,123 | 53 |
| Total current liabilities | 19,954 | 18,443 |
| | | |
| Contingent Earnout Liability | 70,961 | 37,916 |
| Revenue interest liability | 63,354 | 38,600 |
| Common stock warrant liabilities | 19,254 | 78 |
| Finance lease obligation, net of current portion | 13,620 | 16,293 |
| Contingent derivative liability | 2,415 | 2,636 |
| Other long-term liabilities | 983 | 711 |
| **Total liabilities** | **190,541** | **114,677** |
| | | |
| **Commitments and contingencies (Note 13)** | | |
| | | |
| **Stockholders' equity (deficit)** | | |
| Preferred stock, $0.0001 par value; 20,000,000 shares designated as of December 31, 2024 and 2023; 0 shares issued and outstanding as of December 31, 2024 and 2023 | — | — |
| Common stock, $0.0001 par value; 250,000,000 shares authorized as of December 31, 2024 and 2023; 130,027,509 and 103,673,728 shares issued and outstanding as of December 31, 2024 and 2023, respectively | 13 | 10 |
| Additional paid-in capital | 633,333 | 550,850 |
| Accumulated deficit | (686,015) | (537,314) |
| Total stockholders' equity (deficit) | (52,669) | 13,546 |
| **Total liabilities and stockholders' equity (deficit)** | **$ 137,872** | **$ 128,223** |

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, | |
|---|---|---|
| | 2024 | 2023 |
| **Operating expenses:** | | |
| Research and development | $ 88,599 | $ 76,550 |
| General and administrative | 25,799 | 23,497 |
| Total operating expenses | 114,398 | 100,047 |
| **Loss from operations** | **(114,398)** | **(100,047)** |
| | | |
| Other income (expense), net | | |
| Interest income | 4,104 | 5,467 |
| Change in fair value of Contingent Earnout Liability | (33,045) | (10,023) |
| Interest expense | (9,277) | (6,599) |
| Change in fair value of derivatives | 3,915 | (260) |
| Employee retention credit | — | 3,107 |
| Loss on extinguishment of debt | — | (2,421) |
| Total other expense, net | (34,303) | (10,729) |
| **Net loss and comprehensive loss** | **$ (148,701)** | **$ (110,776)** |
| | | |
| Net loss per share attributable to common stockholders, basic and diluted | $ (1.26) | $ (1.07) |
| Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted | 118,479,097 | 103,420,238 |

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

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

| | Common Stock | | Additional Paid-in Capital | Accumulated Deficit | Total Stockholders' Equity (Deficit) |
|---|---|---|---|---|---|
| | Shares | Amount | | | |
| **Balance as of December 31, 2022** | **103,229,013** | **$ 10** | **$ 543,456** | **$ (426,538)** | **$ 116,928** |
| Proceeds from the exercise of stock options | 444,715 | — | 566 | — | 566 |
| Stock-based compensation | — | — | 6,828 | — | 6,828 |
| Net loss | — | — | — | (110,776) | (110,776) |
| **Balance as of December 31, 2023** | **103,673,728** | **$ 10** | **$ 550,850** | **$ (537,314)** | **$ 13,546** |
| Issuance of stock in public offering, net of issuance costs | 15,410,000 | 2 | 43,044 | — | 43,046 |
| Issuance of stock in registered direct offerings, net of issuance costs | 8,490,808 | 1 | 21,744 | — | 21,745 |
| Issuance of stock under ATM Facility, net of issuance costs | 1,333,596 | — | 6,809 | — | 6,809 |
| Issuance of commitment shares pursuant to Common Stock Purchase Agreement | 115,705 | — | 708 | — | 708 |
| Proceeds from sale of stock under Common Stock Purchase Agreement | 500,000 | — | 2,530 | — | 2,530 |
| Proceeds from the exercise of stock options | 503,672 | — | 1,511 | — | 1,511 |
| Stock-based compensation | — | — | 6,137 | — | 6,137 |
| Net loss | — | — | — | (148,701) | (148,701) |
| **Balance as of December 31, 2024** | **130,027,509** | **$ 13** | **$ 633,333** | **$ (686,015)** | **$ (52,669)** |

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

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

| | Year Ended December 31, | |
|---|---|---|
| | **2024** | **2023** |
| **Cash flows from operating activities** | | |
| Net loss | $ (148,701) | $ (110,776) |
| Adjustments to reconcile net loss to net cash used in operating activities: | | |
| Depreciation expense | 5,104 | 5,659 |
| Stock-based compensation expense | 6,137 | 6,828 |
| Change in fair value of Contingent Earnout Liability | 33,045 | 10,023 |
| Non-cash interest expense | 7,754 | 3,099 |
| Change in fair value of derivatives | (3,915) | 260 |
| Loss on disposal of property and equipment | 4 | 18 |
| Loss on extinguishment of debt | — | 2,421 |
| Amortization expense | 2,086 | 2,060 |
| Non-cash operating lease costs | 53 | 50 |
| Amortization of SVB debt discount | — | 482 |
| Changes in operating assets and liabilities: | | |
| Accounts receivable | — | 31 |
| Prepaid expenses and other current assets | 88 | (388) |
| Accounts payable | (1,962) | 4,811 |
| Accrued expenses | 2,238 | 2,167 |
| Operating lease obligation | (53) | (50) |
| Net cash used in operating activities | (98,122) | (73,305) |
| | | |
| **Cash flows from investing activities** | | |
| Purchase of property and equipment | (1,572) | (2,280) |
| Proceeds from maturity of short-term investments (certificates of deposit) | — | 2,107 |
| Net cash used in investing activities | (1,572) | (173) |
| | | |
| **Cash flows from financing activities** | | |
| Proceeds from issuance of stock in public offering, net of underwriting fees | 43,396 | — |
| Payments of costs related to public offering | (350) | — |
| Proceeds from issuance of stock and warrants in registered direct offerings, net of placement agent fees | 43,126 | — |
| Proceeds from Revenue Interest Purchase Agreement, net of issuance costs | 20,000 | 39,377 |
| Payments of transaction costs related to Revenue Interest Purchase Agreement | (500) | (1,450) |
| Proceeds from issuance of stock under ATM Facility, net of issuance costs | 6,809 | — |
| Proceeds from sale of stock under Common Stock Purchase Agreement | 2,530 | — |
| Proceeds from the exercise of stock options | 1,511 | 566 |
| Proceeds from JDRF Agreement | 240 | 80 |
| Payments of finance lease principal | (2,579) | (2,256) |
| Principal payments on SVB loan | — | (31,500) |
| Payments for debt prepayment and extinguishment costs | — | (310) |
| Net cash provided by financing activities | 114,183 | 4,507 |
| | | |
| Net increase (decrease) in cash, cash equivalents and restricted cash | 14,489 | (68,971) |
| Cash, cash equivalents and restricted cash at the beginning of the period | 80,801 | 149,772 |
| **Cash, cash equivalents and restricted cash at the end of the period** | **$ 95,290** | **$ 80,801** |
| | | |
| **Supplemental disclosure:** | | |
| Cash paid for interest on SVB loan | $ — | $ 1,613 |
| | | |
| **Supplemental disclosure of noncash activities:** | | |
| Purchase of property and equipment in accounts payable and accrued expenses | $ 92 | $ 284 |
| Debt discount from embedded contingent derivative liability | $ 1,552 | $ 2,354 |
| Issuance of commitment shares pursuant to Common Stock Purchase Agreement | $ 708 | $ — |

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 subsidiaries (unless the context indicates otherwise, collectively, the "Company") is pioneering the development and manufacture of off-the-shelf, universally implantable, bioengineered human tissues, advanced tissue constructs and organ systems with the goal of improving the lives of patients and transforming the practice of medicine. The Company is leveraging its regenerative medicine technology platform to develop proprietary product candidates 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 a Business Combination Agreement, dated as of February 17, 2021 (the "Merger Agreement"), by and among Humacyte, Inc. ("Legacy Humacyte"), AHAC and Hunter Merger Sub, Inc. ("Merger Sub"), a 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 (such transactions, the "Merger," and, collectively with the other transactions described in the Merger Agreement, the "Reverse Recapitalization"). On the Closing Date, AHAC changed its name to Humacyte, Inc. and Legacy Humacyte changed its name to Humacyte Global, Inc. ("Global"). The Merger was accounted for as a reverse recapitalization in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"), and under this method of accounting, AHAC was treated as the acquired company for financial reporting purposes and Legacy Humacyte was treated as the acquirer. Operations prior to the Merger are those of Legacy Humacyte.

### Liquidity

Since its inception in 2004, the Company has generated no product revenue and has incurred operating 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, proceeds from a revenue interest purchase agreement and, to a lesser extent, through governmental and other grants. At December 31, 2024 and December 31, 2023, the Company had an accumulated deficit of $686.0 million and $537.3 million, respectively. The Company's operating losses were $114.4 million and $100.0 million for the years ended December 31, 2024 and 2023, respectively. Net cash flows used in operating activities were $98.1 million and $73.3 million during the years ended December 31, 2024 and 2023, respectively. Substantially all of the Company's operating 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 further disclosed in Note 6, on May 12, 2023, Humacyte, Inc. and Global entered into a Revenue Interest Purchase Agreement (the "Purchase Agreement") with two purchasers, both affiliates of Oberland Capital Management LLC (the "Purchasers"), and another affiliate of Oberland Capital Management LLC ("Oberland"), as agent for the Purchasers (the "Agent"), to obtain financing with respect to the further development and commercialization of the Company's ATEV, to repay the Company's then-existing credit facility with Silicon Valley Bank ("SVB"), and for other general corporate purposes. As of December 31, 2024, $64.2 million was recorded as a revenue interest liability on the consolidated balance sheets.

The Purchase Agreement contains customary representations and warranties and affirmative covenants for transactions of this type, including, among others, the provision of financial and other information to the Purchaser, notice to the Purchaser upon the occurrence of certain material events, and compliance with applicable laws. The Purchase Agreement also contains customary negative covenants, including certain restrictions on the ability to incur indebtedness and grant liens or security interests on assets. On February 18, 2024, the Company reached an agreement with the Purchasers and the Agent to waive certain breaches related to, and extend the deadline for certain post-closing obligations under, the Purchase Agreement, including the requirement for the Company to deliver a leasehold mortgage in favor of the Agent over the Company's headquarters. On May 8, 2024, the Company agreed with the Purchasers to amend the Purchase Agreement to remove requirements related to the leasehold mortgage. In exchange for removing this requirement, the Company agreed to fund an account in the amount of $54.0 million over which the Agent has certain consent and other rights to $50.0 million

of the funds. The Company funded an account with the required $54.0 million on August 14, 2024. As of December 31, 2024, the $50.0 million was classified as restricted cash on the accompanying consolidated balance sheets.

As further disclosed in Note 9, on September 24, 2024, the Company entered into a common stock purchase agreement with Lincoln Park Capital Fund, LLC ("Lincoln Park") for an equity line financing (the "Common Stock Purchase Agreement"). The Common Stock Purchase Agreement provides that, subject to the terms and conditions set forth therein, the Company has the sole right, but not the obligation, to sell to Lincoln Park shares of the Company's common stock, par value $0.0001 per share ("Common Stock"), having an aggregate value of up to $50.0 million (the "Purchase Shares") over a 24-month period. The Company controls the timing and amount of any sales of Purchase Shares to Lincoln Park pursuant to the Common Stock Purchase Agreement in its sole discretion. As of December 31, 2024, the Company had $47.5 million in remaining availability for sales of Common Stock under the Common Stock Purchase Agreement. As of December 31, 2024, the Company had completed sales of shares under the Common Stock Purchase Agreement that provided $2.5 million in gross proceeds.

As further disclosed in Note 9, on September 1, 2022, the Company entered into an agreement with Jefferies LLC for the sale from time to time of up to $80.0 million of shares of Common Stock pursuant to a sales agreement (the "ATM Facility"). In December 2024, the Company completed sales of shares under the ATM Facility that provided net proceeds $6.8 million, and from December 31, 2024 through March 31, 2025, the Company completed sales of shares to under the ATM Facility that provided net proceeds of approximately $0.4 million. As of December 31, 2024, $73.0 million remained available under the ATM Facility.

As of December 31, 2024, the Company had available cash and cash equivalents of $44.9 million. Subsequent to December 31, 2024, in March 2025, the Company completed a public offering of Common Stock, which provided approximately $46.6 million in net proceeds. See Note 15 — Subsequent Events for further information.

Before consideration of management's plans described below, the Company believes its cash and cash equivalents on hand and existing capacity under its Common Stock Purchase Agreement will be sufficient to fund operations at least into March 2026. The future viability of the Company beyond that point is dependent on its ability to generate cash flows from the sale of Symvess and raise additional capital to finance its operations. The Company plans to seek additional funding through private or public equity financings, debt financings, debt refinancing or restructuring, collaborations, strategic alliances, and marketing, distribution or licensing arrangements. Adequate capital may not be available to the Company when needed or on acceptable terms. If the Company is unable to raise capital, the Company plans to implement a program that delays, reduces, suspends or ceases certain of its planned capital expenditures, research and development programs or any future commercialization efforts, which would have a negative impact on its business, prospects, operating results and financial condition. Based on the Company's current cash and cash equivalents on hand and existing capacity under its Common Stock Purchase Agreement, and after considering management's plans, the Company believes it has the ability to fund operations at least into the middle of 2026.

**2. Summary of Significant Accounting Policies**

**Basis of Presentation**

The Company has prepared the accompanying financial statements in conformity with 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.

**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 assets, accruals for research and development activities, contingent earnout liability, revenue interest liability, derivatives, fair value of common stock warrants 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.

**Reclassifications**

Certain prior year amounts have been reclassified to conform to the current year presentation. None of these reclassifications had a material impact on the Company's consolidated financial statements.

**Segments**

The Company is developing proprietary, bioengineered, acellular human tissues, advanced tissue constructs and organ systems 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 operations are managed and reported to its Chief Executive Officer, the Company's chief operating decision maker ("CODM"), on a consolidated basis. The CODM evaluates financial performance, allocates resources and monitors budget versus actual results based on the Company's consolidated statements of operations. The measure of segment assets provided to and reviewed by the CODM is reported on the consolidated balance sheets as total assets. Segment asset information is not used by the CODM to evaluate performance, allocate resources or make strategic decisions. Under the current organizational and reporting structure, the Company operates and manages its business on a consolidated basis as one reportable and operating segment.

As a single reportable segment entity, the Company's segment performance measure is consolidated net (loss) income. Consolidated net (loss) income is used to monitor the budget versus actual results and to help make key operating decisions such as the allocation of budget between research and development and general and administrative expenses. Significant segment expenses within net loss include research and development and general and administrative expenses, which are each separately presented on the Company's consolidated statements of operations. Other segment items within net loss include interest income, interest expense, the change in fair value of the Company's Contingent Earnout Liability and the change in fair value of derivatives.

Additional disaggregated significant segment expenses that are not separately presented on the Company's consolidated statements of operations are presented below.

***Research and Development Expenses***

| | Year Ended December 31, | |
|---|---|---|
| **($ in thousands)** | **2024** | **2023** |
| **Direct Expenses** | | |
| Vascular Trauma | $ 2,181 | $ 3,976 |
| AV Access | 6,620 | 8,748 |
| PAD | 143 | 306 |
| Total | 8,944 | 13,030 |
| **Unallocated Expenses** | | |
| External services | 7,071 | 6,106 |
| Materials and supplies | 21,765 | 13,705 |
| Payroll and personnel expenses | 36,537 | 30,118 |
| Other research and development expenses | 14,282 | 13,591 |
| Total | 79,655 | 63,520 |
| **Total research and development expenses** | **$ 88,599** | **$ 76,550** |

Direct expenses for the Company's vascular trauma, AV access for hemodialysis and PAD indications include costs related to the Company's clinical trials, including fees paid to CROs, consultants, clinical sites and investigators. Costs related to development activities which broadly support multiple programs using the Company's technology platform, including personnel, materials and supplies, external services costs, and other internal expenses, such as facilities and overhead costs, are not allocated to individual research and development programs. Other research and development expenses reported in the table above include direct costs not identifiable with a specific product candidate, including costs associated with the Company's research and development platform used across programs, process development,

manufacturing analytics and preclinical research and development for prospective product candidates and new technologies.

***Non-cash Operating Expenses***

| ($ in thousands) | Year Ended December 31, 2024 | 2023 |
|---|---|---|
| Depreciation expense | $ 5,104 | $ 5,659 |
| Stock-based compensation expense | 6,137 | 6,828 |

**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, 2024 and 2023.

**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 U.S. Cash deposits typically exceed federally insured limits. As of December 31, 2024 and 2023, cash and cash equivalents consisted of cash on deposit with banks denominated in U.S. dollars and investments in money market funds.

**Restricted Cash**

The Company classifies as restricted cash all cash pledged as collateral to secure long-term obligations and all cash whose use is otherwise limited by contractual provisions. As of December 31, 2024, restricted cash includes $50.0 million maintained in an account that is not subject to the Company's unilateral control, in accordance with the amended Purchase Agreement, as further disclosed in Note 6. As of December 31, 2024 and 2023, the Company classified $0.2 million in funds maintained in a separate deposit account to secure a letter of credit for the benefit of the lessor of the Company's headquarters lease, and $0.1 million in cash balances held as collateral for the Company's employee credit card program as restricted cash.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the consolidated balance sheets to the total of the amounts shown in the consolidated statements of cash flows as of December 31, 2024 and 2023.

| *($ in thousands)* | As of December 31, 2024 | 2023 |
|---|---|---|
| Cash and cash equivalents | $ 44,937 | $ 80,44 |
| Restricted cash included in prepaid expenses and other current assets | 144 | 14 |
| Restricted cash included in long-term assets | 50,209 | 20 |
| Total cash, cash equivalents and restricted cash | $ 95,290 | $ 80,80 |

**Employee Retention Credit**

The Coronavirus Aid, Relief, and Economic Security Act (the "CARES Act") provided refundable employee retention credits, which could be used to offset payroll tax liabilities. Under the provisions of the extension of the CARES Act, the Company qualified for the employee retention credit for the first three quarters of 2021, and the Company applied for the credit in February 2023. As there is no authoritative guidance under U.S. GAAP for accounting for grants to for-profit business entities, the Company accounted for the grant by applying Accounting Standards Codification ("ASC") 450, *Contingencies*. The Company received an employee retention credit of $3.1 million in July 2023, and recognized the credit as a component of other income (expense), net on the consolidated statement of operations and comprehensive loss during the second quarter of 2023. The Company considered the collection of the receivable probable and recognized the credit

after the Company received notices from the Internal Revenue Service, (the "IRS"), specifying the amount of the credit receivable and all uncertainties were resolved regarding receipt of the credit.

**Revenue Interest Liability**

On May 12, 2023, Humacyte, Inc. and Global entered into a Revenue Interest Purchase Agreement (the "Purchase Agreement") with the Purchasers and another affiliate of Oberland, as agent for the Purchasers. The revenue interest liability associated with the Purchase Agreement is presented net of a debt discount comprised of issuance costs, transaction costs, the fair value of a freestanding option agreement related to the Purchase Agreement, and the fair value of embedded derivatives requiring bifurcation on the consolidated balance sheets. The Company imputes interest expense associated with this liability using the interest method. The effective interest rate is calculated based on the rate that would enable the debt to be repaid in full over the anticipated life of the arrangement. The interest rate on the liability may vary during the term of the agreement depending on a number of factors, including the level and expected timing of forecasted net sales. If the level and timing of any forecasted net sales and related payments change, the Company will prospectively adjust the effective interest and the related amortization of the liability and related issuance costs on a quarterly basis.

**Contingent Derivative Liability**

The Purchase Agreement contains certain features that meet the definition of embedded derivatives requiring bifurcation as a separate compound financial instrument apart from the Revenue Interest Liability. The contingent derivative liability related to the Put Option, as defined in Note 6 — Revenue Interest Purchase Agreement, was initially measured at fair value upon issuance and is subject to remeasurement at each reporting period with changes in fair value recognized as other income (expense) in the consolidated statements of operations and comprehensive loss, classified in change in fair value of derivatives.

**JDRF Award**

On April 1, 2023, the Company entered into an Industry Discovery and Development Partnership Agreement with Breakthrough T1D (f/k/a JDRF International) ("JDRF," and such agreement, the "JDRF Agreement") to further develop and perform preclinical testing of the Company's BioVascular Pancreas ("BVP"), a product candidate designed to deliver insulin-producing islets using the ATEV as a means of treating patients with type 1 diabetes. According to the terms of the JDRF Agreement, JDRF will provide funding up to $0.8 million ("JDRF Award") based on the achievement of certain research and development milestones related to the Company's BVP. The JDRF Agreement refers to the total cumulative payments the Company has received from JDRF as of any point in time as the "Actual Award."

The Company received the first milestone payment of $80 thousand in April 2023 upon execution of the JDRF Agreement. In May 2024, the Company received the second milestone payment of $90 thousand and the third milestone payment of $150 thousand, based on the achievement of certain research and development milestones specified in the JDRF Agreement. As of December 31, 2024, the Actual Award totaled $320 thousand.

As further disclosed in Note 13, in accordance with the JDRF Agreement the Company has agreed to pay JDRF a one-time royalty, to be paid in three equal installments following the first commercial sale of any product containing the Company's technology identified in the JDRF Agreement, and an additional royalty equal to the Actual Award after net sales exceed $250 million. In the event of a license, sale or transfer of the Company's rights to the product's technology identified in the JDRF Agreement or a change of control transaction, the Company is obligated to pay JDRF a payment equal to 10% of any license or purchase price payments received by the Company up to an amount equal to four times the Actual Award (the "Royalty Cap"), less any previous royalty payments paid towards the Royalty Cap (the "Disposition Payment").

The JDRF Agreement expires on the date on which the Company has paid JDRF all of the above mentioned royalty payments. If the JDRF Agreement is terminated earlier in accordance with its terms, royalties based on previously received milestone payments would remain due after a termination by JDRF without cause. As the royalties are contractually required to be paid upon achieving these milestones even after the termination of the JDRF Agreement, the Company determined that the JDRF Actual Award payments are to be classified as a liability on the consolidated balance sheets. The JDRF liability related to the Actual Award payments is reported at amortized cost and is included in other long-term liabilities in the consolidated balance sheets. The Disposition Payment was determined to meet the definition of an embedded derivative requiring bifurcation and is measured at fair value each reporting period with changes in fair value

recognized as other income (expense) in the consolidated statements of operations and comprehensive loss, classified in change in fair value of derivatives.

**Concentration of Credit Risk**

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents, including amounts classified as restricted cash. Total cash balances exceeded insured balances by the FDIC as of December 31, 2024 and 2023. The Company believes it mitigates this risk by monitoring the financial stability of the institutions holding material cash and cash equivalents balances. The Company maintains the majority of these balances at a Global Systemically Important Bank, as designated by the Financial Stability Board. The Company has cash equivalents that are invested in highly rated money market funds that are invested only in obligations of the U.S. government and its agencies. The Company has not experienced any credit loss relating to its cash and cash equivalents.

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

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 shares of Common Stock outstanding during the period without consideration of potentially dilutive shares of Common Stock. Diluted net loss per share attributable to common stockholders reflects the potential 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 incurred losses for the years ended December 31, 2024 and 2023, basic and diluted net loss per share is the same for each period.

The following potential shares of Common Stock were excluded from the computation of diluted net loss per share for each period because including them would have had an antidilutive effect:

| | Year Ended December 31, | |
|---|---|---|
| | 2024 | 2023 |
| Exercise of options under stock plan | 12,274,139 | 11,919,421 |
| Warrants to purchase Common Stock | 14,079,314 | 5,588,506 |

The 15,000,000 Contingent Earnout Shares (defined below) are excluded from the anti-dilutive table for all 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. The Option Agreement, as defined in Note 6 — Revenue Interest Purchase Agreement, is excluded from the anti-dilutive table for the years ended December 31, 2024 and 2023, based on the Company's assumption that the Option Agreement will not be exercised unless the Company's stock price exceeds $7.50 per share, the minimum purchase price under the Option Agreement.

**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. 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:

| Property and equipment | Estimated Useful Lives (Years) |
|---|---|
| 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, 2024 and 2023, 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, 2024 and 2023.

**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. 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, 2024 and 2023, 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, 2024 and 2023, 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 2021 although carry-forward attributes that were generated prior to 2021 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, 2024 and 2023, 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, 2024 and 2023, 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 CROs and consultants, including in connection with clinical trials, and other related clinical trial fees, such as for clinical site fees and investigator grants related to patient screening and treatment, conduct of clinical trials, 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, which conduct preclinical studies and clinical trials. 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.

**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 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**

***Public and Private Placement 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 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* ("ASC 815").

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 Common Stock, 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 shares of 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.

***Registered Direct Offering Warrants***

As further disclosed in Note 9, in October 2024, the Company completed a registered direct offering whereby Common Stock warrants were issued to purchase up to 5,681,820 shares of Common Stock (the "October 2024 RDO Warrants"). In November 2024, the Company completed a registered direct offering whereby Common Stock warrants were issued to purchase up to 2,808,988 shares of Common Stock of the Company, (the "November 2024 RDO Warrants"). Together the October 2024 RDO Warrants and the November 2024 RDO Warrants are referred to as the "Registered Direct Offering Warrants").

The Company evaluated the Registered Direct Offering Warrants to determine the appropriate financial statement classification upon issuance. The Registered Direct Offering Warrants are not mandatorily redeemable and are considered to be freestanding instruments as they are separately exercisable into common shares. The Company is not required to transfer assets to settle the warrants, except potentially as a result of a fundamental transaction (defined in the agreement to include various merger and change in control transactions). As such, the Registered Direct Offering Warrants were not classified as liabilities under ASC 480. The Company then evaluated the Registered Direct Offering Warrants under ASC 815.

The agreements governing the Registered Direct Offering Warrants include a provision, the application of which could result in a different settlement value for the warrants. The Warrants cannot be exercised if after the exercise the warrant holder would own more than 4.99% of the Company's outstanding Common Stock ("Beneficial Ownership Limitation"). The holder may elect to increase the Beneficial Ownership Limitation to 9.99%. The Beneficial Ownership Limitation constitutes an exercise contingency in that it limits or defers the exercise of some of the Registered Direct Offering Warrants if the limitation would otherwise be reached, depending on the number of shares of Common Stock that are outstanding. The exercise contingency is not based on either an observable market or an observable index, so it does not preclude the Warrants from being considered indexed to the Company's own stock.

In the event of a fundamental transaction, if the warrant holder elects to have the Company repurchase the warrant, the Black-Scholes value of the warrant is calculated with adjustments to the stock price and volatility of the shares on the market. These are not standard adjustments in determining the fair value of an option. As the volatility adjustment provision violates the fixed-for-fixed rule, the Registered Direct Offering Warrants are not considered to be "indexed to the Company's own stock" and therefore are not classified in stockholders' equity. As the Registered Direct Offering 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.

**Contingent Earnout Liability**

Pursuant to the Merger Agreement, following the closing of the Merger (the "Closing"), Legacy Humacyte equity holders are entitled to receive additional merger consideration of up to 15,000,000 additional shares of 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 ("Contingent Earnout Liability") at the Reverse Recapitalization date and subsequently remeasured at each reporting date with changes in fair value recorded as a component of other income (expense), net in the consolidated statements of operations and comprehensive loss.

The estimated fair value of the Contingent Earnout Liability was determined using a Monte Carlo simulation 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 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 10-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 "other long-term assets", and the current and non-current portions of the operating lease liabilities are included in "other current liabilities", and "other long-term liabilities", respectively, on the consolidated 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 consolidated 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 its ongoing V007 and V012 Phase 3 clinical trials, successful commercialization of Symvess and regulatory approval and commercialization of its product candidates, if approved, the expected size of the target populations for the Company's product candidates, the degree of market acceptance of Symvess, and if approved by regulatory authorities, our product candidates, the availability of third-party coverage and reimbursement, development by competitors of new technological innovations, the ability to manufacture Symvess and its 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 Company's implementation and

maintenance of effective internal controls, and the ability to secure additional capital to fund operations and the 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 to sell, market and distribute its 6 millimeter ATEV for certain specified indications outside the United States.

**Recently Adopted Accounting Pronouncements**

In November 2023, the FASB issued ASU No. 2023-07, "Segment Reporting (Topic 280), Improvements to Reportable Segment Disclosures" ("ASU 2023-07"). The FASB issued this update to improve the disclosures about an entity's reportable segments, including providing more detailed information about a reportable segment's expenses, enhancing interim disclosure requirements and providing new segment disclosure requirements for entities with a single reportable segment. This standard is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. The Company adopted ASU 2023-07 effective December 31, 2024 on a retrospective basis. The adoption of ASU 2023-07 did not change the way the Company identifies its reportable segments. The adoption had no impact on the consolidated financial statements, but it resulted in incremental disclosures within the Company's notes to the consolidated financial statements. See the "Segments" section above for further information.

**Recently Issued Accounting Pronouncements**

In December 2023, the FASB issued ASU No. 2023-09, "Income Taxes (Topic 740), Improvements to Income Tax Disclosures" ("ASU 2023-09"). The FASB issued this update to improve the transparency and comparability of income tax disclosures, including requiring consistent categories and greater disaggregation of information in the rate reconciliation and further disaggregation of income taxes paid by jurisdiction. This standard is effective for fiscal years beginning after December 15, 2024, with early adoption permitted. Entities should apply the amendments prospectively, with retrospective application permitted. This ASU is applicable to the Company's Annual Report on Form 10-K for the fiscal year ending December 31, 2025. The Company is currently evaluating the impact of adopting ASU 2023-09 on its disclosures included in the notes to the consolidated financial statements.

In November 2024, the FASB issued ASU No. 2024-03, "Income Statement — Reporting Comprehensive Income — Expense Disaggregation Disclosures (Subtopic 220-40), Disaggregation of Income Statement Expenses ("ASU 2024-03"). In January 2025, the FASB issued ASU No. 2025-01, "Income Statement — Reporting Comprehensive Income — Expense Disaggregation Disclosures (Subtopic 220-40), Clarifying the Effective Date ("ASU 2025-01"). ASU 2024-03 requires additional disclosure about the nature and amounts of expenses included in certain expense captions presented on the income statement to enhance the transparency of the relevant expense captions. ASU 2024-03, as clarified by ASU 2025-01, is effective for annual reporting periods beginning after December 15, 2026 and interim reporting periods within annual reporting periods beginning after December 15, 2027, with early adoption permitted. Entities may elect to apply the amendments either prospectively or retrospectively. The Company is currently evaluating the impact of adopting ASU 2024-03 on its disclosures included in the notes to the consolidated financial statements.

### 3. Fair Value Measurements

The Company's assets and liabilities that were measured at fair value on a recurring basis were as follows:

| | Fair Value Measured as of December 31, 2024 | | | |
|---|---|---|---|---|
| *($ in thousands)* | Level 1 | Level 2 | Level 3 | Total |
| Assets: | | | | |
| Cash equivalents (money market funds) | $ 32,044 | $ — | $ — | $ 32,044 |
| Common Stock Purchase Agreement derivative asset | — | 672 | — | 672 |
| Total financial assets | $ 32,044 | $ 672 | $ — | $ 32,716 |
| Liabilities: | | | | |
| Contingent Earnout Liability | $ — | $ — | $ 70,961 | $ 70,961 |
| Contingent derivative liability | — | — | 2,415 | 2,415 |
| Private Placement Warrants liability | — | — | 385 | 385 |
| October 2024 RDO Warrants liability | — | — | 12,437 | 12,437 |
| November 2024 RDO Warrants liability | — | — | 6,432 | 6,432 |
| Option Agreement liability | — | — | 64 | 64 |
| JDRF Agreement derivative liability | — | — | 121 | 121 |
| Total financial liabilities | $ — | $ — | $ 92,815 | $ 92,815 |

| | Fair Value Measured as of December 31, 2023 | | | |
|---|---|---|---|---|
| *($ in thousands)* | Level 1 | Level 2 | Level 3 | Total |
| Assets: | | | | |
| Cash equivalents (money market funds) | $ 78,995 | $ — | $ — | $ 78,995 |
| Total financial assets | $ 78,995 | $ — | $ — | $ 78,995 |
| Liabilities: | | | | |
| Contingent Earnout Liability | $ — | $ — | $ 37,916 | $ 37,916 |
| Contingent derivative liability | — | — | 2,636 | 2,636 |
| Private Placement Warrants liability | — | — | 78 | 78 |
| Option Agreement liability | — | — | 35 | 35 |
| JDRF Agreement derivative liability | — | — | 28 | 28 |
| Total financial liabilities | $ — | $ — | $ 40,693 | $ 40,693 |

The Company's money market funds are classified within Level 1 of the fair value hierarchy because they are valued using quoted market prices. The carrying values of cash, prepaid expenses and other current assets, accounts payable, accrued expenses and other current liabilities as of December 31, 2024 and 2023 approximated their fair values due to the short-term nature of these items.

The fair value of the Contingent Earnout Liability, contingent derivative liability related to the Put Option (as defined in Note 6 — Revenue Interest Purchase Agreement and discussed below), Private Placement Warrants liability, liabilities associated with the Registered Direct Offering Warrants (as defined in Note 9 — Stockholders' Equity (Deficit) and Warrants), Option Agreement liability (as defined in Note 6 — Revenue Interest Purchase Agreement), and the derivative liability associated with the JDRF Agreement Disposition Payment are based on significant unobservable inputs, which represent Level 3 measurements within the fair value hierarchy. The fair values of the Private Placement Warrants liability and the liabilities associated with the Registered Direct Offering Warrants are included in common stock warrant liabilities on the consolidated balance sheets. The fair values of the Option Agreement liability and the derivative liability associated with the JDRF Agreement Disposition Payment are included in other long-term liabilities on the consolidated balance sheets.

**Common Stock Purchase Agreement**

The Company evaluated the Common Stock Purchase Agreement and determined that the agreement should be accounted for in accordance with ASC 815-40, "*Derivatives and Hedging — Contracts on an Entity's Own Equity*". Accordingly, the Company recorded a derivative asset with an initial fair value based on the 115,705 shares of Common Stock issued to Lincoln Park as consideration for its irrevocable commitment to purchase up to $50.0 million in shares of Common Stock. The initial fair value of $0.7 million was based on the closing price of the Common Stock on September 24, 2024, which was $6.12 per share, and the derivative asset is reported as a component of long-term assets on the consolidated balance sheets. Subsequent changes in the fair value of the derivative asset are dependent upon, among other things, changes in the closing share price of Common Stock, the quantity and purchase price of the shares purchased by Lincoln Park during the reporting period and the unused capacity under the Common Stock Purchase Agreement. The Common Stock Purchase Agreement is subsequently remeasured at each reporting date with changes in fair value recorded within Change in fair value of derivatives in the consolidated statements of operations and comprehensive loss. The change in fair value of the derivative asset between the September 24, 2024 issuance date and December 31, 2024 was insignificant.

**Contingent Earnout Liability**

The following table presents a summary of the changes in the fair value of the Contingent Earnout Liability:

| | Contingent Earnout Liability | |
|---|---|---|
| | Year Ended December 31, | |
| *($ in thousands)* | 2024 | 2023 |
| Fair value as of beginning of period | $ (37,916) | $ (27,893) |
| Change in fair value included in other income (expense), net | (33,045) | (10,023) |
| Fair value as of end of period | $ (70,961) | $ (37,916) |

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 Common Stock price, expected volatility, risk-free rate, expected term and expected dividend yield (see Note 9 — Stockholders' Equity (Deficit) and Warrants). Contingent earnout payments involve certain assumptions requiring significant judgment and actual results can differ from assumed and estimated amounts.

**Contingent Derivative Liability**

The debt pursuant to the Purchase Agreement, as defined in Note 6, contains an embedded derivative related to the Put Option, as defined in Note 6, requiring bifurcation as a single compound derivative instrument. The Company estimated the fair value of the derivative liability using a "with-and-without" methodology. The "with-and-without" methodology involves valuing the whole instrument on an as-is basis and then valuing the instrument without the individual embedded derivative. The difference between the entire instrument with the embedded derivative compared to the instrument without the embedded derivative was the fair value of the derivative liability at issuance and each subsequent reporting period. In determining the fair value of the contingent derivative 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. The estimated probability and timing of underlying events triggering the exercisability of the Put Option contained within the Purchase Agreement, forecasted cash flows and the discount rates are significant unobservable inputs used to determine the estimated fair value of the entire instrument with the embedded derivative. As of December 31, 2024, the discount rates used to calculate the value of the contingent derivative liability were 14.2% to calculate the present-value of the revenue forecast and 11.8% to calculate the present-value of the payoff of the Put Option. As of December 31, 2023, the discount rates used to calculate the value of the contingent derivative liability were 14.5% to calculate the present-value of the revenue forecast and 17.1% to calculate the present-value of the payoff of the Put Option.

The following table presents a summary of the changes in the fair value of the contingent derivative liability, which is classified as a Level 3 financial instrument:

| | Contingent Derivative Liability | |
|---|---|---|
| | Year Ended December 31, | |
| *($ in thousands)* | 2024 | 2023 |
| Fair value as of beginning of period | $ (2,636) | $ — |
| Fair value of embedded derivative upon issuance of debt | (1,552) | (2,354) |
| Change in fair value included in other income (expense), net | 1,773 | (282) |
| Fair value as of end of period | $ (2,415) | $ (2,636) |

**Registered Direct Offering Warrants Liabilities**

The following table presents a summary of the changes in the fair value of the Registered Direct Offering Warrants liabilities during the year ended December 31, 2024:

| *($ in thousands)* | October 2024 RDO Warrants | November 2024 RDO Warrants |
|---|---|---|
| Fair value as of beginning of period | $ — | $ — |
| Issuances | (15,249) | (6,132) |
| Change in fair value included in other income (expense), net | 2,812 | (300) |
| Fair value as of end of period | $ (12,437) | $ (6,432) |

In determining the fair value of the Registered Direct Offering Warrants liabilities, the Company used the Black-Scholes valuation model to estimate the fair value utilizing assumptions including the current Company stock price, expected volatility, risk-free rate, expected term and expected dividend yield (see Note 9 — Stockholders' Equity (Deficit) and Warrants).

**Private Placement Warrants Liability**

The following table presents a summary of the changes in the fair value of the Private Placement Warrants liability:

| | Private Placement Warrants | |
|---|---|---|
| | Year Ended December 31, | |
| *($ in thousands)* | 2024 | 2023 |
| Fair value as of beginning of period | $ (78) | $ (80) |
| Change in fair value included in other income (expense), net | (307) | 2 |
| Fair value as of end of period | $ (385) | $ (78) |

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 assumptions including the current Company stock price, expected volatility, risk-free rate, expected term and expected dividend yield (see Note 9 — Stockholders' Equity (Deficit) and Warrants).

## 4. Property and Equipment, Net

Property and equipment, net consisted of the following:

| *($ in thousands)* | As of December 31, 2024 | 2023 |
|---|---|---|
| Scientific and manufacturing equipment | $ 29,059 | $ 28,400 |
| Computer equipment | 100 | 125 |
| Software | 1,024 | 682 |
| Furniture and fixtures | 1,066 | 1,066 |
| Leasehold improvements | 27,901 | 27,844 |
| | 59,150 | 58,117 |
| Accumulated depreciation | (36,087) | (31,326) |
| Property and equipment, net | $ 23,063 | $ 26,791 |

Depreciation expense totaled $5.1 million and $5.7 million for the years ended December 31, 2024 and 2023, respectively. All long-lived assets are maintained in the United States.

## 5. Accrued Expenses

Accrued expenses consisted of the following:

| *($ in thousands)* | As of December 31, 2024 | 2023 |
|---|---|---|
| Accrued external research, development and manufacturing costs | $ 4,889 | $ 3,845 |
| Accrued employee compensation and benefits | 6,242 | 5,238 |
| Accrued professional fees | 293 | 257 |
| Total | $ 11,424 | $ 9,340 |

## 6. Revenue Interest Purchase Agreement

### Revenue Interest Purchase Agreement

On May 12, 2023, the Company and Global entered into the Purchase Agreement with the Purchasers and another affiliate of Oberland, as agent for the Purchasers, to obtain financing with respect to the further development and commercialization of the Company's ATEV, to repay the Company's then-existing credit facility with SVB, and for other general corporate purposes. Pursuant to the Purchase Agreement, on May 12, 2023, the Purchasers purchased certain revenue interests (the "Revenue Interests") from Global in exchange for an aggregate investment amount of up to $150.0 million (the "Investment Amount") to be paid in multiple tranches. On May 12, 2023, the Company received an initial payment of $40.0 million, less certain transaction expenses, which was used to repay in full the Company's then-existing obligations under the Loan Agreement with SVB, as defined in Note 7 — Debt.

In February 2024, the FDA accepted the Company's BLA for an indication in vascular trauma, and in accordance with the Purchase Agreement, on March 11, 2024, the Company received a subsequent installment of $20.0 million. In accordance with the amended Purchase Agreement, the Company was entitled to receive up to $90.0 million in subsequent installments subject to the terms and conditions set forth in the Purchase Agreement, as follows: (i) $40.0 million, at the Company's option, upon the Company receiving FDA approval of the ATEV for the vascular trauma indication on or prior to December 31, 2024 and (ii) $50.0 million, at the Company's option, upon reaching $35.0 million trailing worldwide three-month net sales any time prior to December 31, 2025. Each tranche was dependent on the satisfaction of the conditions and receipt of funds from the previous tranche. The FDA granted full approval for the Company's BLA on December 19, 2024, and as of December 31, 2024, the Company did not elect to draw the additional $40.0 million that became available under the Purchase Agreement. As of December 31, 2024, the Company is not entitled to draw on any further installments under the Purchase Agreement.

Pursuant to the Purchase Agreement, the Revenue Interests entitle the Purchasers to receive a royalty initially equal to 7.5% (the "Rate") of global net sales of the Company's products (subject to a lower rate for net sales by specified licensees outside the United States), to be paid on a calendar quarterly basis (the "Revenue Interest Payments").

If the Purchasers do not receive cumulative Revenue Interest Payments equal to 100% of the amount funded to date (the "Cumulative Purchaser Payments") by the last business day of 2028 (the "Test Date"), the Rate will increase to a rate that, had such increased rate applied during the period from May 12, 2023 through the Test Date, would have provided the Purchasers with cumulative Revenue Interest Payments equal to the Cumulative Purchaser Payments as of the Test Date. Additionally, Global will be required to pay the Purchasers an amount equal to 100% of the Cumulative Purchaser Payments as of the Test Date less the total Revenue Interest Payments made by Global to the Purchasers under the Purchase Agreement as of the Test Date. Global's obligation to make Revenue Interest Payments terminates on the date on which the Purchasers have received Revenue Interest Payments of 150% of the Cumulative Purchaser Payments unless the Purchase Agreement is terminated earlier due to the Purchaser's exercise of a Put Option, the Company's exercise of a call option, or by mutual consent. However, if the Purchasers have not received such Revenue Interest Payments as of the Test Date, the Purchase Agreement will instead terminate on the date on which the Purchasers receive Revenue Interest Payments of 195% of the Cumulative Purchaser Payments.

Under the Purchase Agreement, Global has an option (the "Call Option") to repurchase the Revenue Interests and terminate the Purchase Agreement at any time upon advance written notice. Additionally, the Purchasers have an option (the "Put Option") to terminate the Purchase Agreement and to require Global to repurchase the Revenue Interests upon enumerated events such as a bankruptcy event, an uncured material breach, a material adverse effect or a change of control. If (i) the Put Option is exercised by May 12, 2026, or (ii) the Call Option is exercised on or prior to May 12, 2026, then in each case, the required repurchase price will be 175% of the Cumulative Purchaser Payments (minus the aggregate Revenue Interest Payments Global has made to the Purchasers as of such date). If a Put Option or Call Option is exercised after May 12, 2026, the required repurchase price will be 195% of the Cumulative Purchaser Payments (minus the aggregate Revenue Interest Payments Global has made to the Purchasers as of such date).

The Purchase Agreement contains customary representations and warranties and affirmative covenants for transactions of this type, including, among others, the provision of financial and other information to the Purchaser, notice to the Purchaser upon the occurrence of certain material events, and compliance with applicable laws. The Purchase Agreement also contains customary negative covenants, including certain restrictions on the ability to incur indebtedness and grant liens or security interests on assets. On February 18, 2024, the Company reached an agreement with the Purchasers and the Agent to waive certain breaches related to, and extend the deadline for certain post-closing obligations under, the Purchase Agreement, including the requirement for the Company to deliver a leasehold mortgage in favor of the Agent over the Company's headquarters. On May 8, 2024, the Company agreed with the Purchasers to amend the Purchase Agreement, the effect of which was to remove requirements related to the leasehold mortgage. In exchange for the removal of these requirements, the Company funded an account in an amount of $54.0 million on August 14, 2024, over which the Agent has certain consent and other rights to $50.0 million of the funds. As of December 31, 2024, the $50.0 million was classified as restricted cash on the accompanying consolidated balance sheets.

The Company has provided a parent company guaranty to guarantee the payment in full of the obligations under the Purchase Agreement. The Company's obligations under the parent company guaranty and Global's obligations under the Purchase Agreement and the Revenue Interests are secured by a perfected security interest on substantially all of the Company's and its subsidiaries' assets.

The Purchase Agreement is considered a sale of future revenues and accounted for as long-term debt recorded at amortized cost using the interest method.

The Company recorded a revenue interest liability related to the Purchase Agreement on the accompanying consolidated balance sheet on the date the Company entered into the Purchase Agreement, net of a debt discount comprised of $2.1 million issuance costs and of transaction costs, the $0.1 million fair value allocated to the Option Agreement, defined below, and the $2.4 million initial fair value of the bifurcated contingent derivative liability related to the Put Option. The revenue interest liability is based on the Company's contractual repayment obligation to the Purchasers, based on the current estimates of future revenues, over the life of the Purchase Agreement. The Company imputes interest expense associated with this liability using the interest method. The effective interest rate is calculated based on the rate that would enable the debt to be repaid in full over the anticipated life of the arrangement. The interest rate on this liability

may vary during the term of the agreement depending on a number of factors, including the level and expected timing of forecasted net sales. The Company evaluates the interest rate quarterly based on its current net sales forecasts. If the level and timing of any forecasted net sales and related payments change, the Company prospectively adjusts the effective interest and the related amortization of the liability and related issuance costs on a quarterly basis.

As of December 31, 2024 and 2023, $64.2 million and $38.6 million, respectively, was recorded as a revenue interest liability. As of December 31, 2024, $0.9 million of the revenue interest liability was included in other current liabilities on the consolidated balance sheet. The estimated effective annual interest rate as of December 31, 2024 and 2023 was 13.7% and 14.1%, respectively. The Company recorded $7.7 million and $3.1 million in interest expense related to the Purchase Agreement for the years ended December 31, 2024 and 2023, respectively. The Company incurred and paid $0.5 million of transaction costs during the year ended December 31, 2024 in connection with the Purchase Agreement. The transaction costs were capitalized to debt discount and are being amortized to interest expense over the estimated term of the debt, consistent with the issuance and transaction costs incurred in 2023 discussed above.

The Put Option under the Purchase Agreement that is exercisable by the Purchasers upon certain contingent events was determined to be an embedded derivative requiring bifurcation and separately accounted for as a single compound derivative instrument. At May 12, 2023, the Company recorded the initial fair value of the derivative liability of $2.4 million as a debt discount. On March 11, 2024, upon the issuance of the second installment of the Purchase Agreement of $20.0 million, the Company estimated the fair value of the embedded derivative and recorded a $1.6 million increase in fair value as a debt discount. The debt discount is being amortized to interest expense over the expected term of the debt using the interest method. See Note 3 — Fair Value Measurements for a further discussion of the fair value of the contingent derivative liability associated with the Put Option.

Revenue Interest Payments made as a result of the Company's net product sales will reduce the revenue interest liability. During the years ended December 31, 2024 and 2023, the Company did not record any product sales revenue.

The following table summarizes the revenue interest liability activity during the year ended December 31, 2024:

| ***($ in thousands)*** | | |
|---|---|---|
| Revenue interest liability at December 31, 2023 | $ | 38,600 |
| Proceeds from revenue interest purchase agreement | | 20,000 |
| Transaction costs paid | | (500) |
| Debt discount from embedded contingent derivative liability | | (1,552) |
| Interest expense recognized | | 7,691 |
| Revenue interest liability at December 31, 2024 | $ | 64,239 |

**Option Agreement**

In connection with the Purchase Agreement, the Company also entered into an option agreement with TPC Investments III LP and TPC Investment Solutions LP (the "Option Agreement"), which gave TPC Investments III LP and TPC Investment Solutions LP (the "Holders") the right to purchase, in the aggregate, up to $10.0 million worth of shares of Common Stock (the "Option") at a purchase price per share equal to the greater of $7.50, or the 15 day volume-weighted average price as of the exercise date, exercisable in cash only at any time prior to the earlier of (i) December 31, 2026 and (ii) the closing date of a corporate reorganization. The Holders also received certain registration rights relating to the shares underlying the Option pursuant to the Option Agreement. The Holders purchased $1,950,000 shares of Common Stock in the Offering, as defined in Note 9, and as of December 31, 2024, the Holders have the right to purchase up to $8,050,000 of shares of Common Stock under the Option Agreement.

The Option granted to the Holders represents a freestanding instrument separate from the purchaser commitments outlined in the Purchase Agreement. The Option Agreement does not qualify for the equity contract scope exception under ASC 815-40 and the Company recorded the Option as a liability ("Option Agreement liability") on the consolidated balance sheet at an initial fair value of $55 thousand, and subsequent changes in the fair value are recognized in the consolidated statements of operations and comprehensive loss at each reporting date. The fair value of the Option Agreement liability as of December 31, 2024 and 2023 was $64 thousand and $35 thousand, respectively.

**7. Debt**

Pursuant to the Purchase Agreement, on May 12, 2023, $40.0 million, less certain transaction expenses, was funded to the Company, which was used to repay in full the Company's existing obligations under its term loan agreement with SVB and SVB Innovation Credit Fund VIII, L.P., entered into on March 30, 2021, as amended in June 2021 and September 2021 (the "Loan Agreement").

In connection with the termination of the Loan Agreement, the Company paid a prepayment premium of $0.3 million and recorded a loss on extinguishment of debt of $2.4 million during the year ended December 31, 2023 in other income (expense), net in the consolidated statements of operations and comprehensive loss.

**8. Leases**

The Company's finance leases relate to its headquarters, which was substantially completed in June 2018 and is being leased through May 2033, and its operating lease relates to the land lease associated with its headquarters.

As of December 31, 2024 and 2023, the Company had finance lease liabilities of $16.5 million and $18.9 million, respectively, and right-of-use assets of $15.5 million and $17.3 million, respectively. As of both December 31, 2024 and 2023, the Company had operating lease liabilities of $0.6 million and right-of-use assets of $0.6 million. As of December 31, 2024 and 2023, operating lease right-of-use assets are included in other long-term assets on the consolidated balance sheets. As of December 31, 2024 and 2023, approximately $0.5 million and $0.6 million, respectively, of the operating lease liabilities is included in other long-term liabilities on the consolidated balance sheets, and the remaining balance is classified in other current liabilities on 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:

| | Year Ended December 31, | |
|---|---|---|
| *($ in thousands)* | **2024** | **2023** |
| Finance lease cost | | |
| Amortization of right-of-use assets | $ 2,086 | $ 2,060 |
| Interest on lease liabilities | 1,523 | 1,709 |
| Total finance lease cost | 3,609 | 3,769 |
| Operating lease cost | 105 | 105 |
| Total lease cost | $ 3,714 | $ 3,874 |

| | Year Ended December 31, 2024 | | Year Ended December 31, 2023 | |
|---|---|---|---|---|
| *($ in thousands)* | **Finance Leases** | **Operating Leases** | **Finance Leases** | **Operating Leases** |
| Operating cash flows from leases | $ (1,523) | $ (105) | $ (1,709) | $ (105) |
| Financing cash flows from leases | $ (2,579) | $ — | $ (2,256) | $ — |
| Weighted-average remaining lease term | 3.74 | 4.25 | 4.13 | 4.74 |
| Weighted-average discount rate | 8.50 % | 8.50 % | 8.50 % | 8.50 % |

As of December 31, 2024, the maturities of the Company's lease liabilities were as follows:

| *($ in thousands)* | Finance Leases | Operating Leases |
|---|---|---|
| 2025 | $ 4,212 | $ 105 |
| 2026 | 4,282 | 105 |
| 2027 | 2,718 | 105 |
| 2028 | 2,190 | 105 |
| 2029 | 2,257 | 105 |
| Thereafter | 5,772 | 259 |
| Total | 21,431 | 784 |
| Less: present value discount | (4,894) | (205) |
| Lease liabilities | $ 16,537 | $ 579 |

**9. Stockholders' Equity (Deficit) and Warrants**

**Public Offering**

On February 29, 2024, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Cowen and Company, LLC and Cantor Fitzgerald & Co., as representatives of the several underwriters named therein (collectively, the "Underwriters"), relating to the issuance and sale in an underwritten offering (the "Offering") of 15,410,000 shares of Common Stock, which included a full exercise of the Underwriters' option to purchase additional shares, at a price to the public of $3.00 per share. The net proceeds to the Company from the Offering were approximately $43.0 million after deducting underwriting discounts and commissions and Offering expenses. The Offering closed on March 5, 2024.

In March 2025, the Company completed a public offering of Common Stock that provided approximately $46.6 million in net proceeds. See Note 15 — Subsequent Events for further information.

**Equity Line Financing**

On September 24, 2024, the Company entered into the Common Stock Purchase Agreement with Lincoln Park for an equity line financing, which provides that, subject to the terms and conditions set forth therein, the Company has the sole right, but not the obligation, to sell to Lincoln Park shares of Common Stock having an aggregate value of up to $50.0 million over a 24-month period. The Company controls the timing and amount of any sales of Purchase Shares to Lincoln Park pursuant to the Common Stock Purchase Agreement in its sole discretion. In consideration for entering into the Common Stock Purchase Agreement, the Company issued 115,705 shares of Common Stock (the "Commitment Shares") to Lincoln Park. The Company did not receive any cash proceeds from the issuance of the Commitment Shares. The fair value of the Common Stock Purchase Agreement was measured on the issuance date based on the fair value of the Commitment Shares, which was the consideration given to Lincoln Park in exchange for entering into the agreement. The fair value of the Commitment Shares on the issuance date was determined to be $0.7 million based on the closing price of the Common Stock on September 24, 2024, which was $6.12 per share. The Company recognized the fair value of the Commitment Shares as a non-current asset as a component of other long-term assets on the consolidated balance sheets. The Common Stock Purchase Agreement is subsequently remeasured at each reporting date with changes in fair value recorded within Change in fair value of derivatives in the consolidated statements of operations and comprehensive loss. As of December 31, 2024, the Company has sold 500,000 shares to Lincoln Park for aggregate gross proceeds of $2.5 million, and the Company had $47.5 million in remaining availability for sales of Common Stock under the Common Stock Purchase Agreement. During the year ended December 31, 2024, the Company incurred $0.2 million of transaction costs related to the Common Stock Purchase Agreement, consisting of legal and professional fees, which were expensed in the consolidated statements of operations and comprehensive loss. As of December 31, 2024, there were $0.1 million of unpaid transaction costs related to the Common Stock Purchase Agreement included in accounts payable on the consolidated balance sheets.

**Registered Direct Offerings**

On October 4, 2024, the Company entered into a securities purchase agreement with an institutional investor pursuant to which the investor purchased 5,681,820 shares of Common Stock and warrants to purchase up to 5,681,820 shares of Common Stock in a registered direct offering (the "October 2024 Registered Direct Offering"). See below for additional information regarding the October 2024 RDO Warrants. The purchase price for one share of Common Stock and one warrant issued in the October 2024 Registered Direct Offering was $5.28. The net proceeds to the Company from the October 2024 Registered Direct Offering were approximately $28.0 million after deducting placement agent's fees and offering expenses of approximately $2.0 million. The October 2024 Registered Direct Offering closed on October 7, 2024. During the year ended December 31, 2024, the Company expensed $0.1 million of transaction costs related to the October 2024 Registered Direct Offering in the consolidated statements of operations and comprehensive loss. As of December 31, 2024, there were $0.1 million of unpaid transaction costs related to the October 2024 Registered Direct Offering included in accounts payable on the consolidated balance sheets.

On November 13, 2024, the Company entered into a securities purchase agreement with an institutional investor pursuant to which the investor purchased 2,808,988 shares of Common Stock and warrants to purchase up to 2,808,988 shares of Common Stock in a registered direct offering (the "November 2024 Registered Direct Offering"). See below for additional information regarding the November 2024 RDO Warrants. The purchase price for one share of Common Stock and one warrant issued in the November 2024 Registered Direct Offering was $5.34. The net proceeds to the Company from the November 2024 Registered Direct Offering were approximately $14.9 million after deducting offering expenses of approximately $0.1 million. The November 2024 Registered Direct Offering closed on November 15, 2024. All offering costs were expensed in the consolidated statements of operations and comprehensive loss. As of December 31, 2024, there were $0.1 million of unpaid transaction costs related to the November 2024 Registered Direct Offering included in accounts payable on the consolidated balance sheets.

**ATM Facility**

On September 1, 2022, the Company entered into the ATM Facility for the sale from time to time of up to $80.0 million of shares of Common Stock. In December 2024, the Company sold an aggregate of 1,333,596 shares of Common Stock under the ATM Facility at an average price of $5.26 per share for net proceeds of approximately $6.8 million after deducting sales commissions of approximately $0.2 million. From December 31, 2024 through March 31, 2025, the Company sold an aggregate of 75,793 shares of Common Stock under the ATM Facility at an average price of $5.04 per share for net proceeds of approximately $0.4 million.

**Common Stock**

As of December 31, 2024, the Company's Second Amended and Restated Certificate of Incorporation authorized the Company to issue 250,000,000 shares of Common Stock. The number of authorized shares of Common Stock may be increased or decreased (but not below the number of shares then outstanding or reserved for issuance) by the affirmative vote of the holders of a majority in interest 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, 2024, no dividends have been declared. The Purchase Agreement limits the Company's ability to pay cash dividends to the holders of Common Stock.

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 any preferred stockholders of their liquidation preferences, holders of Common Stock are entitled to share ratably in all remaining assets of the Company.

As of December 31, 2024 and 2023, the Company had reserved Common Stock for future issuances as follows:

| | December 31, | |
|---|---|---|
| | 2024 | 2023 |
| Common Stock reserved for Contingent Earnout Shares | 15,000,000 | 15,000,000 |
| Common Stock reserved for Common Stock Purchase Agreement | 12,000,000 | — |
| Common Stock reserved for ATM Facility | 18,666,404 | — |
| Common Stock reserved for Option Agreement [1] | 1,073,333 | 1,333,334 |
| Exercise of options outstanding under stock plans | 12,274,139 | 11,919,421 |
| Options available for issuance under stock plans | 5,817,353 | 1,492,057 |
| Shares available for grant under ESPP | 1,030,033 | 1,030,033 |
| Warrants to purchase Common Stock | 14,079,314 | 5,588,506 |
| | 79,940,576 | 36,363,351 |

(1) As of December 31, 2024, assumes the exercise of the $8,050,000 of shares of Common Stock remaining under the Option, and as of December 31, 2023, assumes the exercise of the entire Option, as provided for in the Option Agreement, both at the minimum purchase price of $7.50 per share.

**Preferred Stock**

The Company's Second Amended and Restated Certificate of Incorporation provides the Company's board of directors with the authority to issue preferred stock, par value $0.0001 per share, 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 certificate 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, 2024 and 2023.

**Warrants**

The Company had the following Common Stock warrants outstanding as of December 31, 2024 and 2023:

| | December 31, | |
|---|---|---|
| | 2024 | 2023 |
| Legacy Humacyte Common Stock Warrants | 411,006 | 411,006 |
| Private Placement Warrants | 177,500 | 177,500 |
| Public Warrants | 5,000,000 | 5,000,000 |
| October 2024 RDO Warrants | 5,681,820 | — |
| November 2024 RDO Warrants | 2,808,988 | — |
| Total Common Stock Warrants | 14,079,314 | 5,588,506 |

***Legacy Humacyte Common Stock Warrants***

In connection with the Company's Loan Agreement, in 2021 the Company granted warrants to the lenders to purchase 411,006 shares of common stock at an exercise price of $10.28 per share (such warrants, "Legacy Humacyte Common Stock Warrants"). The Company recognized the fair value of the warrants within stockholders' equity using a Black-Scholes valuation model, as the settlement of the warrants is indexed to the Common Stock. There were no exercises or expirations of warrants during the year ended December 31, 2024, and there were no issuances, exercises or expirations of warrants during the year ended and December 31, 2023.

***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. See Note 3 — Fair Value Measurements for a summary of the change in the fair value of the Private Placement Warrants during the years ended December 31, 2024 and 2023. The remeasurement of the Private Placement Warrant liability to a fair value of $0.4 million as of December 31, 2024 from $0.1 million as of December 31, 2023 resulted in a non-cash loss of $0.3 million for the year ended December 31, 2024, compared to an insignificant non-cash gain for the year ended December 31, 2023. The remeasurement of the Private Placement Warrant liability is classified within Change in fair value of derivatives 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:

| | As of December 31, | |
|---|---|---|
| | 2024 | 2023 |
| Market price of public stock | $ 5.05 | $ 2.84 |
| Exercise price | $ 11.50 | $ 11.50 |
| Expected term (years) | 1.65 | 2.65 |
| Expected share price volatility | 128.0 % | 75.0 % |
| Risk-free interest rate | 4.22 % | 4.09 % |
| 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 were initially recognized as equity on the Closing Date at a fair value of $2.80 per share.

***Registered Direct Offering Warrants***

The October 2024 RDO Warrants were immediately exercisable. October 2024 RDO Warrants to purchase 2,840,910 shares of Common Stock have an exercise price of $5.28 per share, and will expire 180 days from the date of issuance. The remaining October 2024 RDO Warrants to purchase 2,840,910 shares of Common Stock have an exercise price of $5.28 per share, and will expire 1,640 days from the date of issuance.

The October 2024 RDO Warrants were initially recognized as a liability on the issuance date at a fair value of $15.2 million. The remeasurement of the October RDO Warrants liability to a fair value of $12.4 million as of December 31, 2024 resulted in a non-cash gain of $2.8 million for the year ended December 31, 2024, classified within Change in fair value of derivatives in the consolidated statements of operations and comprehensive loss. See Note 3 — Fair Value Measurements for a summary of the change in the fair value of the October 2024 RDO Warrants during the year ended December 31, 2024.

The October 2024 RDO Warrants were valued using the following assumptions under the Black-Scholes valuation model:

| | 180 Day Warrants | | 1,640 Day Warrants | |
|---|---|---|---|---|
| | December 31, 2024 | October 7, 2024 | December 31, 2024 | October 7, 2024 |
| Market price of public stock | $ 5.05 | $ 5.50 | $ 5.05 | $ 5.50 |
| Exercise price | $ 5.28 | $ 5.28 | $ 5.28 | $ 5.28 |
| Expected term (years) | 0.27 | 0.50 | 4.27 | 4.50 |
| Expected share price volatility | 106.7 % | 99.0 % | 88.4 % | 86.7 % |
| Risk-free interest rate | 4.27 % | 4.36 % | 4.25 % | 3.79 % |
| Estimated dividend yield | 0 % | 0 % | 0 % | 0 % |

The November 2024 RDO Warrants were immediately exercisable. November 2024 RDO Warrants to purchase 1,404,494 shares of Common Stock have an exercise price of $5.34 per share, and will expire 180 days from the date of issuance. The remaining November 2024 RDO Warrants to purchase 1,404,494 shares of Common Stock have an exercise price of $5.34 per share, and will expire 1,640 days from the date of issuance.

The November 2024 RDO Warrants were initially recognized as a liability on the issuance date at a fair value of $6.1 million. The remeasurement of the November 2024 RDO Warrants liability to a fair value of $6.4 million as of December 31, 2024 resulted in a non-cash loss of $0.3 million for the year ended December 31, 2024, classified within Change in fair value of derivatives in the consolidated statements of operations and comprehensive loss. See Note 3 — Fair Value Measurements for a summary of the change in the fair value of the November 2024 RDO Warrants during the year ended December 31, 2024.

The November 2024 RDO Warrants were valued using the following assumptions under the Black-Scholes valuation model:

| | 180 Day Warrants | | 1,640 Day Warrants | |
|---|---|---|---|---|
| | December 31, 2024 | November 15, 2024 | December 31, 2024 | November 15, 2024 |
| Market price of public stock | $ 5.05 | $ 4.84 | $ 5.05 | $ 4.84 |
| Exercise price | $ 5.34 | $ 5.34 | $ 5.34 | $ 5.34 |
| Expected term (years) | 0.37 | 0.50 | 4.37 | 4.50 |
| Expected share price volatility | 106.7 % | 99.2 % | 88.4 % | 86.6 % |
| Risk-free interest rate | 4.22 % | 4.35 % | 4.25 % | 4.20 % |
| Estimated dividend yield | 0 % | 0 % | 0 % | 0 % |

**Contingent Earnout Liability**

Following the Closing, former holders of Legacy Humacyte common and preferred shares are eligible to receive up to 15,000,000 Contingent Earnout Shares 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 ("VWAP") per share of Common Stock quoted on 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. 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 10-year period using the most reliable information available.

See Note 3 — Fair Value Measurements for a summary of the change in the fair value of the Contingent Earnout Liability during the years ended December 31, 2024 and 2023. The remeasurement of the Contingent Earnout Liability to a fair value of $71.0 million at December 31, 2024 from a fair value of $37.9 million at December 31, 2023, resulted in a non-cash loss of $33.0 million for the year ended December 31, 2024, compared to a non-cash loss of $10.0 million for the year ended December 31, 2023 related to the remeasurement of the Contingent Earnout Liability. The remeasurement of the Contingent Earnout Liability is 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:

| | As of December 31, | |
|---|---|---|
| | 2024 | 2023 |
| Current stock price | $ 5.05 | $ 2.84 |
| Expected share price volatility | 84.8 % | 86.7 % |
| Risk-free interest rate | 4.58 % | 3.88 % |
| Estimated dividend yield | 0 % | 0 % |
| Expected term (years) | 10.00 | 10.00 |

**10. Stock-based Compensation**

At Closing, the 2021 Long-Term Incentive Plan, (the "2021 Plan"), and the 2021 Employee Stock Purchase Plan, (the "ESPP"), became effective. Under the 2021 Plan, the Company can grant non-statutory stock options, incentive stock options, stock appreciation rights, restricted stock, restricted stock units, unrestricted stock, performance awards and other forms of awards. Under the ESPP, when and if implemented, eligible employees will be permitted to purchase shares of Common Stock at the lower of 85% of the closing trading price per share of 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.

The 2021 Plan and ESPP provide that on January 1 of each year, 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 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. The Company's board of directors determined that there would be no automatic increase in the number of shares reserved under the 2021 Plan on January 1, 2023. The 2021 Plan share reserve automatically increased on January 1, 2024 by 5,183,686 shares, which was equivalent to 5% of the number of shares of Common Stock outstanding on December 31, 2023. The 2021 Plan share reserve automatically increased on January 1, 2025 by 6,501,375 shares, which was equivalent to 5% of the number of shares of Common Stock outstanding on December 31, 2024. Since the inception of the ESPP, the Company's board of directors has determined that there would be no automatic increase in the number of shares reserved under the ESPP. As of December 31, 2024, 5,817,353 and 1,030,033 shares of Common Stock were available under the 2021 Plan and ESPP, respectively.

Prior to the Closing, Legacy Humacyte had two equity incentive plans, the 2015 Omnibus Incentive Plan, as amended, (the "2015 Plan"), and the 2005 Stock Option Plan (the "2005 Plan"). As a result of the Merger, after the Closing no further awards were granted under either the 2015 Plan or the 2005 Plan. All awards previously granted and outstanding as of the effective date of the Merger were adjusted to reflect the impact of the Merger as set forth in the Merger Agreement, but otherwise retained 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. As of December 31, 2024, 8,578,363, 3,694,124 and 1,652 shares of Common Stock remain reserved for outstanding options issued under the 2021 Plan, the 2015 Plan and the 2005 Plan, respectively. The Company has sufficient authorized and unissued shares to issue Common Stock in satisfaction of any outstanding awards and any awards available for grant 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 award recipients with those of its stockholders. The Company's board of directors or compensation committee 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 Common Stock at the date of grant.

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, | |
|---|---|---|
| | 2024 | 2023 |
| Estimated dividend yield | 0 % | 0 % |
| Expected share price volatility (weighted average and range, if applicable) | 91.8% (90.8% to 92.8%) | 88.6% (88.5% to 89.8%) |
| Risk-free interest rate (weighted average and range, if applicable) | 4.12% (3.54% to 4.41%) | 4.22% (3.58% to 4.39%) |
| Expected term of options (in years) | 6.25 | 6.25 |

- *Fair Value of Common Stock.* The fair value of the Common Stock has been determined based on the closing price of the shares on Nasdaq.
- *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 determined based on a blended approach using the historical share volatility of the Common Stock and that 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. 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.
- *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.

The following table shows a summary of stock-based compensation expense included in the consolidated statements of operations and comprehensive loss for the years ended December 31, 2024 and 2023:

| | Year Ended December 31, | |
|---|---|---|
| *($ in thousands)* | 2024 | 2023 |
| Research and development | $ 2,851 | $ 1,716 |
| General and administrative | 3,286 | 5,112 |
| Total | $ 6,137 | $ 6,828 |

A summary of option activity under the Company's stock option plans during the year ended December 31, 2024 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, 2023 | 11,919,421 | $ 4.64 | 8.3 | $ 383 |
| Granted | 1,640,900 | 6.18 | | |
| Exercised | (503,672) | 3.01 | | |
| Forfeited | (782,510) | 3.89 | | |
| Options outstanding at December 31, 2024 | 12,274,139 | $ 4.96 | 7.7 | $ 16,202 |
| Vested and exercisable, December 31, 2024 | 5,734,589 | $ 6.26 | 6.4 | $ 5,614 |
| Vested and expected to vest, December 31, 2024 | 12,274,139 | $ 4.96 | 7.7 | $ 16,202 |

The weighted-average grant-date fair value per share of options granted during the years ended December 31, 2024 and 2023 was $4.82 and $2.20, respectively. The total intrinsic value of options exercised during the years ended December 31, 2024 and 2023 was $2.0 million and $0.8 million, respectively. As of December 31, 2024, unrecognized stock-based compensation cost for options was $18.1 million and is expected to be recognized over a weighted-average period of 2.7 years.

## 11. Income Taxes

The Company did not record any income tax expense or benefit during the years ended December 31, 2024 and 2023. 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. The majority of 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:

| | As of December 31, | |
|---|---|---|
| *($ in thousands)* | 2024 | 2023 |
| Deferred tax assets: | | |
| Net operating loss | $ 97,880 | $ 80,785 |
| Capitalized research and development | 57,498 | 50,968 |
| Research credits | 27,278 | 20,099 |
| Stock-based compensation | 1,141 | 1,140 |
| Right of use lease liability | 127 | 133 |
| Accrued expenses | 105 | 69 |
| Other | 1 | 1 |
| Total deferred tax asset | 184,030 | 153,195 |
| Less: valuation allowance | (182,867) | (151,677) |
| Total net deferred tax asset | 1,163 | 1,518 |
| | | |
| Deferred tax liabilities: | | |
| Basis difference in fixed assets | (1,041) | (1,385) |
| Right of use lease assets | (122) | (133) |
| Total deferred tax liability | (1,163) | (1,518) |
| Total net deferred tax asset/(liability) | $ — | $ — |

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, 2024 and December 31, 2023.

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. 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.

The reasons for the difference between the actual income tax benefit for the years ended December 31, 2024 and 2023, and the amount computed by applying the statutory Federal income tax rate to losses before income taxes are as follows:

| | December 31, | | | |
|---|---|---|---|---|
| | 2024 | | 2023 | |
| *($ in thousands)* | Amount | Rate | Amount | Rate |
| Income tax benefit at statutory rate | $ (31,227) | 21.0 % | $ (23,263) | 21.0 % |
| State income taxes, net of federal benefit | (2,399) | 1.6 % | (2,066) | 1.9 % |
| Tax credits | (4,548) | 3.1 % | (1,917) | 1.7 % |
| Other nondeductible expenses | 6,702 | (4.5)% | 1,759 | (1.6)% |
| Deferred rate changes | 2,256 | (1.5)% | 2,100 | (1.9)% |
| Deferred tax true-up[(1)] | (1,973) | 1.3 % | 2,860 | (2.6)% |
| Change in valuation allowance | 31,189 | (21.0)% | 20,527 | (18.5)% |
| Provision for income taxes | $ — | 0.0 % | $ — | 0.0 % |

(1) The deferred tax true-up for 2024 and 2023 primarily relates to executive compensation subject to IRC Section 162(m) limitations.

As of December 31, 2024 the Company had approximately $465.0 million and $471.7 million of gross Federal and state net operating losses, respectively. Of this amount, $303.8 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 2044. The state operating loss carryforwards are inclusive of North Carolina net operating losses, which are recorded at a zero benefit.

As of December 31, 2024 and 2023, the Company had Federal and state research tax credit carryforwards of $27.3 million and $20.1 million, respectively. These credit carryforwards will begin to expire in 2025 and will expire completely in 2044.

Net operating loss carryforwards and tax credit carryforwards are subject to review and possible adjustment by the 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.

**12. Retirement Plan**

The Company currently maintains a defined contribution employee retirement plan, or 401(k) plan, for all employees upon their date of hire. The 401(k) plan is intended to qualify as tax-qualified plans under Section 401(k) of the Internal Revenue Code of 1986, as amended. The plan permits 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 401(k) plan by the Company totaled $1.1 million and $1.0 million for the years ended December 31, 2024 and 2023, respectively.

## 13. Commitments and Contingencies

### Patent License Agreements

*Duke University*

In March 2006, the Company entered into a license agreement with Duke University ("Duke"), which was subsequently amended in 2011, 2014, 2015, 2018, 2019 and 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 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.

In December 2023, the Company filed a BLA with the FDA for urgent arterial repair following extremity vascular trauma when synthetic graft is not indicated, and autologous vein use is not feasible. Based on the achievement of this milestone under the Duke license agreement, the Company recorded license fee expense of $0.5 million during the fourth quarter of 2023 in research and development expense in its consolidated statements of operations and comprehensive loss and recorded $0.5 million of license expense payable in accounts payable in the Company's consolidated balance sheets as of December 31, 2023. The Company paid the license fee to Duke during the first quarter of 2024.

In December 2024, the FDA approved the Company's BLA with the FDA for urgent arterial repair following extremity vascular trauma when autologous vein use is not feasible. Based on the achievement of this milestone under the Duke license agreement, the Company recorded license fee expense of $0.5 million during the fourth quarter of 2024 in research and development expense in its consolidated statements of operations and comprehensive loss and recorded $0.5 million of license expense payable in accrued expenses in the Company's consolidated balance sheets as of December 31, 2024. Other payments to Duke under the license agreement were immaterial during the years ended December 31, 2024 and 2023.

*Yale University*

In August 2019, the Company entered into a license agreement with Yale University ("Yale") that granted the Company a worldwide license to the patents related to the BVP (the "BVP License Agreement"). The license granted under the BVP License 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 BVP License 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 "Tubular Prosthesis License Agreement"). The license granted under the Tubular Prosthesis License 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 Tubular Prosthesis License 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 Tubular Prosthesis License Agreement, the Company paid Yale upfront cash fees. The Company has also agreed to pay Yale:

- annual maintenance fees, increasing annually until the fifth anniversary for the BVP License Agreement and until the fourth anniversary for the Tubular Prostheses License Agreement 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, respectively;
- 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 BVP License Agreement and Tubular Prosthesis License Agreement 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 BVP License Agreement and Tubular Prosthesis License Agreement 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 BVP License Agreement and Tubular Prosthesis License Agreement (i) on 90 days' prior written notice to Yale, provided the Company is not in breach of the license agreements and has made all required payments to Yale thereunder and (ii) on written notice to Yale following an uncured material breach. With respect to the BVP License Agreement, the Company's rights under the 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, 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 BVP License Agreement and Tubular Prosthesis License Agreement were immaterial during the periods presented.

**JDRF Agreement**

On April 1, 2023, the Company entered into the JDRF Agreement to further develop and perform preclinical testing of the BVP, as discussed in Note 2 — Summary of Significant Accounting Policies. According to the terms of the JDRF Agreement, JDRF will provide funding up to $0.8 million based on the achievement of certain research and development milestones related to the Company's BVP. The Company received the first milestone payment of $80 thousand in April 2023 upon execution of the agreement. In May 2024, the Company received the second milestone payment of $90 thousand and the third milestone payment of $150 thousand, based on the achievement of certain research and development milestones specified in the JDRF Agreement. As of December 31, 2024, the Actual Award totaled $320 thousand. As of December 31, 2024 and 2023, the carrying value of the JDRF liability is $0.3 million and $0.1 million, respectively. There was $0.1 million and an insignificant amount of interest expense related to the JDRF liability recorded during the years ended December 31, 2024 and 2023, respectively.

In accordance with the JDRF Agreement, the Company has agreed to pay JDRF:

- a one-time royalty in an amount equal to four times the Actual Award, to be paid in three equal installments following the first commercial sale of any product containing the Company's technology identified in the JDRF Agreement;
- an additional royalty equal to the Actual Award at a specified payment date after net sales exceed $250 million; and
- in the event of a license, sale or transfer of the Company's rights to the product's technology identified in the JDRF Agreement or a change of control transaction, a payment equal to 10% of any license or purchase price payments received by the Company up to the Royalty Cap, less any previous royalty payments paid towards the Royalty Cap.

The JDRF Agreement expires on the date on which the Company has paid all of the royalty payments described above. Either party may terminate the JDRF Agreement for cause by providing the other party with written notice and allowing the other party 30 days to cure such breach. JDRF may terminate the JDRF Agreement without cause by providing 90 days' notice to the Company at any time after April 1, 2024. Royalties on previously received milestone payments would remain due after a termination by JDRF without cause.

**Legal Matters**

From time to time, the Company may be involved in various lawsuits, claims, assessments and proceedings, including securities, commercial, intellectual property, product liability, contractual, governmental, employment or other matters that arise in the normal course of business. The Company accrues a liability for a contingency when management believes information available prior to the issuance of the consolidated financial statements indicates it is probable a loss has been incurred as of the date of the consolidated financial statements and the amount of loss can be reasonably estimated. The Company adjusts its accruals to reflect the impact of negotiations, settlements, rulings, advice of legal counsel and other information and events pertaining to a particular case. Legal costs are expensed as incurred.

On November 18, 2024, James A. Cutshall filed a putative class action lawsuit, captioned *Cutshall v. Humacyte, Inc., et al*., No. 1:24-cv-00954 (the "Securities Litigation"), against the Company and certain of the Company's officers in the United States District Court for the Middle District of North Carolina. The complaint in the Securities Litigation asserts claims under Sections 10(b) and 20(a) of the Exchange Act on behalf of a putative class of persons and entities that purchased or otherwise acquired securities of the Company between May 10, 2024 and October 17, 2024, based on allegations that the defendants made or were responsible for false or misleading statements and omissions related to the BLA for the vascular trauma indication and to alleged deficiencies at the Company's Durham, North Carolina manufacturing facility. The Complaint seeks a variety of relief, including unspecified compensatory damages, attorneys fees and costs. On January 31, 2025, the court appointed co-lead plaintiffs. On February 19, 2025, the court entered a scheduling order directing the co-lead plaintiffs to file a consolidated amended complaint by April 24, 2025 and the defendants to answer or otherwise respond to the amended complaint by June 27, 2025.

On January 7 and 10, 2025, putative stockholders of the Company filed two verified stockholder derivative actions in the United States District Court for the Middle District of North Carolina, captioned *Silva v. Sebelius, et al*., No. 1:25-cv-00005 (the "*Silva* Action") and *Misko v. Niklason, et al*., No. 1:25-cv-00028 (the "*Misko* Action"). Each of these derivative actions was brought on behalf of the Company against certain of its current or former directors and officers, as well as Ayabudge LLC. The complaints in each action assert claims for violations of Section 14(a) of the Exchange Act, breach of fiduciary duty, unjust enrichment, abuse of control, gross mismanagement, and waste of corporate assets, based on a variety of allegations including claims that the defendants are responsible for any damages sustained by the Company as a result of the Securities Litigation. The *Misko* Action also includes a claim for contribution against certain defendants under Sections 10(b) and 21(d) of the Exchange Act for any liability the Company may sustain as a result of the Securities Litigation. On February 18, 2025, the court issued an order consolidating the *Silva* Action and the *Misko* Action (collectively, the "Consolidated Derivative Action") and staying the defendants' obligation to respond to any complaint in the Consolidated Derivative Action pending the submission of a proposed scheduling order. On March 11, 2025, the parties entered a joint motion to stay the Consolidated Derivative Action pending final resolution of the Securities Litigation. On March 24, 2025, the court granted the parties' joint motion to stay the Consolidated Derivative Action.

On December 19, 2024, the Company received a demand letter (the "Demand Letter") from a purported stockholder of the Company, demanding that the Board assert claims against certain of the Company's current or former officers and directors for breach of fiduciary duty, gross mismanagement, corporate waste, unjust enrichment, aiding and abetting, violations of Section 14(a) of the Exchange Act, and insider trading, based on a variety of allegations including claims that the Company's current and former officers and directors are responsible for any damages sustained by the Company as a result of the Securities Litigation. On January 24, 2025, the Board appointed a demand evaluation committee to evaluate the claims made in the Demand Letter and report back to the full Board. On February 19, 2025, the purported stockholder who sent the Demand Letter filed a stockholder derivative action in the United States District Court for the Middle District of North Carolina, captioned *Olson v. Niklason*, et al., No. 1:25-cv-00123 (the "*Olson* Action"), alleging that the Company had refused his demand. The complaint in the *Olson* Action asserts substantive claims and allegations that are substantially similar to those asserted in the Consolidated Derivative Action.

The Company disputes all claims asserted against it in the Securities Litigation and disputes that the plaintiffs in the Consolidated Derivative Action and *Olson* Action have standing to assert claims derivatively on its behalf. The Company is currently unable to estimate the potential loss or range of loss, if any, associated with these lawsuits, which could be material. Although there can be no assurance of the outcome of these lawsuits, based on information known by management, the Company has not accrued any material liabilities related to these lawsuits in the consolidated financial statements, as a negative outcome is deemed not probable, nor is any range of loss estimable as of December 31, 2024. Since the outcome of these matters cannot be predicted with certainty, any associated costs could have a material adverse effect on the Company's consolidated results of operations, financial position 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 Date converted into 15,812,735 shares of Common Stock. In August 2021, Fresenius Medical Care invested $25 million as part of a private placement offering related to the Merger (the "PIPE Financing") and received an additional 2.5 million shares of 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 ATEV 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 PAD, 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 (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.

*Agreements with Frenova Renal Research*

In May 2022 and June 2023, the Company entered into three services agreements with Frenova Renal Research ("Frenova"), a subsidiary of Fresenius Medical Care, to conduct a study to review the outcomes of 178,575 adult patients who received in-center dialysis at Fresenius Kidney Care dialysis centers. The Company expensed approximately $0.2 million for clinical research services performed by Frenova during the year ended December 31, 2023 related to these agreements. As of December 31, 2023, the clinical research services contracted for under these agreements with Frenova were fully complete and no further expenses have been incurred related to these agreements.

In June 2024, the Company entered into a master services agreement with Frenova that sets forth the terms by which the Company may engage Frenova to provide certain services for projects, with the services for each project being described in a separate statement of work. As of December 31, 2024, Frenova was engaged to perform clinical research services related to the Company's V012 Phase 3 clinical trial. During the year ended December 31, 2024, amounts expensed in relation to this agreement with Frenova were insignificant and there was an insignificant amount payable to Frenova as of December 31, 2024.

In July 2024, the Company entered into a service agreement with Fresenius Medical Care Deutschland GmbH ("Fresenius GmbH"), which provides medical scientific research services through Frenova. Frenova agreed to conduct a study to review patient data of adult hemodialysis patients who received treatment in certain European countries at dialysis centers that are part of Fresenius Medical Care AG. Fresenius Medical Care AG is the German parent company of Fresenius GmbH and ultimately of Fresenius Medical Care. During the year ended December 31, 2024, amounts expensed in relation to this agreement with Fresenius GmbH were approximately $0.1 million. As of December 31, 2024, there was less than $0.1 million payable to Fresenius GmbH included in accounts payable and less than $0.1 million payable to Fresenius GmbH included in accrued expenses on the Company's consolidated balance sheets. During the year ended December 31, 2023, there was $0.1 million of expense recognized for services performed by Fresenius GmbH.

*Arrangements with Yale University*

Dr. Niklason serves as an Adjunct Professor in Anesthesia at Yale University. As of December 31, 2024 and 2023, the Company was a party to license agreements with Yale University, as described in Note 13 — Commitments and Contingencies above.

Amounts expensed in relation to the license agreements with Yale University were $0.1 million during each of the years ended December 31, 2024 and 2023. There was an insignificant amount payable to Yale as of December 31, 2024 and 2023.

**15. Subsequent Events**

**Public Offering**

On March 25, 2025, the Company entered into an underwriting agreement with TD Securities (USA) LLC, Barclays Capital Inc. and BTIG, LLC, as representatives of the several underwriters named therein, relating to the issuance and sale in an underwritten offering (the "Public Offering") of 25,000,000 shares of Common Stock, at a price to the public of $2.00 per share (the "Firm Shares"). The Company also granted the underwriters a 30-day option to purchase up to an additional 3,750,000 shares of Common Stock at the same price as the Firm Shares. The net proceeds to the Company from the Public Offering were approximately $46.6 million after deducting underwriting discounts and commissions and estimated Public Offering expenses. The Public Offering closed on March 27, 2025.

**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, 2024, 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, 2024.

**Management's Report on Internal Control Over Financial Reporting**

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rule 13a-15(f) under the Exchange Act. Our internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the financial statements for external purposes in accordance with U.S. GAAP. A control system, no matter how well designed and operated, can only provide reasonable, not absolute, assurance that the objectives of the control system are met. Because of these inherent limitations, management does not expect that our internal controls over financial reporting will prevent all errors and all fraud. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with our policies and procedures may deteriorate. Our management, under the supervision of and with the participation of our Chief Executive Officer and Chief Financial Officer, conducted an evaluation of our internal control over financial reporting based on the framework in Internal Control—Integrated Framework issued in 2013 by the Committee of Sponsoring Organizations of the Treadway Commission. Based on the results of its evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2024.

**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. We are an "emerging growth company" as defined in the JOBS Act and we are a non-accelerated filer. For as long as we remain either an "emerging growth company" or a non-accelerated filer, 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, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

**Item 9B. Other Information**

**Director and Officer Trading Arrangements**

On September 12, 2024, William (B.J.) Scheessele, the Company's Chief Commercial Officer, adopted a trading arrangement for the sale of Common Stock that is intended to satisfy the affirmative defense conditions provided by Rule 10b5-1(c) under the Exchange Act. (the "Scheessele 10b5-1 Plan"). The Scheessele 10b5-1 Plan provides for a first possible trade date of December 11, 2024 and terminates automatically on the earlier of the execution of all trades contemplated by the Scheessele 10b5-1 Plan, or September 11, 2025. The Scheessele 10b5-1 Plan provides for the exercise of options to purchase up to 89,050 shares of Common Stock and the related sale of up to 85,900 shares of Common Stock pursuant to its terms.

During the three months ended December 31, 2024, no director or officer (as defined in Rule 16a-1(f) under the Exchange Act) of the Company adopted or terminated any "Rule 10b5-1 trading arrangement" or any "non Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

**Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections**

None.

## Part III

**Item 10. Directors, Executive Officers and Corporate Governance.**

Incorporated by reference from the information in our Proxy Statement for our 2025 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates.

**Item 11. Executive Compensation.**

Incorporated by reference from the information in our Proxy Statement for our 2025 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates.

**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.**

Incorporated by reference from the information in our Proxy Statement for our 2025 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates.

**Item 13. Certain Relationships and Related Transactions, and Director Independence**

Incorporated by reference from the information in our Proxy Statement for our 2025 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates.

**Item 14. Principal Accountant Fees and Services**

Incorporated by reference from the information in our Proxy Statement for our 2025 Annual Meeting of Stockholders, which we will file with the SEC within 120 days of the end of the fiscal year to which this Annual Report on Form 10-K relates.

## 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 |
|---|---|
| 3.1 | 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). |
| 3.2 | Amended and Restated 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 December 12, 2022). |
| 4.1 | Warrant Agreement, dated September 17, 2020, by and between Alpha Healthcare Acquisition Corp. and Continental Stock Transfer & 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). |
| 4.2 | 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). |
| 4.3* | Form of Investor Rights and Lock–up Agreement (incorporated by reference to Exhibit A of 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). |
| 4.4 | 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). |
| 4.5 | 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). |
| 4.6 | Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 to Humacyte, Inc.'s Current Report on Form 8-K, filed with the SEC on October 7, 2024). |
| 4.7 | Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 to Humacyte, Inc.'s Current Report on Form 8-K, filed with the SEC on November 14, 2024). |
| 4.8 | Description of the Company's securities registered pursuant to Section 12 of the Securities Exchange Act of 1934, as amended, (incorporated by reference to Exhibit 4.6 to Humacyte, Inc.'s Annual Report on Form 10-K filed with the SEC on March 28, 2024). |
| 10.1.1 | Revenue Interest Purchase Agreement, dated as of May 12, 2023, by and among Humacyte Global, Inc., Humacyte, Inc. and Hook SA LLC, (incorporated by reference to Exhibit 10.1 to Humacyte, Inc.'s Quarterly Report on Form 10-Q filed with the SEC on August 14, 2023). |
| 10.1.2* | Waiver, dated as of February 18, 2024, by and among Humacyte Global, Inc., Humacyte, Inc. and Hook SA LLC, (incorporated by reference to Exhibit 10.1.2 to Humacyte, Inc.'s Annual Report on Form 10-K filed with the SEC on March 28, 2024). |
| 10.1.3* | Waiver and Amendment, dated as of May 8, 2024, by and among Humacyte Global, Inc., Humacyte, Inc. and Hook SA LLC, (incorporated by reference to Exhibit 10.1 to Humacyte, Inc.'s Quarterly Report on Form 10-Q filed with the SEC on August 13, 2024). |
| 10.2 | Option Agreement, dated as of May 12, 2023, by and among Humacyte, Inc., TPC Investments III LP and TPC Investments Solutions LP, (incorporated by reference to Exhibit 4.1 to Humacyte, Inc.'s Registration Statement on Form S-3, filed with the SEC on June 9, 2023). |

| Exhibit No. | Description |
|---|---|
| 10.3 | Open Market Sale Agreement, dated September 1, 2022, by and between Humacyte, Inc. and Jefferies LLC, (incorporated by reference to Exhibit 1.2 to Humacyte, Inc.'s Registration Statement on Form S-3 (File No. 333-267225), filed with the SEC on September 1, 2022). |
| 10.4 | Purchase Agreement, dated as of September 24, 2024, by and between Humacyte, Inc. and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.1 to Humacyte Inc.'s Current Report on Form 8-K, filed with the SEC on September 25, 2024). |
| 10.5 | Registration Rights Agreement, dated as of September 24, 2024, by and between Humacyte, Inc. and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.2 to Humacyte Inc.'s Current Report on Form 8-K, filed with the SEC on September 25, 2024). |
| 10.6^ | 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). |
| 10.6.1^ | 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). |
| 10.6.2^ | 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). |
| 10.7^ | 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). |
| 10.8^ | 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). |
| 10.9^ | 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). |
| 10.9.1^ | 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). |
| 10.9.2^ | 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). |
| 10.9.3^ | 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). |
| 10.9.4^ | 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). |
| 10.9.5^ | 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). |
| 10.9.6^ | Sixth Amendment to Exclusive Patent License Agreement, dated January 10, 2022, between Duke University and Humacyte Global, Inc. (incorporated by reference to Exhibit 10.7.6 to Humacyte, Inc.'s Annual Report on Form 10-K filed with the SEC on March 29, 2022). |
| 10.10^ | 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). |
| 10.10.1^ | 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). |
| 10.10.2^ * | 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). |
| 10.11^ * | 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). |

| Exhibit No. | Description |
|---|---|
| 10.12+* | 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). |
| 10.13+ | Executive Employment Agreement, dated May 18, 2021, between Dale Sander and Humacyte, Inc. (incorporated by reference to Exhibit 10.11 to Humacyte, Inc.'s Annual Report on Form 10-K, filed with the SEC on March 24, 2023). |
| 10.14+ | 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). |
| 10.15+ | 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). |
| 10.15.1+ | 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). |
| 10.16+ | 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). |
| 10.17+ | 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). |
| 10.18+ | 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). |
| 10.18.1+ | 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). |
| 10.18.2+ | 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). |
| 10.18.3+ | 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). |
| 10.18.4+ | 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). |
| 10.18.5+ | 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). |
| 10.19+ | 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). |
| 10.19.1+ | 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). |
| 10.19.2+ | 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). |
| 10.19.3+ | 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). |
| 10.19.4+ | 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). |
| 10.20+ | 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). |
| 10.21 | 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). |
| 10.21.1 | 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). |

| Exhibit No. | Description |
|---|---|
| 10.21.2 | 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). |
| 10.21.3 | 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). |
| 10.21.4 | 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). |
| 19.1! | Insider Trading Policy |
| 21.1! | Subsidiaries of the Registrant |
| 23.1! | Consent of PricewaterhouseCoopers LLP. |
| 31.1! | 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. |
| 31.2! | 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. |
| 32.1! | 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. |
| 32.2! | 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. |
| 97+ | Humacyte, Inc. Compensation Clawback Policy, (incorporated by reference to Exhibit 97 to Humacyte, Inc.'s Annual Report on Form 10-K filed with the SEC on March 28, 2024). |
| 101! | The following materials from Humacyte, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2024, formatted in Inline XBRL (Inline eXtensible Business Reporting Language): (i) Consolidated Balance Sheets as of December 31, 2024 and 2023, (ii) Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2024 and 2023, (iii) Consolidated Statements of Changes in Stockholders' Equity (Deficit) for the years ended December 31, 2024 and 2023, (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2024 and 2023, and (v) Notes to Consolidated Financial Statements. |
| 104 | Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101). |

! 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) is the type of information the company both customarily and actually treats as private or confidential.

+ 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 31, 2025

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 |
|---|---|---|
| /s/ Laura E. Niklason<br>Laura E. Niklason, M.D., Ph.D. | President, Chief Executive Officer and Director<br>(Principal Executive Officer) | March 31, 2025 |
| /s/ Dale A. Sander<br>Dale A. Sander | Chief Financial Officer, Chief Corporate Development Officer and Treasurer<br>(Principal Financial and Accounting Officer) | March 31, 2025 |
| /s/ Kathleen Sebelius<br>Kathleen Sebelius | Director | March 31, 2025 |
| /s/ John Bamforth<br>John Bamforth | Director | March 31, 2025 |
| /s/ Emery N. Brown<br>Emery N. Brown, M.D., Ph.D. | Director | March 31, 2025 |
| /s/ Michael T. Constantino<br>Michael T. Constantino | Director | March 31, 2025 |
| /s/ Brady W. Dougan<br>Brady W. Dougan | Director | March 31, 2025 |
| /s/ C. Bruce Green<br>C. Bruce Green, M.D. | Director | March 31, 2025 |
| /s/ Keith Anthony Jones<br>Keith Anthony Jones, M.D. | Director | March 31, 2025 |
| /s/ Todd M. Pope<br>Todd M. Pope | Director | March 31, 2025 |
| /s/ Diane Seimetz<br>Diane Seimetz, Ph.D. | Director | March 31, 2025 |
| /s/ Max Wallace<br>Max Wallace, J.D. | Director | March 31, 2025 |
| /s/ Susan Windham-Bannister<br>Susan Windham-Bannister, Ph.D. | Director | March 31, 2025 |

# HUMACYTE, INC. INSIDER TRADING POLICY

## I. PURPOSE

Humacyte, Inc. ("Humacyte" or the "Company") has adopted the following policies and procedures with respect to trading in Humacyte securities by members of Company's board of directors, officers and employees. These policies and procedures are designed to help you comply with insider trading laws, handle confidential information properly and avoid potentially embarrassing public disclosures and the appearance of impropriety. You are receiving this policy because you are a Humacyte officer, director or employee, or an external contractor or consultant who has or may have access to material nonpublic information, and are subject to this policy.

All directors, officers and employees, and external contractors and consultants who have access to material nonpublic information, are responsible for reading these policies and procedures and complying with them. Further, even after you are no longer employed by or affiliated with Humacyte, you must maintain the confidentiality of any confidential or proprietary information obtained during your employment or affiliation with Humacyte.

Penalties for violating these policies and procedures may involve any appropriate remedy, including termination of employment. In addition, the Securities and Exchange Commission (SEC) and criminal prosecutors vigorously enforce insider trading laws. Violation of insider trading laws could result in civil and criminal penalties under applicable federal securities laws.

If you have any questions about the application of these policies and procedures, or if you would like to make a request for an exception, please contact the Chief Financial Officer ("CFO"). Although the CFO generally is responsible for the implementation of these policies and procedures, the board of directors may designate employees to carry out any of the duties described below.

## II. PERSONS COVERED

This policy applies to all (i) directors, officers, employees (permanent or temporary, salaried or hourly) and (ii) external contractors and consultants who have access to material nonpublic information, of Humacyte and its subsidiaries, both inside and outside the United States (collectively, "covered persons"). This policy also applies to all immediate family members of covered persons, any other members of the covered person's family, and other household members (other than tenants and household employees) of covered persons (collectively, "family members"). This policy further applies to all corporations, limited liability companies, partnerships, trusts or other entities controlled by covered persons or family members.

## III. COVERED TRANSACTIONS

This policy applies to all transactions in all Humacyte securities, which may include common stock, preferred stock, debt securities, warrants or options to acquire common stock, derivative securities, units or any other type of securities that the Company may issue. This policy also applies to securities of other companies about which you learn material nonpublic information during the course of your relationship with Humacyte.

## IV. POLICY AGAINST INSIDER TRADING

### A. General Prohibition Against Insider Trading

Federal and state laws prohibit "insider trading," the purchase or sale of securities, in breach of a fiduciary duty or other relationship of trust and confidence, on the basis of material nonpublic information about the security. Any covered person, or any other person designated by this policy, who has material nonpublic information relating to Humacyte may not, until the information becomes public or is no longer material:

- engage in transactions in Humacyte securities, directly or indirectly, except as specifically noted herein;
- recommend the purchase or sale of any Humacyte securities;
- engage in any other action to take personal advantage of that information, including but not limited to, passing on or "tipping" that information to someone who uses it for personal gain, regardless of the quantity of securities traded;
- disclose material nonpublic information to persons within Humacyte whose jobs do not require them to have that information, or outside of Humacyte to other persons, including, but not limited to family, friends, business associates, investors and expert consulting firms, unless any such disclosure is made in express accordance with Humacyte's policies regarding the protection or authorized external disclosure of information concerning the Company; or
- assist anyone engaged in the above activities.

Tipping arises when a covered person discloses material nonpublic information about Humacyte or another publicly-traded entity to another person or recommends another person to trade in the securities of a company while in possession of material nonpublic information about that company, and that person either (i) trades in a security of the company in respect of which you provided information or (ii) provides the information to a third person who then makes a trade in a related security. Tipping is illegal even if you do not personally make a trade or otherwise benefit from disclosing the information.

In addition, any covered person who learns of material nonpublic information about another entity, including an entity with whom Humacyte does business, may not trade in that entity's securities until the information becomes public.

Although you may believe it is necessary or justifiable for independent reasons (such as the need to raise money for an emergency expenditure) to engage in a transaction involving Humacyte's securities, there are no exceptions to this policy's prohibition against insider trading. Even the appearance of impropriety must be avoided to preserve Humacyte's reputation for adhering to the highest standards of conduct.

To ensure compliance with this policy, all covered persons must protect the confidentiality of material nonpublic information, by, for example, avoiding casual conversations about such information in public areas and storing files containing material nonpublic information in secure locations. This policy also covers communications and postings made through the Internet. You must not post any nonpublic or confidential information on the Internet, including through chatrooms, discussion groups, or social media platforms. This includes anonymous posts or discussion on the Internet. For more information, please see the Company's social media policy.

Because insider trading law is complex, you should contact the CFO if you have any questions about whether information in your possession is material or nonpublic or if a proposed transaction or communication would violate the insider trading laws. You must also report any unauthorized disclosure of material nonpublic information, whether inadvertent or otherwise, immediately to the CFO.

**B. What Information is "Material"?**

For the purposes of these policies and procedures, information is "material" if a reasonable investor would consider that information important in making a decision to trade securities. It is also information that, if disclosed, is reasonably likely to affect the market price of Humacyte's securities. Both positive and negative information can be material. Further, courts and the SEC have declined to identify all information that could be deemed to be material.

Some examples of material information include:

- quarterly or annual earnings information and guidance, including estimates or revisions;
- discussions, proposals or agreements for a significant merger, acquisition or divestiture;
- threatened litigation or administrative actions, or material developments in such matters;
- significant new or prospective contracts, licensing or collaboration agreements;
- significant developments or announcements involving the U.S. Food and Drug Administration and any Humacyte products, regulatory applications, or clinical trials;

- significant changes in marketing, pricing strategies or market share;
- significant research and development initiatives, clinical studies, clinical data or new product prospects;
- changes in business strategies;
- changes in key members of management;
- a significant cybersecurity breach or incident;
- changes in debt ratings; and
- stock splits or changes in dividend policies.

The foregoing list does not include all of the information that could be deemed to be material.

### C. What Information is "Nonpublic"?

Information is "nonpublic" if it has not been widely disseminated to the public, such as through a press release carried over a major news service, a public filing with the SEC or materials sent to stockholders (e.g., a proxy statement or widely disseminated prospectus).
Information is also nonpublic if it has been widely disseminated to the public, but sufficient time has not elapsed to permit the investment community to absorb and evaluate the information. In general, one full business day after public release is deemed sufficient for investor absorption and evaluation.

The distribution of information through narrower channels may be insufficient to make it public. For example, merely posting information on a website may not satisfy the "widely disseminated" standard to make such information public. Also, the fact that nonpublic information is reflected in rumors in the marketplace does not mean that the information has been publicly disseminated. It is important to note that even after information becomes public, many aspects relating to a matter may remain nonpublic.

## V. RULES FOR SPECIFIC TRANSACTIONS

In addition to the general prohibition on insider trading described above, certain specific transaction types and related activities are prohibited by this policy.

### A. Participation in Expert Networks or Similar Consulting Arrangements

You are not permitted to provide information or services about or relating to Humacyte to "expert network firms" or similar consulting firms. Expert network firms may seek to engage you as a consultant due to your knowledge of Humacyte, or your knowledge of our industry overall. Your provision of such consulting services creates the risk that you may use or disclose, deliberately or inadvertently, Humacyte's confidential information or engage, or

assist another party in engaging, in activities that are detrimental to or competitive with the Company. Such activity may also violate federal securities laws. Accordingly, participation in such organizations is strictly prohibited.

**B. Derivatives Transactions**

You may not engage in derivative transactions involving Humacyte's securities.
Derivative transactions are speculative transactions that permit a person to leverage his or her investment using a relatively small amount of money. Transactions in options (other than stock options issued by Humacyte) may create the appearance that a covered person is trading based on material nonpublic information and may focus a covered person's attention on Humacyte's short-term performance. Examples of derivative transactions include, but are not limited to, purchases and sales of put and call options.

**C. Hedging, Pledging and Lending**

You are prohibited from hedging and lending Humacyte securities in any transaction, including by entering into any short sales, swaps, options, puts, calls, forward contracts or any other similar derivatives transaction. Unless authorized in advance by the Board of Directors of Humacyte, you are prohibited from pledging Humacyte securities in any transaction.

**D. Short Sales**

You may not engage in short selling of Humacyte securities. Selling short includes transactions in which you borrow securities from a broker, sell them, and eventually buy securities on the market to cover the number of securities borrowed from the broker. Profit is made if the price of the securities decreases during the period of borrowing. Short sales may evidence an expectation on the part of the seller that the securities will decline in value, and therefore have the potential to signal to the market that the seller lacks confidence in the Company's prospects.

**E. Margin Accounts**

You may not engage in purchasing Humacyte securities on margin. Purchasing Humacyte securities on margin involves the use of borrowed money from a brokerage firm to purchase the securities. Holding Humacyte securities in a margin account means that the securities can be sold to pay a loan to the brokerage firm. Covered persons are prohibited from holding Humacyte securities in a margin account because a margin sale might occur at a time when the covered person is aware of material nonpublic information.

**F. Post-Termination Transactions**

You may not engage in trading in Humacyte securities while in the possession of material nonpublic information after your relationship with the Company has ended. This policy continues to apply to transactions in Humacyte securities even after termination of service to Humacyte. If an individual is in possession of material non-public information when

his or her service terminates, that individual may not trade in Humacyte securities until that information has become public or is no longer material.

## VI. WHEN TRADING IS GENERALLY PERMITTED

To help directors, officers and employees conduct trades in Humacyte securities in compliance with the general prohibition described above, Humacyte has established mechanisms for effecting trades in the company's securities in compliance with these policies and procedures. If you are not certain whether a proposed transaction complies with the mechanisms described below, you should contact the CFO.

### A. Window Periods

The Company requires that covered persons limit their trading in Company securities to prescribed "Window Periods." The periods between Window Periods are considered "Blackout Periods". Covered persons may not engage in trades in Company securities during Blackout Periods. The requirement to make trades during a Window Period does not apply to transactions described below under the headings "Rule 10b5-1 Plan Trading," "Option Exercises," "Estate Planning and Gifts," "Employee Stock Purchase Plans" and "Tax Obligations."

Under this policy, a Window Period begins at market opening on the second business day after the Company has issued its usual press release announcing quarterly results and ends two weeks prior to the end of the applicable fiscal quarter. The Company retains the discretion to close a Window Period in the event of any major corporate development that has not been announced to the public. The closing or opening of any Window Period will be announced by email and by posting on Humacyte's intranet. If you think you have any material nonpublic information during the Window Period, however, you must consult the CFO before trading Humacyte securities.

Humacyte also strongly encourages employees, family members and close associates of any officer, employee or member of the board of directors to confine their trading in Humacyte securities to a Window Period. While there is no violation of insider trading rules if it can be shown that a family member or other person associated with a director, officer or employee acted independently when trading and without knowledge of material nonpublic information, a strong presumption may arise that material nonpublic information has been shared with such person by the officer, employee or member of the board of directors.

### B. Special Blackout Periods

The Company may impose special periods during which certain covered persons will be prohibited from trading or otherwise effecting transactions in Humacyte securities ("special blackout periods") even though the Window Period would otherwise be open. This would be the case, for example, for Company employees working on a material merger or acquisition transaction, or another event that could involve material nonpublic information. If a special blackout period is imposed, the Company will notify affected individuals by sending them a

notice. The Company will also notify affected individuals at the end of such special blackout period.

Please note that special blackout periods may apply to all individuals working on material transactions or other matters that could involve material nonpublic information, even if those individuals only have a limited role in the transaction. A special blackout period for these matters is not necessarily limited to individuals who are on any particular team or function. The determination of whether a project or transaction is material will be made by the CFO in consultation with the Disclosure Committee.

### C. Rule 10b5-1 Plan Trading

To avoid liability for insider trading, officers and members of the board of directors may wish to rely upon the affirmative defenses established by Rule 10b5-1 under the Securities Exchange Act of 1934 (the "Exchange Act"). Rule 10b5-1 is available to an individual or entity who purchases or sells a security under a binding contract, specific instruction or written plan that the person or entity put into place before becoming aware of material nonpublic information (such a written plan, a "Rule 10b5-1 plan"). If the trading plan meets all of the requirements of Rule 10b5-1, Humacte securities may be purchased and sold under such plan without regard to certain insider trading considerations, and such trades would not be restricted to the window periods under this policy.

The Company strongly encourages any of the following covered persons who wish to trade in Humacyte securities to limit such trading activity to Rule 10b5-1 plans adopted in accordance with this policy: (i) members of the board of directors, (ii) officers appointed by the board of directors and (iii) members of the Humacyte leadership team (HLT). In addition, other covered persons who wish to trade in Humacyte securities may be encouraged to limit their trading activity to Rule 10b5-1 plans adopted in accordance with this policy, based on the determination of the CFO.

A covered person who enters into a Rule 10b5-1 plan is strongly discouraged from trading in any securities of the Company outside of the Rule 10b5-1 plan.

To create a Rule 10b5-1 plan, you must enter into a written plan for trading securities that must:

- specify the amount, price and date of the transaction(s);
- include a written formula, algorithm or computer program for determining the amount, price and date of the transaction(s); or
- not permit the person for whom shares are being purchased or sold to exercise any subsequent influence over how, when or whether to effect purchases or sales, while at the same time ensuring that the person effecting the trades is not aware of any material nonpublic information at the time of the trades.

In order to rely on the defense, a person must adopt a Rule 10b5-1 plan that meets all of the rule's requirements. These include a requirement that the plan include a representation certifying that the person adopting the plan is doing so in good faith, at a time when he or she is not in possession of material nonpublic information and not as part of a plan to evade the insider trading prohibitions. Additionally, a director or officer adopting a new Rule 10b5-1 plan may not have any other outstanding Rule 10b5-1 plan, and may not subsequently enter into any additional Rule 10b5-1 plan, subject to certain exceptions. Frequent amendment of, or deviation from, a trading plan may make it difficult for an insider to demonstrate that he or she has satisfied the rule's "good faith" requirement.

A Rule 10b5-1 plan must provide for a "cooling off" period before purchases and sales can occur under the plan. For a director or officer, no purchases or sales under the Rule 10b5-1 plan can occur until the later of (i) 90 days after the adoption of the Rule 10b5-1 plan and (ii) two business days following disclosure of the Company's results in a Form 10-Q or Form 10-K for a completed fiscal quarter in which the plan was adopted; provided, however, that in no event will the required cooling off period be longer than 120 days after adoption of the Rule 10b5-1 plan. No purchases or sales under a Rule 10b5-1 plan for a person other than a director or officer may be made until 30 days after adoption of the plan.

Any modification to the amount, pricing, or timing of purchases or sales of securities under a Rule 10b5-1 plan will constitute the termination of the plan and adoption of a new plan, which means that any such modification will trigger the need for the new trading plan to satisfy all of the elements of Rule 10b5-1, including a new cooling off period before trading can begin again.

Stock brokerage firms may assist directors, officers and employees in establishing Rule 10b5-1 plans. To ensure that such arrangements comply with Rule 10b5-1, Humacyte requires that any covered person who wishes to establish a Rule 10b5-1 plan:

- enter into the required contract, provide the required instructions, or adopt the required plan, during a Window Period and otherwise while not in possession of material nonpublic information;
- obtain prior approval from the CFO for such Rule 10b5-1 plan, as well as any amendment of such plan;
- report promptly to the CFO all transactions made pursuant to the Rule 10b5-1 plan, as well as any termination of the plan; and
- adopt a plan with a duration of at least 6 months.

**D. Options Exercises**

Directors, officers and employees who have stock options or other rights granted by Humacyte to purchase securities from the Company may exercise the options or purchase rights at any time permitted under the terms of the applicable option or other agreement so long as the exercise does not involve a broker-assisted cashless exercise. This rule applies only to options

or purchase rights granted by the Company. Rules pertaining to options or purchase rights granted by third parties are described in the sections above captioned "Derivatives Transactions," "Short Sales" and "Margin Accounts." Please be aware, however, that any subsequent sale of securities purchased by means of the exercise of stock options or other rights in accordance with this policy must be made during a Window Period, pursuant to a Rule 10b5- 1 plan, or otherwise approved by the CFO.

### E. Estate Planning and Gifts

Directors, officers and employees may at any time make bona fide gifts of Humacyte securities (such as charitable donations or family gifts or estate planning transfers). Depending on the circumstances, recipients of gifts may be subject to restrictions on subsequent sales of securities. Any such gifts made by directors and officers subject to Section 16 of the Exchange Act must be reported on Form 4 within two business days of the date of the transaction.

Gifts that are part of a plan to circumvent the insider trading rules are not permitted.

### F. Employee Stock Purchase Plans

Purchases of Humacyte stock under the Company's employee stock purchase plan, if any, resulting from periodic or lump sum contributions of money thereto, pursuant to an election made at the time of plan enrollment, are not subject to this policy. Your initial election to participate in the plan, changes to that election for any enrollment period and sales of Humacyte stock purchased pursuant to the plan *are* subject to this policy and must comply therewith.

### G. Tax Obligations

Transactions between covered persons and Humacyte that are undertaken to satisfy tax obligations, such as upon the vesting of restricted stock units and the net issuance of shares, which effectively involves disposing of vested shares to the Company, are exempt under this policy.

## VII. PRE-CLEARANCE PROCEDURES

The following Company personnel may not trade or engage in any other transaction involving the Company's securities (including a securities plan transaction such as an option exercise, a gift, a loan or pledge, a contribution to a trust or any other transfer) without first obtaining pre-clearance of the transaction from the CFO:

- all directors, executive officers and members of HLT who trade outside of a Rule 10b5- 1 plan entered into in accordance with this policy;
- key financial or investor relations employees as designated by the CFO; and
- all such other individuals as designated by the CFO.

This pre-clearance requirement applies regardless of whether (i) the individual subject to pre- clearance possesses material nonpublic information regarding the Company or its securities or
(ii) the trade occurs during a Window Period.

A request for pre-clearance must be submitted to the CFO, or the Chief Executive Officer in the case of requests for pre-clearance made by the CFO, at least two business days prior to consummation of an intended transaction. Notice may be given orally or in writing and should include in the request (i) the transaction type, (ii) the number and type of securities he or she intends to trade, (iii) the intended transaction date, (iv) a confirmation that he or she has reviewed this policy and (v) a confirmation that he or she is not aware of any material nonpublic information about the Company or its securities. Approval or denial of the pre- clearance request will be provided to the insider in writing.

If a proposed transaction receives pre-clearance, the pre-cleared trade must be effected by the close of business on the second business day following receipt of pre-clearance unless (i) the insider becomes aware of material nonpublic information or (ii) the insider is advised by the Company that the pre-clearance has been revoked prior to that time. In the case of either (i) or (ii), the trade must not be completed. For example, if the pre-clearance were issued on a Friday, it would generally be effective through the close of business on the next Tuesday. If the transaction order is not placed within this time period, clearance of the transaction must be re-requested. Notice of a pre-cleared transaction must be provided by the applicable insider to the CFO on the same date of execution. Please note that the date of execution is the trade date and not the settlement date.

## VIII. SECTION 16 POLICY

Covered persons who are Company directors and officers subject to Section 16 of the Exchange Act must follow the additional policies and procedures set forth in Annex A to this policy.

## IX. INQUIRIES

Any person who has a question about this policy or its application to any proposed transaction may obtain additional guidance from the CFO, who can be reached by e-mail at [****]@humacyte.com.

Amended on March 16, 2023.

## ANNEX A

## ADDITIONAL POLICIES AND PROCEDURES ON TRADING HUMACYTE SECURITIES BY COMPANY DIRECTORS AND OFFICERS

### I. INTRODUCTION

Humacyte, Inc. ("Humacyte" or the "Company") has adopted the following policies and procedures with respect to trading in Humacyte securities by the Company's directors and officers. These policies and procedures supplement the Humacyte Insider Trading Policy and are designed to help directors and officers comply with the requirements of Section 16 of the Securities Exchange Act of 1934 (the "Exchange Act").

All persons subject to this policy are responsible for reading these policies and procedures and complying with them. You should direct any questions about the application of these policies and procedures or requests for exceptions, to the Chief Financial Officer ("CFO"). Although the CFO generally is responsible for the implementation of these policies and procedures, the CFO may designate employees to carry out any of the duties described below.

### II. PERSONS AFFECTED

This policy applies to Humacyte's directors and officers. Humacyte's board of directors has designated "officers" for purposes of Section 16, each of whom will be subject to the reporting requirements and "short-swing" profit provisions of Section 16 discussed below. If you are a director of Humacyte or have been designated as an "officer" of Humacyte for the purposes of Section 16, you should read this Annex carefully.

### III. REPORTING AND OTHER TRADING RESTRICTIONS UNDER FEDERAL SECURITIES LAWS

#### A. Section 16(a) Reporting Requirements

Section 16(a) of the Exchange Act requires that Humacyte's insiders file electronic beneficial ownership reports in connection with their purchases and sales of the Company's securities. Securities and Exchange Commission ("SEC") rules require that all filings be made with the SEC electronically and on Humacyte's website. Further, Humacyte is required to disclose in its annual proxy statement the names of all insiders who have failed to timely file all required Section 16(a) reports.

##### 1. Form 3

An insider must file a Form 3 (entitled "Initial Statement of Beneficial Ownership of Securities") with the SEC to report that he or she is an insider and his or her ownership interests in Humacyte. Anyone becoming an insider in the future must file a Form 3 within ten days of becoming an insider.

**2. Forms 4 and 5**

An insider must file a Form 4 (entitled "Statement of Changes in Beneficial Ownership") with the SEC to report a transaction within two business days after the date of such transaction if it results in a change in his or her beneficial ownership of Humacyte's equity securities. There are three general exceptions to the two-business-day reporting requirement.

First, the following types of transactions may be reported on a Form 4 within two business days following the date the insider receives *notice of the transaction* (but in no event later than five business days following the transaction), rather than two business days following the date on which the transaction occurs:

- a transaction pursuant to a Rule 10b5-1 plan under which the insider does not select the date on which the purchases or sales take place; and

- a "discretionary transaction" (as defined in Rule 16b-3) pursuant to an employee benefit plan for which the insider does not select the date on which transactions take place (such as transfers in or out of, or cash withdrawals from, a company stock fund in a 401(k) plan or other employee benefit plan).

Second, certain transactions may, and in a few instances must, be reported on a year- end Form 5 (entitled "Annual Statement of Changes in Beneficial Ownership of Securities"). A Form 5 must be filed with the SEC within 45 days after the end of such fiscal year by each person who was an insider for any part of a company's fiscal year (unless he or she has no transactions to report on the Form 5). There are certain limited types of stock transactions that the SEC has designated as eligible for Form 5 filing (rather than a Form 4 filing). Insiders also must report on a Form 5 all transactions that occurred during the fiscal year that should have been, but were not, reported earlier on Form 4.

Third, the following types of transactions do not trigger any Form 4 or Form 5 filing requirement:

- an acquisition under an employee stock purchase plan;

- a transaction (other than a "discretionary transaction") under certain employee benefit plans, such as pension plans, 401(k) plans, or related excess benefit plans;

- an acquisition through a stock split, stock dividend or other pro rata distribution to stockholders of the Company;

- an acquisition under certain dividend or interest reinvestment plans; and

- an acquisition or disposition as a result of a domestic relations orders (such as a divorce decree).

Although these transactions do not require the filing of a Form 4 or Form 5, the next Form 4 or Form 5 filed after the occurrence of one of these transactions should reflect the effects of these transactions in the column reporting post-transaction security ownership.

### 3. Preparation of Forms 3, 4 and 5

Although the responsibility for the timely filing of reports and compliance with trading restrictions rests with each individual required to report or comply, the CFO will prepare and file Forms 3, 4, and 5 on behalf of insiders who are Company directors and officers. All Forms 3, 4, and 5 prepared on behalf of an insider will be based on information provided by the insider. Accordingly, all insiders must fill out and deliver to the CFO a Form ID (a form to obtain access codes to file on the SEC's electronic filing system).

## B. Section 16(b) Short-Swing Profit Liability

Section 16(b) of the Exchange Act allows the Company to recover any profit realized by one of its insiders resulting from any combination of purchases and sales of Humacyte's equity securities within a period of less than six months. Such liability arises without regard to whether any such transactions occur during the Window Period referred to above. Profits are determined for this purpose by matching the highest sales price during the period with the lowest purchase price and are to be recovered even though the insider realized no actual profit for the period or he or she sustained a net loss. Although the purpose of the statute is to prevent trading on the basis of material nonpublic information, the recovery provision operates without regard to the intent of the insider or the actual possession of material nonpublic information and may not be waived by the Company.

The restrictions on "short-swing" trading apply not only to trading in Humacyte's securities but also to any "derivative security." Thus, for example, a grant or exercise of options (other than grants or exercises made under a plan that is exempt from Section 16) would be considered to be a "purchase" or sales of Humacyte securities under Section 16. Other transactions not necessarily thought to involve purchases, such as corporate mergers, also may be covered. The SEC has exempted certain transactions, such as purchases under employee benefit plans that have been approved by stockholders or the board of directors, from the "short-swing" profit recovery provisions of Section 16 (but not the reporting provisions).
Directors and officers remain subject to these Section 16 requirements and restrictions for a period of up to six months after terminating their positions with Humacyte.

**Exhibit 21.1**

Subsidiaries of Humacyte, Inc.

Humacyte Global, Inc.
Humacyte Europe Limited

**Exhibit 23.1**

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (Nos. 333-272550, 333-267225 and 333-267222) and Form S-8 (Nos. 333-278296 and 333-260561) of Humacyte, Inc. of our report dated March 31, 2025 relating to the financial statements, which appears in this Form 10-K.

/s/ PricewaterhouseCoopers LLP
Raleigh, North Carolina
March 31, 2025

**Exhibit 31.1**

**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 31, 2025

By: /s/ Laura E. Niklason

Name: Laura E. Niklason, M.D., Ph.D.

Title: President and Chief Executive Officer

**Exhibit 31.2**

**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 31, 2025

By: /s/ Dale A. Sander

Name: Dale A. Sander

Title: Chief Financial Officer, Chief Corporate Development Officer and Treasurer

**Exhibit 32.1**

**CERTIFICATION**

In connection with the Annual Report on Form 10-K of Humacyte, Inc. (the "Company") for the fiscal year ended December 31, 2024 (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 31, 2025

By: /s/ Laura E. Niklason

Name: Laura E. Niklason, M.D., Ph.D.

Title: President and Chief Executive Officer

**Exhibit 32.2**

**CERTIFICATION**

In connection with the Annual Report on Form 10-K of Humacyte, Inc. (the "Company") for the fiscal year ended December 31, 2024 (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 31, 2025

By: /s/ Dale A. Sander

Name: Dale A. Sander

Title: Chief Financial Officer, Chief Corporate Development Officer and Treasurer