Risk Factors Comparison 2024-03-28 to 2023-03-24 Form: 10-K

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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** ~~common stock~~. You should carefully consider the risks described below, together with all of the other information included in this Annual Report on Form 10- K. The risks and uncertainties described below are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently believe to be immaterial may also adversely affect our business. In that event, the trading price of our **securities** ~~common stock~~ could decline and you could lose all or part of your investment. Summary of Risk Factors The following is a summary of the principal risks to which our business, operations and financial performance are subject. Each of these risks is more fully described in the individual risk factors immediately following this summary. • We have never generated product revenue and have incurred significant losses to date. We expect to continue to incur losses for the foreseeable future and may never generate product revenue or be profitable. We will need to raise additional capital to finance our operations, which we may not be able to do on acceptable terms or at all. • If our clinical trials fail to demonstrate safety and efficacy to the satisfaction of the FDA or similar regulatory authorities outside the United States or do not otherwise produce favorable results, we may incur significant additional costs or experience significant delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates. • Our near- term prospects are dependent on the success of our 6 millimeter HAV, and if we are unable to successfully develop and commercialize it, our business, operating results and financial condition will be materially harmed. • We may experience delays or difficulties in the enrollment of patients in our clinical trials, which may delay or prevent additional clinical trials and our receipt of necessary marketing approvals. • Lack of experience by investigators and surgeons with our HAVs can lead to incorrect implantation or follow- up procedures which could harm the results of our clinical trials and market acceptance of our HAVs, if approved. • We may not be successful in our efforts to use our proprietary scientific technology platform to build a pipeline of additional product candidates. • Even if our HAVs receive marketing approval in the future for one or more of our product candidates, they may fail to achieve the degree of market acceptance by physicians, patients, third- party payors and others in the medical community necessary for commercial success. • The sizes of the market opportunities for our product candidates have not been established with precision and are estimates that management believes to be reasonable. If these market opportunities are smaller than we estimate or if any approval that we obtain is based on a narrower definition of the relevant patient population, our revenue and ability to achieve profitability might be materially and adversely affected. • Our distribution agreement with Fresenius Medical Care imposes obligations on us that may restrict our ability to operate our business in ways we believe to be in our long- term best interest. • If we receive approval for a product candidate that is not subject to our distribution agreement with Fresenius Medical Care, and we are unable to establish our own marketing, sales and distribution capabilities or are unable to enter into agreements with third parties do so, we may not be able to generate product revenue and will have to alter our development and commercialization plans. • The ~~ongoing effects of the COVID- 19 pandemic may continue to adversely impact our business, including our manufacturing efforts and clinical trials. • The~~ manufacture of our product candidates is complex, we have not manufactured commercial product, and we may encounter difficulties in production. If we or any third- party manufacturer encounter such difficulties, our ability to supply our product candidates for clinical trials or, if approved, for commercial sale could be delayed or halted entirely. • The terms of ~~our existing indebtedness~~ **the Purchase Agreement** may limit our ability to incur future debt. • We rely on third parties to conduct and support our clinical trials, and those third parties may not perform satisfactorily, including by failing to adhere to regulatory requirements or our stated protocols or to meet deadlines for the completion of such trials. • We rely on third- party suppliers, including sole source suppliers, to provide certain components for our product candidates. Any failure by a third- party supplier to supply these components for manufacture may delay or impair our ability to complete our clinical trials and to commercialize our product candidates. • We intend to rely on our strategic, global partnership with Fresenius Medical Care to undertake, or assist with, the marketing, sale and distribution of certain of our product candidates in certain markets if we receive marketing approval from relevant regulatory authorities. Disruption of this arrangement could materially adversely affect our business, prospects, operating results and financial condition. • Our ability to successfully commercialize our products may be impaired if we are unable to obtain and maintain effective intellectual property rights for our proprietary scientific technology platform and product candidates. • We may be required to take write- downs or write- offs, restructuring and impairment or other charges that could have a significant negative effect on our financial condition, results of operations and stock price, which could cause you to lose some or all of your investment. Risks Related to the Development and Commercialization of Our Product Candidates If our clinical trials **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 ~~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 **, 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, 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, no products based on HAVs have been approved in the United States **,** ~~or in~~ 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** , ~~and we~~ **because of the nature of the HAVs,** ~~may~~ **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 ~~succeed~~ **successful, we be delayed** in obtaining marketing approval ~~even if we view our~~ - **or** ~~clinical trials as successful. Data obtained from preclinical and clinical activities, and manufacturing comparability studies, are also subject to varying interpretations, which~~ may **not receive** ~~delay, limit or prevent~~ marketing approval **at all** . ~~In such circumstances, we could experience significant delays, or~~ **For example** ~~be prevented from~~ , ~~developing or~~ **our** ~~commercializing our HAVs, and our business, prospects, operating results and financial condition could be materially harmed. Our~~ V006 trial did not meet its primary endpoint, ~~and if~~ **which has delayed development of the HAV 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~~ **even** if we receive FDA approval for our HAVs, we may face a number of difficulties if the results of our clinical trials are unfavorable, inconclusive, or only modestly favorable or if there are safety concerns, such as adverse events (" AEs ") or ~~serious adverse events (" SAEs ")~~ , which could include clotting, mechanical failure, immunological rejection or infection, that could outweigh potential benefits associated with such product candidates. This could result in: • obtaining approval for indications or patient populations that are not as broad as intended or desired; • obtaining approval with, or later becoming subject to, labelling that includes significant use or distribution restrictions or significant safety warnings; • being subject to a REMS or equivalent requirement from a comparable foreign regulatory agency, to ensure that the benefits of a biological product outweigh its risks or to change the way the product is used; • being required to perform additional clinical trials to support approval or comparability or being subject to additional post- marketing testing requirements; • having regulatory authorities withdraw their approval of the product; • being sued; or • suffering damage to our reputation. Any of these events could cause us to incur significant additional costs, significant delays and prevent us from achieving or maintaining market acceptance of or commercializing one or more of our product candidates. ~~If we experience failures or delays in our preclinical and clinical programs, we would be prevented from developing and commercializing our product candidates in a timely matter, if at all. A number of factors impact the timing of our preclinical and clinical programs and the development and commercialization of our product candidates. We cannot guarantee that any clinical trials will be conducted as planned or completed on schedule, if at all. Events that prevent successful or timely completion of the development of our product candidates beyond unfavorable or inconclusive clinical trial results include, among others, the following: • delays in the testing, validation, manufacturing or delivery of our product candidates to the clinical sites; • delays in reaching — or inability to reach — agreement with the FDA or other regulatory agencies on trial design; • delays in reaching agreement on acceptable terms with prospective clinical research organizations (" CROs ") and clinical trial sites; • delays in obtaining required IRB approval at each clinical trial site; • delays in recruiting suitable patients in sufficient volume to participate in our clinical trials and in having those patients complete participation in our clinical trials or return for follow- up, including delays related to the ongoing effects of the COVID- 19 pandemic; • the occurrence of SAEs associated with any of our product candidates that are viewed to outweigh their potential benefits; • imposition of a clinical hold by regulatory agencies, including after an inspection of our clinical trial sites; • failure by CROs, other third parties or us to adhere to clinical trial requirements; • failure to perform in accordance with the FDA' s good clinical practices (" GCP ") or current good tissue practices (" cGTP "), or applicable regulatory guidelines in other countries; • clinical trial sites dropping out of, or being removed from, a trial; or • changes in regulatory requirements and guidance that require amending or submitting new clinical protocols or data. Any inability to successfully complete development of our product candidates would likely result in significant additional costs to us, create delays in filing a BLA for regulatory approval of our product candidates and impair our ability to generate revenue. Clinical trial delays could also allow our competitors to bring products to market before we do, which could materially impair our ability to successfully commercialize our product candidates and may harm our business and prospects.~~ Our progress in early stage clinical trials may not be indicative of long-

term efficacy in late stage clinical trials, and our progress in trials for one product candidate may not be indicative of progress in trials for another product candidate. The product candidates in our pipeline are at various stages of development. Trial designs and results from previous studies are not necessarily predictive of our future clinical trial designs or results, and initial results of ongoing trials may not be confirmed upon full analysis of the complete trial data. A number of companies in the biotechnology industry have suffered significant setbacks in late- stage clinical trials even after achieving promising results in earlier stage clinical trials, and we may experience similar setbacks. Favorable results in clinical trials for one of our product candidates also do not necessarily indicate that we will obtain positive results in clinical trials related to other product candidates. The novelty of our proprietary scientific technology platform adds another layer of risk that early- stage clinical trials may not be indicative of long- term efficacy in our late- stage clinical trials. If we are unable to demonstrate favorable results in future clinical trials for our various product candidates, we expect that our business, prospects, operating results and financial condition will be materially adversely affected. Additionally, several of our past, planned and ongoing clinical trials utilize an " open- label " trial design. An " open- label " clinical trial is one where both the patient and investigator know whether the patient is receiving the investigational product candidate. Some open- label clinical trials test only the investigational product candidate without a comparator. Open- label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open- label clinical trials are aware when they are receiving treatment. Open- label clinical trials may be subject to a " patient bias " where patients perceive their symptoms to have improved merely due to their awareness of receiving an experimental treatment. In addition, open- label clinical trials may be subject to an " investigator bias " where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. The results from an open- label trial may not be predictive of future clinical trial results with any of our product candidates when studied in an environment with an active control. Interim, " topline, " and preliminary data from our clinical trials that we announce or publish from time to time may change as more patient data become available and are subject to audit and verification procedures that could result in material changes in the final data. From time to time, we may publicly disclose preliminary or topline data from our clinical trials, which is based on a preliminary analysis of then- available data, and the results and related findings and conclusions are subject to change following a more comprehensive review of the data related to the particular study or trial. We also make assumptions, estimations, calculations and conclusions as part of our analyses of data, although we may not have received or had the opportunity to fully and carefully evaluate all data at the time such preliminary or topline results are released. As a result, the topline or preliminary results that we report may differ from future results of the same studies, or different conclusions or considerations may qualify such results, once additional data have been received and fully evaluated. Topline data also remain subject to audit and verification procedures that may result in the final data being materially different from the preliminary data we previously published. As a result, topline data should be viewed with caution until the final data are available. From time to time, we may also disclose interim data from our clinical trials. Interim data from clinical trials that we may complete are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available, or as patients from our clinical trials continue other treatments for their disease. Adverse differences between preliminary or interim data and final data could significantly harm our business prospects. ~~If the interim, topline, or preliminary data that we report differ from actual results, or if others, including regulatory authorities, disagree with the conclusions reached, our ability to obtain approval for, and commercialize, our product candidates may be harmed, which could harm our business, operating results, prospects or financial condition.~~ In addition, the information we choose to publicly disclose regarding a particular clinical trial is based on what is typically extensive information, and you or others may not agree with what we determine is material or otherwise appropriate information to include in our disclosure. If SAEs occur at an unacceptable rate or other unacceptable side effects are identified in our HAVs we may need to delay, abandon or limit development and marketing of our product candidates. Our HAVs may prove to have undesirable or unintended side effects, toxicities or other characteristics that may preclude us from obtaining marketing approval. ~~The reported SAEs related to the HAV for hemodialysis access, a patient population which typically has a high prevalence of existing medical conditions, are detailed in the table below which summarizes results from our V006 HUMANITY Phase 3 study in which subjects were randomized to receive either a HAV or a commercially available expanded polytetrafluoroethylene (" ePTFE ") graft. SAEs Reported in V006 Phase 3 Clinical Study in AV Access Number of SAEs (% of total subjects) Description of SAEHAVePTFENumber of subjects in V006 study177 178 General disorders and administration conditions: Implant site extravasation0 (0. 0) % 1 (0. 6) % Infections and infestationsVascular access site infection0 (0. 0) % 5 (2. 8) % Injury, poisoning and procedural complications: Anastomotic stenosis1 (0. 6) % (0. 0) % Description of SAENumber of SAEs (% of total subjects) HAVePTFEVascular access site hematomas1 (0. 6) % (0. 0) % Vascular access site hemorrhage0 (0. 0) % 3 (1. 7) % Vascular access site pain1 (0. 6) % 0 (0. 0) % Vascular access site pseudoaneurysm10 (5. 6) % 0 (0. 0) % Vascular access site rupture2 (1. 1) % 0 (0. 0) % Vascular access site thrombosis41 (23. 2) % 28 (15. 7) % Skin and subcutaneous tissue disorders: Skin necrosis0 (0. 0) % 1 (0. 6) % Vascular disorders: Steal syndrome2 (1. 1) % 2 (1. 1) % Subclavian vein occlusion0 (0. 0) % 1 (0. 6) % Vascular stenosis34 (19. 2) % 27 (15. 2) % Venous stenosis3 (1. 7) % 9 (0. 0) % In our V002 and V004 Phase 2 clinical studies in PAD in 35 subjects, another patient population which typically has a high prevalence of existing medical conditions, the SAEs reported for the HAV are detailed in the table below. SAEs Reported in V002 and V004 Phase 2 Clinical Studies in PAD Description of SAENumber of SAEs (% of total subjects) Number of subjects in V002 and V004 studiesN = 35Arterial bypass thrombosis3 (8) % Anastomotic stenosis1 (3) % Graft thrombosis2 (6) % Vascular graft complication1 (3) %~~ If our HAVs are associated with undesirable side effects in clinical trials or have negative characteristics that are unexpected, we may need to perform additional clinical trials, abandon their development or limit development to more narrow uses or subpopulations in which the undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk- benefit perspective. Even if one of our product candidates is approved, the FDA and other regulatory authorities

may **limit** ~~take action to withdraw it from~~ the ~~market if~~ **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, if approved, marketing of our product candidates. **For more information, see the section of this Annual Report on Form 10- K titled " Business."** We are currently enrolling patients in several clinical trials, including in our **V012** ~~V005 trial, which is a Phase 2 / 3 clinical trial of our 6 millimeter HAV in traumatic vascular repair and our V007~~ trial, which is a Phase 3 clinical trial comparing the safety and efficacy of our 6 millimeter HAV 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 ~~. Additionally, the COVID- 19 pandemic has had and may continue to have a sustained impact on our ability to recruit and follow up with patients~~ . We may not be able to initiate or continue clinical trials for our product candidates if we are unable to locate and enroll a sufficient number of eligible patients to participate in these trials as required by the FDA and other regulatory authorities, and as such our product candidates could be delayed or otherwise adversely affected. Patient enrollment and trial completion is affected by many factors including the: • size of the patient population and process for identifying subjects; • availability of clinical trial research resources at clinical sites due to ongoing effects of the COVID- 19 pandemic; • 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 ongoing impact of the COVID- 19 pandemic or future pandemics or similar events on patients' willingness and ability to participate in clinical trials or on study site policies; • ability to obtain and maintain subject consent; • risk that enrolled subjects will drop out before completion of the trial; • patient referral practices of physicians; and • ability to monitor subjects adequately during and after treatment. If we have difficulty enrolling a sufficient number of patients to conduct our clinical trials as planned, we may need to delay, limit or terminate ongoing or planned clinical trials, any of which would have an adverse effect on our business, financial condition, results of operations and prospects. Our HAVs are currently in various stages of preclinical and clinical testing ~~and have not been widely used~~ . We do not have the personnel capacity to directly conduct or manage all of the clinical trials that are necessary for the development of our HAVs. Therefore, we rely, and will continue to rely, on third parties to assist us in managing, monitoring and conducting our clinical trials. Some of the investigators in our clinical trials have not been, and, if our HAVs receive marketing approval, surgeons may not be, previously exposed to the implantation and follow- up procedures related to their use. As a result, our HAVs may be, and have been in the past, incorrectly implanted and follow- up procedures may be performed incorrectly, resulting in ~~violations of our trial protocols,~~ increased interventions or failure of the HAV **, and complicating interpretation of clinical trial results** . Our efforts to educate investigators, surgeons and interventionalists regarding the proper techniques for use of our HAVs both during clinical trials and following potential commercialization may be costly, prove unsuccessful and could materially harm our ability to continue the clinical trials or **commence** marketing of our HAVs. Regulatory authorities may also seek to impose restrictive labeling or proactive communication obligations on any marketing approval granted for use of our HAVs as a result, which could reduce market acceptance of any of our HAVs that receive marketing approval. We currently have no products approved for sale and, while we are developing a number of product candidates, we have invested and continue to invest a substantial portion of our efforts and financial resources in the development of our 6 millimeter HAV. None of our remaining product geometries and modifications have advanced beyond preclinical development. As a result, in the near term we are dependent on the success of our 6 millimeter HAV, and if we are unable to successfully develop, obtain marketing approval for, and commercialize it, our business, along with our operating results and financial condition, will be materially harmed. Even if we succeed with the development of our 6 millimeter HAV, our ability to generate product revenue and become profitable from our 6 millimeter HAV depends on our assumptions regarding the relevant market opportunity and the degree of market acceptance for our products, once approved, for which our estimates may prove inaccurate, and market acceptance in any approved indication, which may never occur. A key element of our strategy is to use our proprietary scientific technology platform to expand our pipeline of HAVs and to progress other product candidates into and through clinical development. We may not be able to identify or develop future product candidates that are safe and effective. Even if we are successful in building our pipeline, the potential product candidates that we identify may not be suitable for clinical development, including if they have harmful side effects or other characteristics that render them unlikely to receive marketing approval or achieve market acceptance. Research programs to identify new product candidates require substantial technical, financial and human resources, and we may focus our efforts and resources on potential programs or product candidates that ultimately prove to be unsuccessful. If we do not successfully develop and commercialize additional product candidates based upon our technology, we may have difficulty generating product revenue in the future, which could result in significant harm to our business, prospects, operating results and financial condition and adversely affect our stock price. Even with the requisite approvals from the FDA in the United States, the European Commission in the EU and other regulatory authorities internationally, the commercial success of our HAVs will depend, in part, on the acceptance of physicians, patients and health care payors, as medically necessary, cost- effective and safe. Any product that we commercialize may not gain acceptance by physicians, patients, health care payors and others in the medical community due to ethical, social, medical and legal concerns. If these products do not achieve an adequate level of acceptance, we may not generate significant product revenue and may not become profitable. The degree of market acceptance of any of our product candidates that receives marketing approval will depend on a number of factors, including: • the efficacy and potential advantages of our product candidates compared with alternative products or methods, including convenience and ease of administration; • the prices we charge for our products, if approved; •

the availability of third- party coverage and adequate reimbursement; • the willingness of the target patient population to try new products and methods and of physicians to use these products and methods; • the quality of our relationships with patient advocacy groups; • the strength of marketing and distribution support; • the availability of the product and our ability to meet market demand; • the prevalence and severity of any side effects; and • any restrictions on the use of our products, if approved. Our estimates of the market opportunity for certain of our product candidates are based on a number of internal and third- party estimates. While we believe our assumptions and the data underlying these estimates are reasonable, they may be inaccurate or based on imprecise data. In addition, the assumptions and conditions underlying the estimates may change at any time. For example, the number of patients who ultimately use our product candidates, if approved by regulatory authorities, and our total market opportunities for such product candidates, will depend on, among other things, pricing and reimbursement, market acceptance of those product candidates and patient access, and may be lower than we estimate. Additionally, any approval we receive for our product candidates may be based on a narrower definition of the relevant patient population than we have estimated. Either of these circumstances could materially harm our business, financial condition, results of operations and prospects. We face and will continue to face substantial competition, which may result in others discovering, developing or commercializing competing products before or more successfully than we do, which may adversely affect our ability to successfully market or commercialize our HAVs. The development and commercialization of new biological products is highly competitive and subject to rapid change and technological advancements. If approved, we expect our HAVs would compete with the use of a patient' s own blood vessels, as well as a variety of marketed products, such as conventional synthetic grafts, xenografts, and allografts, as well as developing technologies. We expect to face competition with respect to any additional product candidates that we may seek to develop or commercialize in the future from a variety of sources, including major pharmaceutical companies, specialty pharmaceutical companies and biotechnology companies, hospital product- focused companies, as well as public and private universities and research organizations. Many of our existing or potential competitors, either alone or with their strategic partners, have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining marketing approvals and marketing 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 result in our competitors establishing a strong market position before we are able to enter the market. We plan to seek marketing approval for our HAVs in the United States as a biologic and in the EU as a medicinal product. In both the United States and the EU, our competitors may try to market vascular conduits similar to our product candidates as medical devices. Such competitive products could have comparable characteristics and could function similarly in the body (and could even be protein- based like our product candidates). Companies may be able to obtain marketing approval for such products on the basis of less data than the data required for a BLA and marketing similar products as devices could permit our competitors to circumvent regulatory exclusivity for biologics in the United States and medicinal products in the EU. We expect to rely on our strategic, global relationship with Fresenius Medical Care for the development and commercialization of certain of our product candidates. As discussed in more detail in the section of this Annual Report on Form 10- K titled " Business — Distribution — Distribution Agreement with Fresenius Medical Care, " Fresenius Medical Care will have the exclusive right to develop outside of the United States and EU and commercialize outside of the United States, among other things, our 6 millimeter x 42 centimeter HAV and all improvements thereto, and modifications and derivatives thereof (including any changes to the length, diameter, or configuration of the foregoing), which we refer to as the distribution product, for use in vascular creation, repair, replacement or construction (including renal replacement therapy for dialysis access, the treatment of vascular trauma, and the treatment of PAD, but excluding coronary artery bypass graft, pediatric heart surgery, or adhering pancreatic islet cells onto the outer surface of the distribution product for use in diabetic patients). We refer to these indications wherein Fresenius Medical Care has rights to develop and commercialize Humacyte' s products as the field. The distribution agreement also imposes a number of restrictions on our business. For instance, outside the United States, the distribution agreement restricts our ability to engage a distributor for the distribution product outside the field or for HAV products other than the distribution product: we have granted Fresenius Medical Care (i) an exclusive right of first negotiation for exclusive distribution rights outside the United States for the distribution product for use outside the field, and (ii) an exclusive right of first negotiation for exclusive distribution rights outside the United States for our other HAV products, if any, subject, in each case, to certain conditions. These and other obligations may restrict our ability to operate our business in ways we believe are in our long- term best interest, which could harm our business and our prospects. We currently have limited internal marketing, sales or distribution capabilities, and our management team has limited experience commercializing products following marketing approval. If one of our product candidates that is not subject to the distribution agreement with Fresenius Medical Care receives marketing approval, we will be required either to develop these capabilities internally or to make arrangements with third parties for the marketing, sales and distribution of the relevant product candidate. The establishment and development of our own marketing, sales and distribution functions will be expensive and time- consuming and may delay any product launch, and we may ultimately be unable to successfully develop the product candidate. In addition, or in the alternative, we could seek one or more partners to handle some or all of the marketing, sales and distribution activities associated with any such product candidate. However, we may face

significant competition in seeking appropriate strategic partners, and the negotiation process is time consuming and complex. Therefore, we may not be able to enter into arrangements with third parties to do so on favorable terms or at all. In the event we are unable to develop our own marketing, sales and distribution functions or collaborate with a third- party organization for this purpose, we may not be able to successfully commercialize a product candidate that is not subject to the distribution agreement with Fresenius Medical Care, which would adversely affect our ability to generate revenue. Further, whether we commercialize any such product candidate on our own or rely on a third party to do so, our ability to generate revenue will be dependent on the effectiveness of the organization performing these functions. Even if we receive marketing approval for our HAVs, there is uncertainty with respect to third- party coverage and reimbursement of our HAVs. They may also be subject to unfavorable pricing regulations, third- party reimbursement practices or healthcare reform initiatives, any of which could harm our business, prospects, operating results and financial condition. There is uncertainty around third- party coverage and reimbursement of newly approved regenerative medicine type products, even those with the RMAT designation from FDA, such as our 6 millimeter HAV for **urgent arterial repair following extremity vascular trauma, which received the RMAT designation in 2023, and our 6 millimeter HAV for** AV access for performing hemodialysis, which received the RMAT designation in 2017. In the United States, third- party payors, including government payors such as the Medicare and Medicaid programs, play an important role in determining the extent to which medical products and biologics will be covered and reimbursed. The Medicare and Medicaid programs increasingly are used as models for how private payors and government payors develop their coverage and reimbursement policies. Currently, no RMAT tissue engineered product has established coverage and reimbursement by the CMS. Even if our HAVs receive approval from regulatory authorities, it is difficult to predict what CMS or any comparable foreign regulatory agency will decide with respect to coverage and reimbursement for novel products such as ours, as there is no body of established practices and precedents for these types of products. The healthcare industry is acutely focused on cost containment, both in the United States and elsewhere. Government authorities and third- party payors have attempted to control costs by limiting coverage and the amount of reimbursement. These payors may not view our products, if any, as cost- effective, and coverage and reimbursement may not be available to our customers or may not be sufficient to allow our products, if any, to be marketed on a competitive basis. Cost- control initiatives could also cause us to decrease any price we might establish for products, which could result in lower than anticipated product revenue. Moreover, eligibility for reimbursement does not imply that any product will be paid for in all cases or at a rate that covers our costs, including our costs related to research, development, manufacture, sale and distribution. Reimbursement rates may vary, by way of example, according to the use of the product and the clinical setting in which it is used. If the prices for our products, if any, decrease or if governmental and other third- party payors do not provide adequate coverage or reimbursement, our business, prospects, operating results and financial condition will suffer, perhaps materially. 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 our product candidates be approved and covered by Medicare Part B or Part D, and fail to fall within a statutory exclusion, such as that for an orphan drug, those 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 increased the cost of a covered Medicare Part B or Part D approved product 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 our HAVs and any other product candidates that we develop in the future. We face an inherent risk of product liability exposure related to the testing of our product candidates in human clinical trials and will face an even greater risk, if and when we commercially sell our HAVs and any other product

candidates that we may develop. If we cannot successfully defend ourselves against claims that our product candidates or products caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in: • decreased demand for any product candidates or products that we develop or sell, leading to loss of revenue; • injury to our reputation and significant negative media attention; • withdrawal, or slower enrollment, of clinical trial participants; • significant costs to defend the related litigation and reduced resources of our management to pursue our business strategy; • substantial monetary awards to trial participants or patients; and • inability to further develop or commercialize our product candidates. We currently hold limited product liability insurance coverage, and it may not be adequate to cover all liabilities that we may incur. We also may not be able to maintain insurance coverage at a reasonable cost or in an amount adequate to satisfy any liability that may arise. ~~The ongoing effects of the COVID- 19 pandemic has impacted our business and we expect it to continue to do so. We have experienced delays in the ongoing enrollment of our clinical trials as a result of COVID- 19. If there is a resurgence of COVID- 19 in the United States and elsewhere, we may experience disruptions that could severely impact our business and clinical trials, including: • further delays or difficulties in enrolling patients in our clinical trials; • delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff; • delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials, including interruption in global shipping that may affect the transport of clinical trial materials; • shortages of clinical trial site and hospital and clinic staff supporting the conduct of our clinical trials; • risk that participants enrolled in our clinical trials will acquire COVID- 19 while the clinical trial is ongoing, or will withdraw from the clinical trial due to concerns over COVID- 19, which could impact the results of the clinical trial, including by increasing the number of observed adverse events, or reducing the statistical power of the clinical trials; • delays in necessary interactions with regulators, ethics committees and other important agencies and contractors due to limitations in employee resources; • changes to the clinical endpoints, statistical analysis plan, or enrollment plans for ongoing clinical trials due to limitations in patients, resources, or sites, including due to COVID- 19; and • unanticipated deaths of clinical trial patients due to COVID- 19 or due to lack of healthcare resources and follow- up as a consequence of COVID- 19. The extent to which ongoing effects of the COVID- 19 pandemic impacts our business and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence.~~ Risks Related to Manufacturing Our Product Candidates The **manufacture of our product candidates is complex, we have not manufactured commercial product, and we 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 our product candidates for clinical trials or, if approved, for commercial sale could be delayed or halted entirely. The** process of manufacturing our HAVs is complex, highly regulated and subject to multiple risks. The manufacture of biologics such as our HAVs has been, and continues to be, susceptible to product loss due to **a range of factors including** 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 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, product defects and other supply disruptions. If microbial, viral or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, ~~such~~ manufacturing ~~facilities~~ may ~~need to~~ be ~~closed~~ **delayed** 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 of our master cell banks would result in significant disruptions to that process. We currently manufacture the 6 millimeter HAVs for our clinical trials at our manufacturing facility in Durham, North Carolina, where we have created a scalable modular manufacturing process, which we refer to as the LUNA200 system, that we believe will enable us to manufacture our HAVs, if approved, in commercial quantities in compliance with ~~current good manufacturing practices (“~~ cGMPs ~~”)~~. Our efforts to scale out our manufacturing operations may not succeed. Scaling out a biologic manufacturing process is a difficult task, as there are risks including, among others, cost overruns, process reproducibility, stability issues, lot consistency and timely availability of raw materials ~~. Prior to the establishment of our internal manufacturing facility, we employed a contract manufacturer who produced our HAVs using a smaller- production system known as the AURA system~~ . We have limited years of experience manufacturing our HAVs in- house with the LUNA200 system, and no experience manufacturing the volume that we anticipate will be required to supply all of our clinical trials or to achieve planned levels of commercial sales following marketing approval, if received. Additionally, our manufacturing process has evolved over time and we may not have the experience, resources, or facility capacity to handle adoption of future changes or expansion of capacity. The forecasts of demand we plan to use to determine order quantities and lead times for components from outside suppliers may be incorrect, and we may be unable to obtain such components when needed and at a reasonable cost. We also ~~may~~ **have** ~~experience~~ **experienced** interruptions in the supply of the raw materials required to manufacture our product candidates, ~~or~~ **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 clinical trial materials, such as our HAVs and other supplies used in our clinical trials, which would negatively impact our ability to conduct our clinical trials. In addition, we may not be able to develop and implement efficient manufacturing capabilities and processes to manufacture our HAVs in sufficient volumes that also satisfy the legal, regulatory, quality, price, durability, engineering, design and production standards required to commercialize our HAVs successfully. If we are unable to produce sufficient quantities of our HAVs for our clinical trial needs or commercialization ~~due to production system limitations~~ , we may need to make additional changes to our manufacturing processes and procedures. Such changes to our manufacturing platform could trigger the need to conduct additional bridging studies between our prior clinical supply and that of any new manufacturing processes and procedures. Should we experience delays or be unable to produce sufficient quantities of our HAVs utilizing our current or a modified version of our manufacturing system, we expect that our development and commercialization efforts would be impaired as a result, which would likely materially adversely affect our business, prospects,

operating results and financial condition. Manufacturing facilities are subject to significant government regulations and approvals, which are often costly and could result in adverse consequences to our business if we fail to comply with the regulations or maintain the approvals. Our manufacturing facility is subject to ongoing regulation and periodic inspection by the FDA and other regulatory authorities to ensure compliance with cGMPs. Failure to follow and document adherence to such regulations or other regulatory requirements may (i) lead to significant delays in the availability of product for our clinical trials, (ii) result in the termination of or a hold being placed on one or more of our clinical trials, ~~or~~ (iii) **require significant modifications to our manufacturing facility, personnel, and procedures, (iv)** delay or prevent filing or approval of marketing applications for our HAVs ~~. To monitor compliance with applicable regulations~~ , ~~the FDA routinely conducts inspections~~ **(v) result in temporary or permanent closures** of **our manufacturing** facilities **,** and **/** ~~may identify potential deficiencies. For~~ **or (vi)** ~~example, the FDA issues what are referred to as " Form 483s " that set forth observations and concerns that are identified during its inspections. Failure to satisfactorily address the concerns or potential deficiencies identified in a Form 483 could~~ result in ~~the issuance of a warning letter, which is a notice of the issues that the FDA believes to be significant regulatory violations requiring prompt corrective actions. Failure to respond adequately to a warning letter, or to otherwise fail to comply with applicable regulatory requirements could result in enforcement, remedial or punitive actions by the FDA or~~ other ~~regulatory authorities~~ **civil or criminal penalties** . Risks Related to Our Reliance on Third Parties We do not independently conduct clinical trials for our product candidates and instead rely on third parties, such as CROs, clinical data management organizations, medical institutions and clinical investigators, to perform various functions, including implanting our HAVs and monitoring patients. The FDA and other regulatory authorities require us and these third parties to comply with GCP and, where applicable, cGTPs for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of patients in clinical trials are protected; ultimately, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and trial protocol. Failure by us or these third parties to do so could require us to enroll additional trial subjects beyond those we anticipate, could require us to modify our protocol, which may cause us to lose previously established Special Protocol Assessment (" SPA ") agreements with the FDA or similar agreements with other regulatory authorities concerning whether the design and size of our clinical trial adequately addresses scientific and regulatory requirements to support marketing approval, or could materially harm our ability to complete our clinical trials, including as a result of the need to remove trial sites and participants from the trial **, 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 HAVs, intervention rates, insufficient training of personnel, variances in medical infrastructure, lack of familiarity with conducting clinical trials in accordance with international regulatory standards, communication difficulties or changes in local regulations. If these third parties do not successfully conduct our clinical trials in accordance with regulatory requirements or our stated protocols, carry out their contractual duties, or meet expected deadlines, we may not be able to obtain, or may be delayed in obtaining, marketing approvals for our product candidates and may not be able to, or may be delayed in our efforts to, successfully commercialize our products if approved by regulatory authorities. We currently rely, and expect to continue to rely, on third parties for the supply of certain components necessary for our product candidates, such as donor tissue, other biologically derived substances, the PGA polymer mesh and the bioreactor bags in which our HAVs are grown. Our suppliers for certain of these materials, including SeraCare for the supply of human plasma and Confluent for the supply of polymer mesh, are sole source suppliers. Failure of one or more of our suppliers, including these sole source suppliers, to deliver components necessary for the production of our HAVs in a timely and sufficient manner, whether due to shortages of such materials, difficulties in scaling up supply to satisfy our clinical trial and commercial needs, contamination, recall, the COVID- 19 pandemic or otherwise, or to source or manufacture such components in accordance with cGMPs and cGTPs, as applicable, could delay our ability to complete our clinical trials, obtain marketing approval and commercialize our product candidates. Establishing additional or replacement suppliers for these components could take a substantial amount of time and it may be difficult to establish replacement suppliers who meet regulatory requirements. In addition, as part of the FDA' s approval of our product candidates, the FDA must review and approve the individual components of our production process, which includes raw materials, the manufacturing processes and facilities of our suppliers. Some of our current suppliers have not undergone this process nor have they had any components included in any product approved by the FDA. If our suppliers fail to comply with applicable regulations, and if we do not qualify alternate suppliers, the clinical development, marketing approval or commercialization of our product candidates could be delayed, thereby increasing our costs to complete clinical development and to obtain marketing approval and depriving us of potential product revenue. We intend to rely on our strategic, global relationship with Fresenius Medical Care to undertake, or assist with, the development and commercialization of certain of our product candidates if we receive marketing approval from relevant regulatory authorities. Disruption of this arrangement could materially adversely affect our business, prospects, operating results and financial condition. Under the distribution agreement, Fresenius Medical Care has the exclusive right to sell and distribute the distribution product in the field outside of the United States. In addition, under the terms of the distribution agreement, Fresenius Medical Care will collaborate with Humacyte in its commercialization of the distribution product in the field in the United States, including adoption of the distribution product as a standard of care in patients for which such use is supported by clinical results and health economic analyses. As a result of our arrangement with Fresenius Medical Care, we expect to be reliant on Fresenius Medical Care to undertake or assist with the development and commercialization, as well as, in some cases, obtaining and maintaining regulatory approval, of the distribution product in the field and for Fresenius Medical Care to do so in a manner consistent with applicable law and regulatory requirements outside of the United States. If Fresenius Medical Care otherwise fails to undertake or assist with the development or commercialization, or obtaining or maintaining regulatory

approvals, of the distribution product in accordance with the terms of the distribution agreement, our business, prospects, operating results and financial condition would be adversely affected, perhaps materially. Fresenius Medical Care also maintains certain discretionary termination rights on a country- by- country basis with respect to any country outside of the United States under the distribution agreement, as discussed in more detail in the section of this Annual Report on Form 10- K titled " Business — Distribution — Distribution Agreement with Fresenius Medical Care. " If the distribution agreement is terminated, we may not be able to secure an alternative distributor in the applicable country on a timely basis or at all, in which case our ability to generate revenues from the distribution product in such country would be harmed. In addition, if Fresenius Medical Care fails to undertake or assist with the development or commercialization, or obtaining or maintaining regulatory approval, as applicable, of the distribution product in a manner consistent with applicable law and regulatory requirements, patient access to, and demand for, the distribution product could be reduced, our reputation could be damaged, and, under certain circumstances, we could be exposed to potential liability. Furthermore, while Fresenius Medical Care has certain commercialization diligence obligations, Fresenius Medical Care is not restricted from offering its own products and services or the products and services of other companies that compete with the distribution product, and may not undertake or assist with the development or commercialization of the distribution product effectively. Risks Related to Our Financial Position and Need for Additional Funding Since inception, we have generated no product revenue, and prior to receipt of marketing approval from regulatory authorities, we will be unable to do so. We incurred net losses of $ **110. 8 million and $** 12. 0 ~~million and $ 26. 5~~ million for the years ended December 31, **2023 and** 2022 ~~and 2021~~, respectively. As of December 31, **2023 and** 2022 ~~and 2021~~, we had an accumulated deficit of $ **537. 3 million and $** 426. 5 million ~~and $ 414. 6 million~~, respectively. **We have historically** ~~Up to the date of the consummation of the Merger, we~~ financed our operations primarily through the sale of equity securities and convertible debt **, proceeds from the Merger and related PIPE Financing, borrowings under loan facilities, 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 ~~. Our V005 and V007 trials are currently enrolling, and we currently intend to submit a BLA to the FDA relating to vascular trauma and a subsequent BLA filing related to AV access for hemodialysis. We also intend to continue scaling out our manufacturing facility to satisfy potential demand if the FDA approves our BLA, advancing preclinical and clinical development of additional clinical applications for our HAVs and funding our operations. Accordingly, we expect to continue to incur substantial operating losses for the foreseeable future, which may fluctuate significantly from quarter- to- quarter and year- to- year~~. To become and remain profitable, we must succeed in obtaining marketing approval for our HAVs in the United States, in commercializing our HAVs, and in developing and commercializing additional product candidates that generate significant revenue. We may never succeed in these activities and, even if we do, may never generate revenue that is sufficient to achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability. Our failure to become and remain profitable would depress the value of our company and could impair our ability to maintain our research and development efforts, expand our business, diversify our product offerings or even continue our operations. A decline in the value of Humacyte could also cause you to lose all or part of your investment in our securities. Our ability to use our net operating loss and tax credit carryforwards to offset future taxable income may be subject to certain limitations. As of December 31, ~~2022~~ **2023**, we had net operating loss carryforwards for federal and state tax purposes of approximately $ ~~322~~ **384** . ~~4~~ **0** million and $ ~~323~~ **383** . ~~9~~ **0** million, respectively, which begin to expire in 2025. In addition, we had tax credit carryforwards for federal and state tax purposes of approximately $ ~~18~~ **20** . 1 million ~~,~~ as of December 31, ~~2022~~ **2023**, which begin to expire in 2025 and will expire completely in ~~2042~~ **2043** . The future utilization of net operating loss and tax credit carryforwards may be limited due to changes in ownership. In general, if we experience a greater than 50 % aggregate change in ownership of certain significant stockholders or groups over a three- year period (which constitutes an ownership change under Section 382 of the Internal Revenue Code of 1986, as amended (the " Code ")), utilization of our pre- change net operating loss carryforwards is subject to an annual limitation under Section 382 of the Code (and similar state laws). The annual limitation generally is determined by multiplying the value of our stock at the time of such ownership change (subject to certain adjustments) by the applicable long- term tax- exempt rate. Such limitations may result in expiration of a portion of the pre- change net operating loss carryforwards before utilization and may be substantial. In the past we may have experienced, and in the future may experience, ownership changes as a result of subsequent shifts in our stock ownership. As a result, if we earn net taxable income, our ability to use our pre- change net operating loss carryforwards to offset United States federal taxable income may be subject to limitations, which could potentially result in increased future tax liability to us. We expect to need to raise additional funding, which may not be available on acceptable terms, or at all, and any failure to obtain capital when needed may force us to delay, limit or terminate our product development or commercialization efforts. We expect to incur significant expenses in connection with our ongoing activities as we seek to (i) scale out our manufacturing facility to satisfy potential demand if our HAVs receive marketing approval in the United States, (ii) continue our preclinical and clinical development efforts, including the ongoing clinical trials, and (iii) obtain marketing approval for our 6 millimeter HAV, and, if marketing approval is obtained, to commercialize our HAVs for one or more approved indications. We will need additional funding in connection with these activities. Our future capital requirements will depend on many factors, including: • the progress and results of our clinical trials and interpretation of those results by the FDA and other regulatory authorities; • the cost, timing and outcome of regulatory review of our product candidates, particularly for approval of our HAVs in the United States; • the scope, progress, results and costs of preclinical development, laboratory testing and clinical trials for our additional product candidates; • the cost and timing of our future commercialization activities, including product manufacturing, marketing and distribution for our HAVs if approved by the FDA, and any other product candidate for which we receive marketing approval in the future; • the amount and timing of revenues, if any, that we receive from commercial sales of any product candidates for which we

receive marketing approval; and • the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property- related claims. Adequate capital may not be available to us when needed or on acceptable terms. If we are unable to raise capital, we could be forced to delay, reduce, suspend or cease our research and development programs or any future commercialization efforts, which would have a negative impact on our business, prospects, operating results and financial condition. As of December 31, **2023, we had cash and cash equivalents of $ 80. 4 million and as of December 31,** 2022 ~~and 2021~~ , we had ~~$ 151. 9 million and $ 225. 5 million, respectively, in~~ cash and cash equivalents and short- term investments **of $ 151. 9 million. Subsequent to December 31, 2023, in March 2024 we completed the Offering (defined below), which provided approximately $ 43. 1 million in net proceeds and received an additional $ 20. 0 million under the Purchase Agreement (defined below)** . Based upon our current operating plan, we believe that our cash and cash equivalents ~~and short- term investments~~ will be sufficient to fund our operations, including clinical trial expenses and capital expenditure requirements, for at least 12 months from the date of this Annual Report on Form 10- K. Pursuant to the terms of ~~our outstanding indebtedness~~ **the Purchase Agreement** , we may be limited in our ability to incur future debt. ~~In March~~ **On May 12,** ~~2021~~ **2023** , ~~Humacyte~~ **the Company and** Global ~~, Inc., or Legacy Humacyte,~~ entered into **the Purchase** ~~a Loan and Security~~ Agreement **with the Purchasers and another affiliate of Oberland, as agent for the Purchasers** (~~as amended,~~ the " **Agent** ~~Loan Agreement~~ ") **, to obtain financing with respect to the further development and commercialization of the Company' s HAV, to repay the Company' s credit facility** with Silicon Valley Bank ~~and~~ **(“** SVB **")** ~~Innovation Credit Fund VIII~~ , ~~L. P., which provides a term loan facility of up to $ 50. 0 million with a maturity date of March 1, 2025. We became a co- borrower under the Loan Agreement in connection with the Merger. The obligations of Humacyte~~ and **for** ~~Legacy Humacyte under the Loan Agreement are secured by substantially all of their~~ **other general corporate purposes** ~~assets, except for their intellectual property~~ . Pursuant to the terms of the ~~Loan~~ **Purchase** Agreement, we are limited in our ability to incur additional indebtedness **without** ~~. In addition, a failure to comply with~~ the ~~covenants under~~ **prior written consent of** the ~~Loan~~ **Purchasers. The Purchasers have an option to terminate the Purchase** Agreement ~~could result in an~~ **and to require Global to repurchase the Revenue Interests in the** event ~~of default and an acceleration of amounts due. If an event of default occurs~~ that ~~is not waived by the lenders, and the lenders accelerate any amounts due,~~ we **incur additional** ~~may not be able to make accelerated payments, and the lenders could seek to enforce their security interests in the collateral securing such~~ indebtedness **in violation** ~~, which could have a material adverse effect on our business and results~~ of ~~operations. Our payment obligations under~~ the ~~Loan~~ **terms of the Purchase** Agreement ~~reduce cash available to fund working capital, capital expenditures, research and development and other corporate purposes, and limit our ability to obtain additional financing for working capital, capital expenditures, expansion plans and other investments, which may in turn limit our ability to implement our business strategy, heighten our vulnerability to downturns in our business, the industry, or in the general economy, limit our flexibility in planning for, or reacting to, changes in our business and the industry and prevent us from taking advantage of business opportunities as they arise. If market rates increase, we will have to pay additional interest on this indebtedness, which would further reduce cash available for our other business needs~~ . We cannot assure you that our business will generate sufficient cash flow from operations **, 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 ~~enable us to make required and timely payments on our indebtedness, or to~~ fund our operations. To date, we have not ~~requested or~~ obtained marketing approval for, or commercialized, any of our product candidates, which may make it difficult for you to evaluate the success of our business to date and to assess our future viability. We are a development- stage company. Our operations to date, with respect to the development of our product candidates, have been limited to organizing and staffing our company, business planning, raising capital, identifying markets for our product candidates, undertaking preclinical studies and clinical trials of our product candidates for various potential indications and establishing research and development, manufacturing and distributing collaborations. We have not yet demonstrated the ability to obtain marketing approval for a product, to manufacture an approved product at commercial scale or to successfully commercialize an approved product. Consequently, any predictions you make about our financial prospects may not be as accurate as they could be if we had received marketing approval and begun commercializing a product. Risks Related to Government Regulation We may not obtain marketing approval from the FDA for any of our product candidates even if we successfully complete our clinical trials, which failure would materially harm our business, prospects, operating results and financial condition. Prior to commercialization, biologics, like our HAVs, require the submission of a BLA to, and approval of the BLA by, the FDA. A BLA must be supported by extensive preclinical and clinical data, as well as extensive information regarding chemistry, manufacturing and controls (" CMC "), sufficient to demonstrate the safety, purity, potency and effectiveness of the applicable product candidate to the satisfaction of the FDA. ~~We have never submitted a~~ **In February 2024, the FDA accepted and granted priority review for our first** BLA ~~for~~ **seeking** approval **of** ~~or~~ **our** ~~otherwise~~ **HAV for urgent arterial repair following extremity vascular trauma when synthetic graft is not indicated and autologous vein use is not feasible, but there can be no assurance that we will** ~~obtained~~ -- **obtain** FDA approval **for that indication or** for any of our product candidates. The BLA approval process is expensive and uncertain, it may take several years to complete, and we may not be successful in obtaining such approval. The FDA has substantial discretion in the approval process and decisions made by the FDA can be unpredictable ~~. The FDA may use its discretion at any time to withdraw statements or representations, including written statements, that it has made or may make to us regarding our product candidates, clinical trials or the BLA process~~ . The number and types of preclinical studies and clinical trials that will be required for BLA approval varies depending on the product candidate, the disease or the condition that the product candidate is designed to target and the regulations applicable to any particular product candidate. The FDA could delay, limit or deny approval of our product candidates for many reasons, including because it: • may not deem the product candidate to be adequately safe or effective; • may not find the data from preclinical studies, clinical trials or CMC data sufficient to support approval; • may not approve the manufacturing processes or facilities associated with the product candidate; • may conclude that the long- term integrity of the

product candidate for which approval is being sought has not been sufficiently demonstrated; • may change approval policies or adopt new regulations; or • may not accept a submission due to, among other reasons, the content or formatting of the submission. In some cases, the FDA may agree to an SPA for a clinical trial, when it determines that the trial is adequately designed to provide necessary data to support a license application. Even in such cases, however, the FDA may subsequently abandon the SPA if a substantial scientific issue essential to determining the safety or effectiveness of the product candidate has been identified after the testing has begun. In addition, if a company alters the protocol for a trial, the SPA may no longer apply. Further, the results of pivotal clinical trials are always subject to thorough FDA review. Even highly significant **and favorable** clinical trial results are no guarantee of approval ~~. We currently intend to submit a BLA to the FDA relating to vascular trauma and a BLA for AV access in hemodialysis, based on the results and trial design of our V005 and V007 trials, respectively. The FDA may decline to approve our 6 millimeter HAV on the basis of these or other trial results, or for other reasons~~ . Even if we obtain and maintain approval for our HAVs from the FDA, we may never obtain approval for our HAVs outside of the United States, where the regulatory process is also complex and subject to significant uncertainty. Failure to do so would limit our market opportunities and adversely affect our business. Even if we receive FDA approval to market any biologic in the United States, we must comply with the numerous and varying regulatory and compliance related requirements of other countries, including the submission of extensive preclinical and clinical data, manufacturing and quality information regarding the process and facility, scientific data characterizing the relevant product candidate and other supporting data in order to establish safety and effectiveness. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods, including obtaining reimbursement and pricing approval in select markets. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The marketing approval process in other countries may include all of the risks associated with FDA approval as well as additional, presently unanticipated, risks. Marketing approval in one country does not ensure marketing approval in another, but a failure or delay in obtaining marketing approval in one country may negatively impact the regulatory process in others, including the risk that our product candidates may not be approved for all indications requested and that such approval may be subject to limitations on the indicated uses for which the product candidate may be marketed. Even if we seek " rolling review " or priority review, the review time for BLAs for our product candidates may be longer and more expensive than for other products because of the novelty and complexity of our product candidates, which would delay our ability to begin commercialization and earn product revenues. The marketing approval process for novel product candidates such as ours may take longer to complete and be more expensive than the process for other, better known or extensively studied pharmaceutical or other product candidates. **On December 12, 2023, we submitted our BLA for the HAV in urgent arterial repair following extremity vascular trauma when synthetic graft is not indicated and autologous vein use is not feasible.** We ~~may be eligible for~~ **submitted our BLA using** a " rolling review **,** " ~~of a BLA,~~ which means we may submit completed modules of a BLA rather than waiting until every module of the BLA is completed before submitting the full BLA for FDA review. Such " rolling review " is common for indications that are part of one of FDA' s expedited programs, such as our 6 millimeter HAV, which has received Fast Track and RMAT designations for AV access in hemodialysis **, and RMAT designation for urgent arterial repair following extremity vascular trauma** . ~~The~~ **In February 2024, the** FDA **accepted** ~~may also designate one or~~ **our** ~~more of our product candidates for~~ **BLA in the vascular trauma indication and granted** priority review **of that** ~~after we submit a~~ BLA. Under priority review, the FDA' s goal is to review an application within six months of the 60- day filing date, compared to ten months for a standard review. Even ~~if~~ **though** we **have** ~~are able to utilize~~ **utilized** a " rolling review " and **we have received** ~~/ or the FDA designates one or more of our product candidates for~~ 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 HAVs to treat congenital pediatric heart defects. We may be unable to obtain such designation or to maintain the benefits associated with orphan drug designation, including market exclusivity, which may cause our revenue, if any, to be reduced. Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with a patient population of fewer than 200, 000 in the United States, or a patient population of 200, 000 or more in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States for that drug or biologic. Orphan drug designation must be requested before submitting a BLA. In the United States, orphan drug designation entitles a party to financial incentives such as opportunities for grant funding towards clinical trial costs, tax advantages and user- fee waivers. After the FDA grants orphan drug designation, the generic identity of the drug or biologic and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. **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~~ **even** if one of our **biological** product candidates receives orphan exclusivity, the FDA can still approve ~~other~~ **different** drugs **or biologics** ~~that have a different active ingredient~~ for use in treating the same indication or disease, as well as the same drug or biologic for a different indication or disease. The FDA can also approve the same drug or biologic for the same indication or disease if the subsequent drug or biologic demonstrates clinical superiority. Furthermore, the FDA can waive orphan exclusivity if we are unable to manufacture sufficient supply of our product. Inadequate funding for the FDA and other government agencies, including from government shut downs, global health concerns or other disruptions to these agencies' operations, could hinder

their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business. The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, policy changes, and the effects of the COVID- 19 pandemic. Average review times at the FDA have fluctuated in recent years as a result. Disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and / or approved by necessary government agencies, which could adversely affect our business. In addition, government funding of other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable. We may experience delays or rejections based upon additional government regulation from future legislation or administrative action, or changes in regulatory agency policy during the period of product development, clinical trials and the review process. In addition, disruptions at the FDA and other agencies may also slow the time necessary for new product candidates to be reviewed and / or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years the U. S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA and other government employees and stop critical activities. If a prolonged government shutdown occurs, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations. Even if we receive marketing approval for a product candidate, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and subject us to significant penalties if we fail to comply with applicable regulatory requirements. If we obtain marketing approval for any of our product candidates, the approved product will be subject to ongoing regulatory requirements from the FDA and, if applicable, non- U. S. regulatory authorities. Any marketing approval that we receive for our product candidates may be subject to limitations on the indicated uses for which the product may be marketed or contain requirements for potentially costly post-marketing follow- up trials to monitor the safety and efficacy of the product. The FDA could also approve our product candidates with a REMS, which could include significant restrictions on distribution and / or use of our products. In addition, if the FDA and non- U. S. regulatory authorities approve any of our product candidates, we will be subject to extensive and ongoing regulatory requirements by the FDA and other regulatory authorities with regard to the manufacturing, labelling, packaging, AE reporting, storage, advertising, distribution, promotion and recordkeeping for our products. If we, our product candidates or the manufacturing facilities for our product candidates fail to comply with regulatory requirements of the FDA and, if relevant, other non- U. S. regulatory authorities, we could be subject to administrative or judicially imposed sanctions, including the following: • issuance of warning letters or untitled letters by regulatory authorities asserting that we are in violation of the law; • imposition of injunctions or significant civil monetary penalties or pursuit by regulatory authorities of civil or criminal prosecutions and fines **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 any or our product candidates that had received marketing approval, substantially reduce our revenue, increase the costs of operating our business, and cause us significant reputational damage, among other consequences. If we ultimately receive approval for any product candidates in jurisdictions outside the U. S., we expect to be subject to similar ongoing regulatory oversight by the relevant foreign regulatory authorities. Our products may be subject to product recalls that could harm our reputation and could materially and adversely affect our business, financial condition, operating results, cash flows and prospects. The FDA and other regulatory agencies strictly regulate the promotional claims that may be made about prescription products, if approved. In particular, while the FDA permits the dissemination of truthful and non- misleading information about an approved product, the FDA restricts our ability to promote a product for uses that are not approved by the FDA. The misuse or off- label use of our product may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory authorities if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business. We may also face risks in other non- U. S. jurisdictions from product recalls and advertising / promotion rules. We could also face product liability suits or regulatory delays due to defects in our products, which could be expensive and time- consuming and result in substantial damages payable by us and increases in our insurance rates. Designation of our product candidates for expedited programs, such as Fast Track designation, Breakthrough Therapy Designation, or RMAT designation, or accelerated approval by the FDA, or priority designation by the Department of Defense, may not lead to a faster development or regulatory review or approval process, and even if granted, will not increase the likelihood that our product candidates will receive marketing approval. In 2014, the FDA granted Fast Track designation for our 6 millimeter HAV for use in the creation of AV access for hemodialysis, ~~and,~~ in 2017, the FDA granted RMAT designation for our 6 millimeter HAV for the creation of vascular access for performing hemodialysis ~~. We have submitted a request for~~ **and in 2023, the FDA granted** RMAT designation ~~of the~~ **for our 6 millimeter** HAV for **urgent arterial repair following extremity** vascular trauma ~~but there is no guarantee that the FDA will grant this request~~ . **We** ~~And we~~ have not received designations pursuant to any of the FDA' s expedited programs for **PAD** ~~peripheral artery disease~~ or our other indications, although we may in the future seek such designations if such product candidates meet the criteria for that designation. ~~As a result, even if we submit a BLA for trauma, our Fast Track and RMAT designations, and their attendant benefits, may not apply to this requested indication unless the FDA~~

~~grants our request for RMAT 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. ~~We may seek accelerated approval for our HAV relating to vascular trauma. A product candidate may be eligible for accelerated approval if it treats a serious or life- threatening condition, generally provides a meaningful advantage over available therapies, and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. As a condition of accelerated approval, the FDA may require that a sponsor of a product receiving accelerated approval perform adequate and well- controlled confirmatory clinical trials post- approval. These confirmatory trials must be completed with due diligence. In addition, the FDA currently requires the pre- approval of promotional materials as a condition for accelerated approval, which could adversely impact the timing of the commercial launch of the product. Even if we do receive accelerated approval, we may not experience a faster development or regulatory review or approval process, and receiving accelerated approval does not provide assurance of ultimate full FDA approval. Accelerated approval may also be withdrawn if, among other things, a confirmatory trial required to verify the predicted clinical benefit of the product fails to verify such benefit or if such trial is not conducted with due diligence.~~ In addition, in 2018, our HAV product candidate was assigned a priority designation by the Secretary of Defense under Public Law 115- 92. Similar to the designations described above that FDA may grant, a priority designation by the Department of Defense does not change the standards for approval but may expedite the development or approval process. Healthcare reform measures could hinder or prevent our product candidates' commercial success. Our industry is highly regulated, and changes in or revisions to laws and regulations that make gaining coverage of and adequate reimbursement for our product candidates more difficult or subject to different criteria and standards may adversely impact our business, prospects, operating results and financial condition. In the United States, there have been and we expect there will continue to be a number of legislative, regulatory and other changes to the healthcare system to contain or reduce healthcare costs that may adversely affect our ability to set a price we believe is fair for our product candidates, our ability to generate revenues and achieve or maintain profitability, and the availability of capital. Federal and state lawmakers regularly propose and, at times, enact legislation that would result in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. ~~For~~ **At the federal level, for** example, ~~ACA, enacted in 2010 and amended by~~ the **Inflation** ~~Health Care and Education~~ **Reduction** ~~Reconciliation~~ Act ~~, contains a number~~ of **2022, or IRA, was signed into law on August 16, 2022. Among other key** provisions ~~that were intended to broaden access to health insurance~~ , ~~reduce~~ **the IRA: • Requires manufacturers to pay rebates** ~~or~~ **for a** ~~constrain the growth of healthcare spending, enhance remedies for fraud and abuse, add transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry, and impose additional health policy reforms. The Bipartisan Budget Act of 2018, among other things, amended the ACA to close the coverage gap in most~~ Medicare **Part B or Part D** drug ~~plans, commonly referred to as~~ **if the price increases for the drug exceed the rate of inflation. • Eliminates** the " donut hole ~~,~~ " ~~in~~ **under Medicare** ~~part~~ **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** ~~greater~~ -- **rebate** ~~discounts~~ **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** ~~. Various members of Congress have expressed a desire to repeal all or~~ **for** ~~portions of~~ **approved products, among** ~~the~~ **other effects** ~~ACA, and in December 2017, portions of the ACA dealing with the individual mandate insurance requirement were effectively repealed by the Tax Cuts and Jobs Act of 2017~~ . **The** ~~On February 10, 2021, the~~ Biden administration **has indicated that lowering prescription drug prices is a priority** ~~withdrew the federal government' s support for overturning the ACA~~ . ~~Further~~ **On October 14** , ~~on January 28, 2021~~ **2022** , President Biden ~~issued~~ **signed** an executive order to **lower prescription drug costs** ~~initiate a special enrollment period~~ for ~~purposes~~ **Americans. In response to this directive, the Center for Medicare and Medicaid Innovation is developing 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 ~~obtaining~~ **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 ~~coverage through~~ **option. Among** ~~the~~ **other things** ~~ACA marketplace~~ , **the** ~~which ran until August 15, 2021. The~~ executive order **directs** ~~also instructs certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. In June 2021, the United States Supreme Court held that the individual plaintiffs and states lacked standing to challenge the constitutionality of the ACA. Additionally, in December 2018, CMS published a final rule permitting further collections and payments to and from certain ACA qualified health plans and health insurance issuers under the ACA risk adjustment program in response to the outcome of federal district court litigation regarding the method CMS uses to determine this risk adjustment. Since then~~ **the HHS Secretary** ~~, the ACA risk adjustment program payment parameters have been updated annually. In addition, CMS published a final rule that gave states greater flexibility, starting in 2020, in setting benchmarks for insurers in the individual and small group marketplaces, which may have the effect of relaxing the essential health benefits required under the ACA for plans sold through such marketplaces. At this time, it remains unclear whether there will be further changes made~~ to **provide a report on actions** ~~the ACA. The ACA, as currently enacted or as amended in the future, may adversely affect our business and operating results, and we do not know how future federal or state legislative or administrative changes relating~~ to **combat excessive** ~~healthcare reform will affect our business. Other legislative changes that have been adopted since enactment of the ACA could also affect potential~~ pricing ~~and utilization of our product candidates. In addition, the Secretary of Health and Human Services, various members of Congress and CMS have made statements and issued proposals regarding containment of drug prices through various means, including enabling CMS to negotiate U. S. drug pricing to align with foreign drug pricing, pricing transparency measures, reform of drug rebate programs, and conditioning coverage and reimbursement of certain drugs upon the prior failure or inadequacy of less expensive therapies, sometimes referred to as " step therapy. " Additionally, there has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U. S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost~~ of prescription drugs ~~under Medicare~~ , **continue to clarify** ~~review the relationship between pricing~~ and ~~manufacturer patient programs,~~ **improve the approval framework for generic drugs** and ~~reform~~ **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** ~~program reimbursement methodologies. At the federal level~~ , **and address price gouging in** ~~on March 11, 2021, President Biden signed~~ the **industry. The** American Rescue Plan Act of 2021 ~~into law, which~~ eliminates the statutory Medicaid drug rebate cap, currently set at 100 % of a drug' s average manufacturer price, for single source and innovator multiple source drugs, beginning January 1, 2024. In addition, ~~at the state level,~~ individual states have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. **We cannot predict how further developments of** ~~Beginning in fiscal year 2018, CMS altered the reimbursement formula on specified covered outpatient drugs (" SCODs "). A SCOD drug product may also be a covered outpatient drug under the 340B program, which allows 340B- participating hospitals to purchase the drug product at the 340B discounted rate and, when prescribing it to a Medicare patient, be reimbursed at the Medicare rate. Under the prior Medicare reimbursement rate, this created a significant, positive gap for~~ **or** ~~340B- participating health care facilities. CMS' s change in the Medicare reimbursement rate for SCODs significantly impacted, or eliminated, the positive gap for 340B- participating health care facilities. The District Court for the District of Columbia invalidated the formula change, but the U. S. Court of Appeals for the District of Columbia Circuit reversed the district court' s decision and found that the~~ changes **to** ~~were within the~~ **these laws** ~~Secretary' s authority. The case is currently under review by the U. S. Supreme Court,~~ and **regulations** ~~a decision is expected by summer of 2022. It is unlikely the Medicare rate litigation~~ will ~~impact 340B pricing for our approved products in the future, but it possible it could~~ affect ~~covered hospitals who might purchase~~ our ~~products~~ **business** . The FDA also released a final rule on September 24, 2020, which went into effect on November 30, 2020, providing guidance for states to build and submit **plans for** importation **of** ~~plans for~~ drugs from Canada. Additionally, on November 20, 2020, HHS finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The 2020 rule also creates a new safe harbor for price reductions reflected at the point- of- sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers. Pursuant to a court order, HHS subsequently delayed the effective date for aspects of the rule, including those relating to pharmacy benefit managers, until 2023. The rule was then effectively delayed until January 1, 2026, as part of the Infrastructure Investment and Jobs Act, which was signed into law on November 15, 2021. In addition, on November 19, 2021, the House of Representatives passed a version of the Build Back Better Act that includes a provision prohibiting the implementation, administration, or enforcement of the rule. Although a number of these, and other proposed measures may require authorization through additional legislation to become effective, and the Biden administration may reverse or otherwise change these measures, Congress has indicated that it will continue to seek new legislative measures to control drug costs. The ultimate content, timing, or effect of any healthcare reform legislation or executive order or the impact that the resulting changes may have on us is uncertain, but we expect there will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of health care. If

we fail to comply with healthcare regulations, we could face substantial penalties and our business, prospects, operating results and financial condition could be adversely affected. Certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients' rights are and will be applicable to our business even though we do not and will not control referrals of healthcare services. We could also be subject to patient privacy regulation by both the U. S. Government and the states in which we conduct our business. Our employees, independent contractors, consultants, commercial partners and vendors may engage in misconduct or other improper activities, including non- compliance with regulatory standards and requirements. The regulations that may affect our ability to operate include, without limitation: • the federal Anti- Kickback Statute, which prohibits, among other things, any person from knowingly and willfully offering, soliciting, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs, even if the person does not have actual knowledge of the statute or specific intent to violate it; • the federal False Claims Act, which prohibits, among other things, individuals or entities from knowingly presenting, or causing to be presented, false claims, or knowingly using false statements, to obtain payment from the U. S. Government; • federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; • the anti- inducement law, which prohibits, among other things, the offering or giving of remuneration, which includes, without limitation, any transfer of items or services for free or for less than fair market value (with limited exceptions), to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary' s selection of a particular provider, practitioner, or supplier of items or services reimbursable by a federal or state governmental program; • the federal transparency requirements under the ACA, including the provision commonly referred to as the Physician Payments Sunshine Act and its implementing regulations, which require applicable manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid, or the State Children' s Health Insurance Program to report annually to CMS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by the physicians described above and their immediate family members. Effective January 1, 2022, these reporting obligations were extended to include transfers of value made to certain non- physician providers such as physician assistants and nurse practitioners; • federal government price reporting laws, which require us to calculate and report complex pricing metrics in an accurate and timely manner to government programs; • federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; • HIPAA, which governs the conduct of certain electronic healthcare transactions and protects the security and privacy of protected health information; and • state law equivalents of each of the above federal laws, such as anti- kickback and false claims laws which may apply to items or services reimbursed by any third- party payor, including commercial insurers. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from participating in federal health care programs and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment, exclusion, or restructuring of our operations could adversely affect our ability to operate our business, prospects, operating results and financial condition. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management' s attention from the operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state privacy and fraud and abuse laws may prove costly. Our business and operations, including our development programs, could be materially disrupted in the event of system failures, security breaches, violations of data protection laws or data loss or damage by us or third parties on which we rely, including our CROs or other contractors or consultants. Our internal computer systems (including our LUNA200 manufacturing system) and those of third parties on which we rely, including our CROs and other contractors and consultants, are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. 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 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. In 2021, a remote code execution vulnerability in Apache Log4j was identified as affecting large amounts of systems worldwide. We were not impacted by the Log4j vulnerability, however we cannot provide assurance that these and other attacks will not have an impact in the future. Although we have general liability insurance coverage, our insurance may not cover all claims, continue to be available on reasonable terms or be sufficient in amount to cover one or more large claims. Additionally, the insurer may disclaim coverage as to any claim. The successful assertion of one or more large claims against us that exceed or are not covered by our insurance coverage or changes in our insurance policies, including premium increases or the imposition of large deductible or co- insurance requirements, could have a material adverse effect on our business, prospects, operating results and financial condition **. 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 under HIPAA. Depending on the facts and circumstances, we could be subject to civil or criminal penalties if we obtain, use, or disclose individually identifiable health information maintained by a HIPAA- covered entity in a manner that is not authorized or permitted by HIPAA. International data protection laws, including Regulation 2016 / 679, known as the General Data Protection Regulation (" GDPR "), may also apply to health- related and other personal information obtained outside of the United States. The GDPR will increase our responsibility and liability in relation to personal data that we process,

and we may be required to put in place additional mechanisms to ensure compliance with the new EU (which also includes the European Economic Area, or " EEA ") data protection rules. Further, the United Kingdom' s **separation from** ~~vote in favor of exiting~~ the EU ~~, often referred to as Brexit,~~ has created more uncertainty with regard to data protection regulation in the United Kingdom (the " UK "). The UK retained the GDPR in UK law, which sits alongside the amended version of the Data Protection Act 2018. The EU adopted an adequacy decision so data can be transferred from the EU to the UK. Additionally, there are no new requirements for transfer from the UK to the EU. However, going forward, the EU and UK' s data protection rules could diverge and data transfers may not be possible and / or new arrangements may need to be put in place. In particular, it is unclear to what extent the UK regime will begin diverging from the GDPR and how data transfers to and from the UK will be regulated. In addition, California recently enacted the California Consumer Privacy Act (" CCPA "), which creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households ~~. The~~ **, and the** CCPA **was supplemented by** ~~became effective on January 1, 2020, but~~ the California Consumer Rights Act (" CPRA ") ~~was recently enacted to strengthen elements of the CCPA effective January 1, 2023~~ . ~~In addition, there~~ **There** are a number of other states that have considered similar privacy proposals, with states like Virginia and Colorado enacting their own privacy laws ~~(also scheduled to come into effect in January 1, 2023 and July 1, 2023, respectively)~~ . These privacy laws may impact our business activities and exemplify the vulnerability of our business to the evolving regulatory environment related to personal data. Compliance with U. S. and international data protection laws and regulations could require us to take on more onerous obligations in our contracts, restrict our ability to collect, use and disclose data, or in some cases, impact our ability to operate in certain jurisdictions. Failure to comply with U. S. and international data protection laws and regulations could result in government enforcement actions (which could include civil or criminal penalties), private litigation and adverse publicity and could negatively affect our operating results and business. Moreover, clinical trial subjects about whom we or our potential collaborators obtain information, as well as the providers who share this information with us, may contractually limit our ability to use and disclose the information. Claims that we have violated individuals' privacy rights, failed to comply with data protection laws, or breached our contractual obligations, even if we are not found liable, could be expensive and time- consuming to defend and could result in adverse publicity that could harm our business. We or the third parties upon which we depend may be adversely affected by natural disasters, and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster. Natural disasters such as hurricanes could severely disrupt our operations and have a material adverse effect on our business, prospects, operating results and financial condition. In addition, flooding, lightning strikes, meteor strikes, and polar vortices could affect our building operations. If a natural disaster, power outage or other unforeseen event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our in- house manufacturing facility, or that otherwise significantly disrupted our operations, it may be difficult or, in certain cases, impossible for us to continue our business for a substantial period of time. The disaster recovery and business continuity plans we have in place currently may prove inadequate in the event of a natural disaster or similar event. We may incur substantial expenses as a result of any natural disaster, which could have a material adverse effect on our business. We are subject to anti- corruption and a variety of other laws governing our international operations. If we fail to comply with these laws, we could be subject to, among other things, civil or criminal penalties, other sanctions and remedial measures, and reputational damage, which could adversely affect our business, prospects, operating results and financial condition. Our operations are subject to anti- corruption laws, including the U. S. Foreign Corrupt Practices Act (" FCPA "), the U. K. Bribery Act and other anti- corruption laws. Anti- corruption laws are interpreted broadly and prohibit companies and their employees, agents, contractors, and partners from authorizing, promising, offering, or providing, directly or indirectly, improper payments or anything else of value to recipients in the public or private sector. We are conducting certain of our trials at a number of trial sites around the world. Certain of these jurisdictions pose a risk of potential FCPA violations, and we have relationships with third parties, including government- affiliated hospitals and universities, whose actions could potentially subject us to liability under the FCPA or local anti- corruption laws. We are also subject to other laws and regulations governing our international operations, including regulations administered by the U. S. Department of Commerce' s Bureau of Industry and Security, the U. S. Department of the Treasury' s Office of Foreign Assets Control, and various non- U. S. government entities, including applicable economic sanctions on countries and persons, customs requirements, currency exchange regulations and transfer pricing regulations. If we fail to comply with applicable anti- corruption laws and other legal requirements, we may become subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, including the loss of export or import privileges and debarment, and face substantial legal expenses. Likewise, even an investigation by U. S. or foreign authorities of potential violations of such laws could damage our reputation. In either case, our business, prospects, operating results and financial condition could be adversely affected. Under certain circumstances, we could also be held liable for the activities of our employees, contractors, and partners that violate anti- corruption laws, even if we do not explicitly authorize or have actual knowledge of such activities. Even allegations of such violations could potentially damage our reputation and harm our business. Risks Related to Our Intellectual Property Our success depends in large part on our and our licensors' ability to obtain and maintain patent and other intellectual property protection in the United States and in other countries with respect to our proprietary scientific technology platform and products. We have sought to protect our proprietary position by filing patent applications in the United States and abroad related to our novel technologies and product candidates that we and / or our licensors view as important to our business. This process is expensive and time- consuming, and we and our licensors may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner. It is also possible that we and / or our licensors will fail to identify patentable aspects of our research and development output before it is too late to obtain patent protection. In some circumstances, we may not have the right to control the preparation, filing and prosecution of patent applications, or to maintain the patents or enforce the patents, covering technology or products that we license from third parties. Our existing patents and

any future patents and the existing and any future licenses to third- party patents we obtain may not be sufficiently broad to prevent others from using our technologies or from developing competing products and technologies. The patent position of biotechnology companies generally is highly uncertain and involves complex legal and factual questions for which legal principles remain unresolved. In recent years, patent rights have been the subject of significant litigation. As a result, the issuance, scope, validity, enforceability and commercial value of our and our licensors' patent rights are highly uncertain. Additionally, changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our owned or licensed patents or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Even if our owned and licensed patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. We, or our licensors, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non-infringing manner. The issuance of a patent is not conclusive as to its scope, validity or enforceability, and our owned and licensed patents may be challenged in the courts or patent offices in the United States and abroad. Such challenges may result in patent claims being narrowed, invalidated or held unenforceable, which could limit our ability to stop or prevent us from stopping others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. Given the amount of time required for the development, testing and regulatory review of future product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours or otherwise provide us with a competitive advantage. The patent protection we obtain for our product candidates may not be sufficient enough to provide us with any competitive advantage or our owned or licensed patents may be challenged. In some instances, agreements through which we license patent rights may not give us control over patent prosecution or maintenance, so that we may not be able to control which claims or arguments are presented, how claims are amended, and may not be able to secure, maintain, or successfully enforce necessary or desirable patent protection from those patent rights. We have not had and do not have primary control over patent prosecution and maintenance for certain of the patents and patent applications we license and therefore cannot guarantee that these patents and applications will be prosecuted or maintained in a manner consistent with the best interests of our business. We cannot be certain that patent prosecution and maintenance activities by our licensors have been or will be conducted in compliance with applicable laws and regulations or will result in valid and enforceable patents. Moreover, some of our in- licensed patents and patent applications are, and our future owned and licensed patents may be, co- owned with third parties. If we are unable to obtain an exclusive license to any such third- party co- owners' interest in any future patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co- owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us. It is possible that defects of form in the preparation or filing of our owned or licensed patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments or extensions. If we or our partners, collaborators, licensees, or licensors, whether current or future, fail to establish, maintain or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our partners, collaborators, licensees, or licensors, are not fully cooperative or disagree with us as to the prosecution, maintenance or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our owned or licensed patents or patent applications, such patents may be invalid and / or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have an adverse impact on our business. Pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until a patent issues from such applications. Assuming the other requirements for patentability are met, currently, the first to file a patent application is generally entitled to the patent. However, prior to March 16, 2013, in the United States, the first to invent was entitled to the patent. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Similarly, we cannot be certain that parties from whom we do or may license or purchase patent rights were the first to make relevant claimed inventions, or were the first to file for patent protection for them. If third parties have filed prior patent applications on inventions claimed in our owned or licensed patents or applications that were filed on or before March 15, 2013, an interference proceeding in the United States can be initiated by such third parties to determine who was the first to invent any of the subject matter covered by the patent claims of such owned or licensed patent applications. If third parties have filed such prior applications after March 15, 2013, a derivation proceeding in the United States can be initiated by such third parties to determine whether our owned or licensed invention was derived from theirs. Moreover, because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, our owned and licensed patents or pending patent applications may be challenged in the courts or patent offices in the United States and abroad. There is no assurance that all of the potentially relevant prior art relating to our owned or licensed patents and patent applications has been found. If such prior art exists, it may be used to invalidate a patent, or may prevent a patent from issuing from a pending patent application. For example, such patent filings may be subject to a third- party submission of prior art to the U. S. Patent and Trademark Office (" USPTO "), or to other patent offices around the world. Alternately or additionally, we may become

involved in post- grant review procedures, oppositions, derivation proceedings, ex parte reexaminations, inter partes review, supplemental examinations, or interference proceedings or challenges in district court, in the United States or in various foreign patent offices, including both national and regional, challenging patents or patent applications in which we have rights, including patents on which we rely to protect our business. An adverse determination in any such challenges may result in loss of the patent or in patent or patent application claims being narrowed, invalidated or held unenforceable, in whole or in part, or in denial of the patent application or loss or reduction in the scope of one or more claims of the patent or patent application, any of which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. In addition, given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. Pending and future patent applications may not result in patents being issued that protect our business, in whole or in part, or which effectively prevent others from commercializing competitive products. Competitors may also be able to design around our owned or licensed patents. Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of our owned or licensed patents or narrow the scope of our patent protection. In addition, the laws of foreign countries may not protect our rights to the same extent or in the same manner as the laws of the United States. For example, patent laws in various jurisdictions, including significant commercial markets such as Europe, restrict the patentability of methods of treatment of the human body more than United States law does. ~~If these~~ **Any such** developments ~~were to occur, they~~ could have a material adverse effect on our ability to generate revenue. Issued patents that we have or may obtain or license may not provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our owned or licensed patents by developing similar or alternative technologies or products in a non- infringing manner. Our competitors may also seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend or assert our owned or licensed patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our owned or licensed patents invalid or unenforceable, or that our competitors are competing in a non- infringing manner. Thus, even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives. Any of the foregoing could have a material adverse effect on our business, financial condition, results of operations and prospects. We may become involved in lawsuits to protect or enforce our patents, which could be expensive, time- consuming and unsuccessful. Competitors may infringe, misappropriate or violate our owned or licensed patents or other intellectual property. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time- consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part. There is also a risk that, even if the validity of such patents is upheld, the court will construe the patent' s claims narrowly and refuse to stop the other party from using the technology at issue on the grounds that our owned or licensed patents do not cover such technology. The standards that courts use to interpret patents are not always applied predictably or uniformly and can change, particularly as new technologies develop. As a result, we do not know how much protection, if any, will be given to our owned or licensed patents if we attempt to enforce them and they are challenged in court. An adverse result in any litigation proceeding could put one or more of our owned or licensed patents at risk of being invalidated or interpreted narrowly. Inequitable conduct is frequently raised as a defense during intellectual property litigation. It is believed that all parties involved in the prosecution of our patent applications have complied with their duties of disclosure in the course of prosecuting our patent applications; however, it is possible that legal claims to the contrary could be asserted if we were engaged in intellectual property litigation, and the results of any such legal claims are uncertain due to the inherent uncertainty of litigation. If a court determines that any party involved in the prosecution of our owned or licensed patents failed to comply with its duty of candor, the subject patent could be held to be unenforceable. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. Intellectual property litigation or other legal proceedings may cause us to incur significant expenses and may also absorb significant management time. Uncertainties resulting from our participation in patent litigation or other proceedings could have a material adverse effect on our business. Third parties may initiate legal proceedings alleging that we are infringing, misappropriating or otherwise violating their intellectual property rights, the outcome of which would be uncertain and could harm our business, prospects, operating results and financial condition. Third parties may assert infringement, misappropriation or other claims against us, or other parties we have agreed to indemnify, based on existing third- party patents or patents that may be granted in the future as well as other intellectual property rights. There may be existing third- party patents or patent applications covering aspects of our technology. Furthermore, because patent applications are published sometime after filing, and because applications can take several years to issue, there may be additional currently pending third- party patent applications that are unknown to us, which may later result in issued patents. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. We may not have sufficient resources to bring these actions to a successful conclusion. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of shares of our common stock. Because of the inevitable uncertainty in intellectual property litigation, we could lose a patent infringement or other action asserted against us regardless of our perception of the merits of the case. If we are found to infringe upon, misappropriate or otherwise violate a third party' s intellectual property rights, we could be required to obtain a license from such third party to continue developing and commercializing our products and technology. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we are able to obtain a license, it may be non- exclusive, thereby giving our competitors

access to the same technologies licensed to us. We could be forced, including by court order, to cease commercializing the implicated technology or product. In addition, in any such proceeding or litigation, we could be found liable for monetary damages, which could be significant, including treble damages and attorneys' fees, if we are found to have willfully infringed a patent. A finding of infringement, misappropriation or that we otherwise violated intellectual property rights could prevent us from commercializing our product candidates or force us to cease some or all of our business operations. If we fail to comply with our obligations in our intellectual property licenses with third parties, we could lose license rights that are important to our business. We are a party to intellectual property license agreements with third parties. For example, we have licenses with each of Duke University and Yale University for patents associated with our proprietary technology, **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 product candidates; • our involvement in the prosecution of the licensed patents and our licensors' overall patent enforcement strategy; • the allocation of ownership of inventions and know- how resulting from the joint creation or use of intellectual property by our licensors and by us and our partners; and • the amounts of royalties, milestones or other payments due under the license agreement. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement. If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, or are insufficient to provide us the necessary rights to use the intellectual property, we may be unable to successfully develop and commercialize the affected product candidates. If we or any such licensors fail to adequately protect this intellectual property, our ability to commercialize our products could suffer. Any disputes with our licensors or any termination of the licenses on which we depend could have a material adverse effect on our business, financial condition, results of operations and prospects. We may not be successful in obtaining necessary intellectual property rights to product candidates for our development pipeline through acquisitions and in- licenses. Although we intend to develop product candidates through our own internal research, we may need to obtain additional licenses from others to advance our research or allow commercialization of our product candidates. However, we may be unable to acquire or in- license intellectual property rights relating to, or necessary for, any such product candidates from third parties on commercially reasonable terms or at all. In that event, we may be unable to develop or commercialize such product candidates. We may also be unable to identify additional, future product candidates that we believe are an appropriate strategic fit for our company and intellectual property relating to, or necessary for, such product candidates. The in- licensing and acquisition of third- party intellectual property is a competitive area, and a number of more established companies are also pursuing strategies to in- license or acquire third- party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, cash resources and greater clinical development and commercialization capabilities. Furthermore, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. In addition, we expect that competition for the in- licensing or acquisition of third- party intellectual property rights for product candidates that are attractive to us may increase in the future, which may mean fewer suitable opportunities for us as well as higher acquisition or licensing costs. We may be unable to in- license or acquire the third- party intellectual property rights for product candidates on terms that would allow us to make an appropriate return on our investment. If we are unable to successfully obtain rights to suitable product candidates, our business, financial condition, results of operations and prospects for growth could suffer. We may be unable to protect the confidentiality of our trade secrets, particularly in light of our reliance on third parties, which increases the possibility that such trade secrets will be disclosed or misappropriated, thus harming our business and competitive position. In addition to our patented technology and products, we rely upon trade secrets, including unpatented know- how, technology and other proprietary information to develop and maintain our competitive position, particularly with respect to our manufacturing process. We seek to protect our trade secrets, in part, through confidentiality agreements with our employees, collaborators and consultants. We seek to have agreements with our employees and selected consultants that obligate them to assign any inventions created during their tenure with us. However, we may not obtain these agreements in all circumstances and the assignment of intellectual property under such agreements may not be self- executing. If the employees, collaborators or consultants that are parties to these agreements breach or violate their respective terms, we may not have adequate remedies for any such breach or violation. Our trade secrets could also be misappropriated by our competitors. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret is difficult, expensive, time- consuming and potentially distracting, and the outcome is unpredictable. In addition, some

courts inside and outside the United States are less willing or unwilling to protect trade secrets. If any of our trade secrets were to be lawfully obtained or independently developed by a competitor or other third party, we would have no right to prevent such a party from using that technology or information to compete with us. If our trade secrets are disclosed to or misappropriated or independently developed by a third party, it would harm our ability to protect our rights and could materially harm our business and competitive position. Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets. We may employ individuals or engage consultants that previously worked with other organizations, including our competitors or potential competitors. Although we seek to ensure that such persons do not use the proprietary information or know- how of others in their work for us, we may be subject to claims that we or they, or both, have inadvertently or otherwise used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third party. Litigation may be necessary to defend against these claims. If we fail in defending any such claims or settling those claims, we may lose valuable intellectual property rights or personnel in addition to paying monetary damages or a settlement. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Patent terms may be inadequate to protect our competitive position on our HAVs or our other product candidates for an adequate amount of time. Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U. S. non- provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our HAVs are obtained, once the patent life has expired, we may face competition, including from other competing technologies. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. We may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting, maintaining, defending and enforcing patents on our product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. Consequently, we may not be able to prevent third parties from practicing our inventions in countries outside the United States, or from selling or importing products made using our inventions in and into 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. Many countries have compulsory licensing laws under which a patent owner may be compelled under specified circumstances to grant licenses to third parties. In addition, many countries limit the enforceability of patents against government agencies or government contractors. In those countries, we may have limited remedies if patents are infringed or if we are compelled to grant a license to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license, which could adversely affect our business, financial condition, results of operations, and prospects. Some of our internal intellectual property and most of our in- licensed intellectual property has been generated under U. S. Government grants and contracts that trigger certain obligations and U. S. Government rights and thus is subject to federal regulations such as " march- in " rights, certain reporting requirements and a preference for U. S.- based companies. Compliance with such regulations may limit our exclusive rights and limit our ability to contract with non- U. S. manufacturers. Some of our internal intellectual property and most of our in- licensed intellectual property has been generated under U. S. Government grants and contracts that trigger certain obligations and U. S. Government rights under federal statutes and regulations, including the Bayh- Dole Act of 1980 and the Federal Technology Transfer Act of 1986. For example, the U. S. Government has a non- exclusive, non- transferable, irrevocable worldwide license to inventions conceived or first actually reduced to practice in the performance of a U. S. Government agreement. In addition, the U. S. Government has certain " march- in " rights to require us to grant exclusive, partially exclusive, or non- exclusive licenses to such inventions for the benefit of a third party if the U. S. Government determines that: (i) action is necessary to alleviate health or safety needs not reasonably met by us, our assignees, our licensees, or, in some cases, our licensors, (ii) action is necessary due to noncompliance with a U. S.- based manufacturing requirement applicable to exclusive licenses, (iii) action is necessary to meet requirements for public use specified by federal regulations and such requirements are not reasonably satisfied by us, our assignees, our licensees, and, in some cases, our licensors, and (iv) with respect to inventions made under funding agreements, adequate steps have not been taken to achieve practical application of the invention. The U. S. Government also has the right to take title to these inventions if we, or the applicable licensor, fails to disclose, elect title to, file or prosecute a patent application for, or defend or obtain a patent covering such inventions within time limits specified in particular funding agreements. The U. S. Government also has varying rights to use and disclose information, including copyrighted works, generated or delivered under a U. S. Government agreement depending on the terms of the

agreement and the nature of the information. Intellectual property generated under a U. S. Government agreement is also subject to certain reporting requirements, compliance with which may require us or the applicable licensor to expend substantial resources. In addition, when inventions that are conceived or first actually reduced to practice under a U. S. Government funding agreement are exclusively licensed, products embodying or produced through the use of such inventions must be manufactured substantially in the United States. This U. S.- based manufacturing requirement may limit our ability to contract with non- U. S. companies to produce a covered product, although this requirement can be waived in certain circumstances. To the extent that any of our licensors' current or future intellectual property is generated in the performance of U. S. Government grants or contracts, these requirements may apply to such intellectual property. If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our marks of interest and our business may be adversely affected. Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names or may be forced to stop using these names, which we need for name recognition by potential partners or customers in our markets of interest. During trademark registration proceedings, we may receive rejections. Although we would be given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in the USPTO and in comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. If we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively and our business may be adversely affected. Intellectual property rights do not necessarily address all potential threats. The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. For example: • others may be able to make products that are similar to any product candidates we may develop or utilize similar technology but that are not covered by the claims of the patents that we own or license or may own or license in the future; • we, or our current or future licensors might not have been the first to make the inventions covered by the issued patent or pending patent application that we own or license or may own or license in the future; • we, or our current or future licensors might not have been the first to file patent applications covering certain of our or their inventions; • others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our owned or licensed intellectual property rights; • it is possible that our and our licensors' pending owned or licensed patent applications or those that we may own or license in the future will not lead to issued patents; • issued patents that we hold rights to may be held invalid or unenforceable, including as a result of legal challenges by our competitors; • our competitors might conduct research and development activities in countries where we do not have patent rights and then use the information learned from such activities to develop competitive products for sale in our major commercial markets; • we may not develop additional proprietary technologies that are patentable; • the patents of others may harm our business; and • we may choose not to file a patent in order to maintain certain trade secrets or know- how, and a third party may subsequently file a patent covering such intellectual property. Should any of these events occur, they could harm our business, financial condition, results of operations, and prospects. Risks Related to Business Matters and Our Ability to Manage Growth Our future success depends on our ability to retain our key employees, consultants and advisors and to attract, retain and motivate qualified personnel. We are highly dependent on the research and development, clinical, regulatory, financial, commercial, and manufacturing expertise of the principal members of our management, scientific and clinical teams. The loss of the services of our executive officers or other key employees could impede the achievement of our research, development and commercialization objectives and seriously harm our ability to successfully implement our business strategy. Furthermore, losing or replacing executive officers and key employees may be difficult and may take an extended period of time because of the limited number of individuals in our industry with the breadth of skills and experience required to successfully develop, gain marketing approval of and commercialize our product candidates. Competition to hire from this limited pool is intense. We also experience competition for the hiring of scientific and clinical personnel from public and private universities and research institutions. In addition, we rely on consultants and advisors, including scientific, commercial and clinical advisors, to assist us in formulating our research and development and commercialization strategy. Our consultants and advisors may have commitments under employment, consulting or advisory contracts with other entities that may limit their availability to us. If we are unable to continue to attract and retain high quality personnel, our ability to pursue our growth strategy will be limited. We expect to increase the size of our workforce in the future, and we may encounter difficulties in managing this growth, which could harm our operations. As of December 31, ~~2022~~ **2023**, we had ~~164~~ **185** employees. As we move forward in our efforts to commercialize our HAVs, if approved, we expect to continue to experience significant growth in the number of our employees and the scope of our operations, particularly in the areas of development, regulatory affairs, manufacturing **, 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; • changes in government regulation; • potential or actual military conflicts or acts of terrorism; • announcements concerning ~~Humacyte~~ **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 ~~the~~ **our** business ~~of Humacyte~~. These projections may vary widely and may not accurately predict the results we actually achieve. Our stock price may decline if our actual results do not match the projections of these securities research analysts. Similarly, if one or more of the analysts who write reports on ~~Humacyte~~ **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 ~~Humacyte~~ **the Company** or fails to publish reports on ~~Humacyte~~ **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, ~~2022~~ **2023**, we had warrants outstanding to purchase up to an aggregate of 5, 588, 506 shares of our common stock and options outstanding to purchase up to an aggregate of ~~7~~ **11**, ~~203~~ **919**, ~~874~~ **421** 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, ~~2022~~ **2023** we also have the ability to issue ~~6~~ **1**, ~~700~~ **492**, ~~888~~ **057** 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 commencing January 1, 2022, in an amount equal to 5 % and 1 %, respectively, of the number of shares of our capital stock outstanding on December 31 of the preceding year, unless our board of directors (the " Board ") acts prior to January 1 of a given year to provide that the increase for such year will be a lesser number. **As** ~~At the end~~ of **December 31,** ~~2021~~ **2023** ~~and 2022~~, **we had** ~~our Board elected not to increase~~ the ~~number~~ **Option outstanding to purchase up to $ 10 million worth** of shares **of our common stock** ~~under the 2021 Plan and the ESPP~~. We may also issue additional shares of common stock or other equity securities of equal or senior rank in the future in connection with, among other things, future acquisitions or repayment of outstanding indebtedness, without stockholder approval, in a number of circumstances. Our issuance of additional shares of common stock or other equity securities of equal or senior rank would have the following effects: • our existing stockholders' proportionate ownership interest in ~~Humacyte~~ **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 ~~may~~ **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 of any existing and future outstanding indebtedness we or our subsidiaries incur. As a result, you may not receive any return on an investment in our securities unless you sell your securities for a price greater than that which you paid for it. The Public Warrants may not be in the money in the future, and they may expire worthless, and the terms of the Public Warrants may be amended in a manner adverse to a holder if holders of at least 50 % of the then outstanding Public Warrants approve of such amendment. In connection with the Merger, the Company assumed 5, 000, 000 publicly- traded warrants (" Public Warrants ") and 177, 500 private placement warrants issued to AHAC Sponsor LLC (the " Sponsor "), Oppenheimer & Co. Inc. and Northland Securities, Inc, in connection with AHAC' s initial public offering (" Private Placement Warrants " and, together with the Public Warrants, the " Warrants "). The Warrants were issued in registered form under a warrant agreement between Continental Stock Transfer & Trust Company, as warrant agent, and 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 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, ~~2022~~ **2023** are derivative liabilities related to the Contingent Consideration ~~and ,~~ the Private Placement Warrants **, and the Purchasers' put option under the 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 and the Private Placement Warrants each reporting period and that the amount of such gains or losses could be material. ~~Prior to the Merger, on April 12, 2021, the Acting Director of the Division of Corporation Finance and Acting Chief Accountant of the SEC together issued a statement regarding the accounting and reporting considerations for warrants issued by special purpose acquisition companies entitled " Staff Statement on Accounting and Reporting Considerations for Warrants Issued by Special Purpose Acquisition Companies (" SPACs ") " (the " SEC Statement "). Specifically, the SEC Statement focused on certain settlement terms and provisions related to certain tender offers following a business combination, which terms are similar to those contained in the Public Warrants. As a result of the SEC Statement, prior to the Merger, AHAC reevaluated the accounting treatment of the Public Warrants and determined to classify the Public Warrants as derivative liabilities measured at fair value, with changes in fair value each period reported in earnings. As a result, included on AHAC' s balance sheet as of December 31, 2020 are derivative liabilities related to embedded features contained within the Public Warrants. In connection with its Amended Annual Report on Form 10- K / A for the year ended December 31, 2020, AHAC reached a determination to restate certain previously issued financial statements and related disclosures for the periods disclosed in order to correct the accounting treatment for the Warrants following the publication of the SEC Statement. As a result, prior to the Merger, AHAC incurred unanticipated costs for accounting and legal fees in connection with or related to the restatement, and we may become subject to additional risks and uncertainties related to the restatement. AHAC restated certain previously issued financial statements and related disclosures for the periods disclosed, and as of September 30, 2021, our management concluded that the conditions causing the material weakness that led to these restatements did not exist. However, in the future, we may determine that we have additional material weaknesses. Our failure to remediate any material weaknesses or failure to identify and address any material weaknesses or control deficiencies could result in inaccuracies in our financial statements and could also impair our ability to comply with applicable financial reporting requirements and related regulatory filings on a timely basis, which could cause investors to lose confidence in our reported financial information, which may result in volatility in and a decline in the market price of our common stock.~~ Our business could be adversely impacted by inflation. Increases in inflation may have an adverse effect on our business. Current and future inflationary effects may be driven by, among other things, supply chain disruptions and governmental stimulus or fiscal policies. Continuing increases in inflation could impact the overall demand for our products, our costs for labor, material and services, and the margins we are able to realize on our products, all of which could have an adverse impact on our business, financial position, results of operations and cash flows. Inflation may also result in higher interest rates, which in turn would result in higher interest expense related to our variable rate indebtedness and any borrowings we undertake to refinance existing fixed rate indebtedness. We may be forced to write- down or write- off assets, restructure our operations, or incur impairment or other charges that could result in losses. Even though these charges may be non- cash items and may not have an immediate impact on our liquidity, the fact that we may report charges of this nature could contribute to negative market perceptions about our securities. In addition, charges of this nature may cause us to be unable to obtain future financing on favorable terms or at all. Accordingly, a stockholder could suffer a reduction in the value of their shares. The obligations associated with being a public company involve significant expenses and will require significant resources and management attention, which may divert from our business operations. As a public company, we are subject to the reporting requirements of the Exchange Act and the Sarbanes- Oxley Act. The Exchange Act requires the filing of annual, quarterly and current reports with respect to a public company' s business and financial condition. The Sarbanes- Oxley Act requires, among other things, that a public company establish and maintain effective internal control over financial reporting. As a result, we will incur significant legal, accounting and other expenses ~~that we did not incur as a private company~~ . Our entire management team and many of its other employees ~~will need to devote~~ **devotes** substantial time to compliance ~~, and may not effectively or efficiently manage our transition into a public company~~ . These rules and regulations ~~will~~ result in our incurring substantial legal and financial compliance costs and will make some activities more time- consuming and costly. For example, these rules and regulations have made it more difficult and more expensive for Humacyte to obtain director and officer liability insurance, and it has accepted reduced coverage. As a result, it may be difficult for us to attract and retain qualified people to serve on the Board or committees of the Board or as executive officers. We are an " emerging growth company " and a " smaller reporting company " within the meaning of the rules adopted by the SEC, and if we take advantage of certain exemptions from disclosure requirements available to emerging growth companies and smaller reporting companies, this could make our securities less attractive to investors and may make it more difficult to compare our performance with other public companies. We are an emerging growth company as defined in the JOBS Act, and we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 (b) of the Sarbanes- Oxley Act, reduced

disclosure obligations regarding executive compensation in periodic reports and proxy statements, and exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. As a result, our stockholders may not have access to certain information they may deem important. We could be an emerging growth company for up to five years from the closing of AHAC' s initial public offering, although circumstances could cause us to lose that status earlier, including if the market value of our common stock held by non- affiliates exceeds $ 700 million as of any June 30 before that time, in which case we would no longer be an emerging growth company as of the following December 31. We cannot predict whether investors will find our securities less attractive because we will rely on these exemptions. If some investors find our securities less attractive as a result of our reliance on these exemptions, the trading prices of our securities may be lower than they otherwise would be, there may be a less active trading market for our securities and the trading prices of our securities may be more volatile. Further, Section 102 (b) (1) of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies (that is, those that have not had a Securities Act registration statement declared effective or do not have a class of securities registered under the Exchange Act) are required to comply with the new or revised financial accounting standards. The JOBS Act provides that an emerging growth company can elect to opt out of the extended transition period and comply with the requirements that apply to non- emerging growth companies, but any such an election to opt out is irrevocable. We have elected not to opt out of such extended transition period, which means that when a standard is issued or revised and it has different application dates for public or private companies, we, as an emerging growth company, can adopt the new or revised standard at the time private companies adopt the new or revised standard. This may make comparison of our financial statements with another public company which is neither an emerging growth company nor an emerging growth company which has opted out of using the extended transition period difficult or impossible because of the potential differences in accounting standards used. Additionally, we are a " smaller reporting company " as defined under the Exchange Act. Smaller reporting companies may take advantage of certain reduced disclosure obligations, including, among other things, providing only two years of audited financial statements. We will remain a smaller reporting company for so long as (1) the market value of our common stock held by non- affiliates is less than $ 250 million as of the last business day of the second fiscal quarter, or (2) our annual revenues in our most recent fiscal year completed before the last business day of our second fiscal quarter are less than $ 100 million and the market value of our common stock held by non- affiliates is less than $ 700 million as of the last business day of the second fiscal quarter. To the extent we take advantage of such reduced disclosure obligations, it may also make comparison of our financial statements with other public companies difficult or impossible. If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results. As a result, stockholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our common stock. Effective internal control over financial reporting is necessary for us to provide reliable financial reports. Any failure to implement new or improved controls necessary to maintain effective internal control over financial reporting, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404 of the Sarbanes- Oxley Act, or our independent registered public accounting firm, may identify deficiencies in our internal control over financial reporting that are deemed to be material weaknesses. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the company' s annual or interim financial statements will not be prevented or detected on a timely basis. ~~Ineffective internal~~ **Our failure to remediate any material weaknesses or failure to identify and address any material weaknesses or** control ~~over~~ **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 ~~also~~ cause investors to lose confidence in our reported financial information, which ~~could have~~ **may result in volatility in and** a **decline in** ~~negative effect on~~ the ~~trading~~ **market** price of our common stock ~~. In connection with its Our assessment is that, after the Merger, we have a sufficiently staffed and technically experienced finance and accounting team to address the financial reporting requirements of a public company. Because the conditions causing the material weakness no longer existed, and are not expected to exist in the foreseeable future, we determined the material weakness did not exist in internal control over financial reporting as of September 30, 2021. Prior to the Merger, AHAC' s management concluded that its disclosure controls and procedures were not effective as of December 31, 2020, and that its internal control over financial reporting was not effective as of December 31, 2020, as a result of a material weakness in controls related to the accounting for the Warrants. As a result, AHAC incurred unanticipated costs for accounting and legal fees in connection with or related to the restatement, and we may become subject to additional risks and uncertainties related to the restatement, such as a negative impact on investor confidence in the accuracy of our financial disclosures, and may face reputational risks for our business. Effective as of the closing of the Merger, our management is responsible for internal control over financial reporting and the former management of AHAC no longer participates in financial reporting~~ . As long as we are an emerging growth company under the JOBS Act or a non- accelerated filer and a " smaller reporting company " as defined in Rule 12b- 2 of the Exchange Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 (b) of the Sarbanes- Oxley Act. An independent assessment of the effectiveness of our internal control over financial reporting could detect deficiencies that our management' s assessment might not. Undetected material weaknesses in our internal control over financial reporting could lead to financial statement restatements and require us to incur the expense of remediation. Anti- takeover provisions in our Second Amended and Restated Certificate of Incorporation and under Delaware law could make an acquisition of ~~our~~ **the** ~~company~~ **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.