



August 6, 2024

VIA EDGAR

U.S. Securities and Exchange Commission
Division of Corporation Finance
Office of Life Sciences
100 F Street, N.E.
Washington, D.C. 20549

Attention: Christine Torney and Vanessa Robertson

Re: Humacyte, Inc.
Form 10-K for the Year Ended December 31, 2023
Filed March 28, 2024
File No. 001-3953

Dear Mses. Torney and Robertson:

Humacyte, Inc. (the "Company," "we," or "our") hereby submits this letter in response to the comments of the staff of the Division of Corporation Finance (the "Staff") of the U.S. Securities and Exchange Commission, dated July 23, 2024, with respect to the above-referenced filing.

Set forth below is the heading and text of the Staff comment, followed by the Company's response.

Form 10-K for the fiscal year ended December 31, 2023
Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations
Results of Operations
Research and Development Expenses, page 99

- 1. You disclose on page 97 that you do not allocate all of your costs by each research and development program. You disclose that a significant amount of your development activities broadly support multiple programs that use your technology platform. Please provide revised disclosure to be included in future filings to clarify which expenses you do allocate by project and clarify if you track any expenses by therapeutic indication. To the extent you do track any research and development expenses by program, provide a breakdown of the expenses tracked by project to be included in future filings.**

Response:

The Company respectfully advises the Staff that, in future filings, the Company will revise its disclosure to clarify which expenses are allocated by therapeutic indication. Please refer to Exhibit A for a representative example of the revised disclosure (deleted text shown as stricken and new text shown in italicized and underlined type).

Please do not hesitate to call me if you have any questions or require any additional information.

Sincerely,

/s/ Dale A. Sander

Dale A. Sander

Chief Financial Officer

cc: Kerry Shannon Burke, Covington & Burling LLP

Exhibit A

Draft Example Disclosure

Components of Results of Operations

Research and Development Expenses

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

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

The majority of our research and development resources are currently focused on our Phase 2 and 3 clinical trials for our 6 millimeter *ATEV* and other work needed to obtain marketing approval for our 6 millimeter *ATEV* for use for vascular repair, reconstruction and replacement, including *indications in* vascular trauma and AV access in hemodialysis in the United States. We have incurred and expect to continue to incur significant expenses in connection with these and our other clinical development efforts, including expenses related to regulatory filings, trial enrollment and conduct, data analysis, patient follow up and study report generation for our Phase 2 and Phase 3 clinical trials. ~~We do not allocate all of our costs by each research and development program for which we are developing our cabinet of ATEVs, as a significant amount of our development activities broadly support multiple programs that use our technology platform. We plan to further increase our research and development expenses for the foreseeable future as we continue the development of our proprietary scientific technology platform and our novel manufacturing paradigm~~

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

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

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

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

Results of Operations

Research and Development Expenses

The following table summarizes our research and development expenses for the periods indicated:

(\$ in thousands)	<u>[Period Ended _____,]</u>		<u>Change</u>	
	<u>[202_]</u>	<u>[202_]</u>	<u>\$</u>	<u>%</u>
<u>Direct Expenses</u>				
<i>Vascular Trauma</i>				
<i>AV Access</i>				
<i>PAD</i>				
<i>Total</i>				
<u>Unallocated Expenses</u>				
External services				
Materials and supplies				
Payroll and personnel expenses				
Other research and development expenses				
<i>Total</i>				
<u>Total research and development expenses</u>				