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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 2024

OR

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

For the transition period from _____ to _____.

Commission File Number: 001-39532

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

Delaware	**85-1763759**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
2525 East North Carolina Highway 54 **Durham, NC**	
(Address of principal executive offices)	**27713** (Zip code)

(919) 313-9633
(Registrant's telephone number, including area code)

Not Applicable
(Former name, former address and former fiscal year, if changed since last report)

Securities registered pursuant to 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	**HUMA**	**The Nasdaq Stock Market LLC**
Redeemable Warrants, each whole warrant exercisable for one share of Common Stock at an exercise price of $11.50	**HUMAW**	**The Nasdaq Stock Market LLC**

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

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		Emerging growth company	☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

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

As of November 1, 2024, 125,859,496 shares of common stock, par value $0.0001, were issued and outstanding.

Humacyte, Inc.
Quarterly Report on Form 10-Q
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FORWARD-LOOKING STATEMENTS

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

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

- the outcome of the United States ("U.S.") Food and Drug Administration ("FDA") review of our Biologics License Application ("BLA") seeking approval of our bioengineered human acellular vessels (Acellular Tissue Engineered Vessel or "ATEV™", formerly referred to as the "Human Acellular Vessel" or "HAV") in urgent arterial repair following extremity vascular trauma when synthetic graft is not indicated and autologous vein graft is not feasible;
- our plans and ability to execute product development, process development and preclinical development efforts successfully and on our anticipated timelines;
- our plans, anticipated timeline and ability to file applications for, and obtain marketing approvals from, the U.S. FDA and other regulatory authorities, including the European Medicines Agency, for our ATEV and other product candidates;
- our ability to design, initiate and successfully complete clinical trials and other studies for our product candidates and our plans and expectations regarding our ongoing or planned clinical trials, including for our V007 and V012 Phase 3 clinical trials;
- the outcome of our ongoing discussions with the FDA concerning our BLA for vascular trauma and the design of our clinical trials;
- our anticipated growth rate and market opportunities;
- the potential liquidity and trading of our securities;
- our ability to raise additional capital in the future;
- our ability to use our proprietary scientific technology platform to build a pipeline of additional product candidates;
- the characteristics and performance of our ATEVs;
- our plans and ability to commercialize our ATEVs and other product candidates, if approved by regulatory authorities;
- the degree of market acceptance of ATEVs, if approved by regulatory authorities, and the availability of third-party coverage and reimbursement;
- our ability to manufacture ATEVs and other product candidates in sufficient quantities to satisfy our clinical trial and commercial needs, if approved by regulatory authorities;
- our expectations regarding our strategic partnership with Fresenius Medical Care Holdings, Inc. ("Fresenius Medical Care") to sell, market and distribute our 6 millimeter ATEV for certain specified indications and in specified markets, if approved by regulatory authorities;
- the expected size of the target populations for our product candidates;
- the anticipated benefits of our ATEVs relative to existing alternatives;
- our assessment of the competitive landscape;

- the performance of other third parties on which we rely, including our third-party manufacturers, our licensors, our suppliers and the organizations conducting our clinical trials;
- our ability to obtain and maintain intellectual property protection for our product candidates as well as our ability to operate our business without infringing, misappropriating or otherwise violating the intellectual property rights of others;
- our ability to maintain the confidentiality of our trade secrets, particularly with respect to our manufacturing process;
- our compliance with applicable laws and regulatory requirements, including FDA regulations, healthcare laws and regulations, and anti-corruption laws;
- our ability to attract, retain and motivate qualified personnel and to manage our growth effectively;
- our estimates regarding how long our existing cash and cash equivalents will be sufficient to fund our anticipated operating expenses, capital expenditures and debt service obligations;
- our future financial performance and capital requirements;
- our ability to implement and maintain effective internal controls; and
- the impact of the overall global economy and increasing interest rates and inflation on our business.

We caution readers not to place undue reliance on any such forward-looking statements, which speak only as of the date they are made. Any forward-looking statements are based on information current as of the date of this Quarterly Report and speak only as of the date on which such statements are made. Actual events or results may differ materially from the results, plans, intentions or expectations anticipated in these forward-looking statements as a result of a variety of factors, many of which are beyond our control. More information on factors that could cause actual results to differ materially from those anticipated is included from time to time in our reports filed with the Securities and Exchange Commission (the "SEC"), including, but not limited to, those described in the sections titled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in this Quarterly Report and our Annual Report on Form 10-K for the year ended December 31, 2023, which we filed with the SEC on March 28, 2024. We disclaim any obligation, except as specifically required by law, to publicly update or revise any such statements to reflect any change in our expectations or in events, conditions or circumstances on which any such statements may be based, or that may affect the likelihood that actual results will differ from those set forth in the forward-looking statements.

PART I – FINANCIAL INFORMATION

Item 1. Financial Statements

Humacyte, Inc.
Condensed Consolidated Balance Sheets
(unaudited)
(in thousands except for share and per share amounts)

	September 30, 2024	December 31, 2023
ASSETS		
Current assets		
Cash and cash equivalents	$ 20,571	$ 80,448
Prepaid expenses and other current assets	2,434	2,830
Total current assets	23,005	83,278
Restricted cash	50,209	209
Property and equipment, net	24,250	26,791
Finance lease right-of-use assets, net	16,013	17,313
Other long-term assets	1,287	632
Total assets	**$ 114,764**	**$ 128,223**
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
Current liabilities		
Accounts payable	$ 6,903	$ 6,490
Accrued expenses	11,151	9,340
Finance lease obligation, current portion	2,831	2,560
Operating lease obligation, current portion	57	53
Total current liabilities	20,942	18,443
Contingent Earnout Liability	76,569	37,916
Revenue interest liability	62,117	38,600
Finance lease obligation, net of current portion	14,379	16,293
Contingent derivative liability	3,105	2,636
Other long-term liabilities	1,373	789
Total liabilities	**178,485**	**114,677**
Commitments and contingencies (Note 11)		
Stockholders' equity (deficit)		
Preferred stock, $0.0001 par value; 20,000,000 shares designated as of September 30, 2024 and December 31, 2023; 0 shares issued and outstanding as of September 30, 2024 and December 31, 2023	—	—
Common stock, $0.0001 par value; 250,000,000 shares authorized as of September 30, 2024 and December 31, 2023; 119,842,940 and 103,673,728 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	12	10
Additional paid-in capital	601,342	550,850
Accumulated deficit	(665,075)	(537,314)
Total stockholders' equity (deficit)	(63,721)	13,546
Total liabilities and stockholders' equity (deficit)	**$ 114,764**	**$ 128,223**

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

Humacyte, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(unaudited)
(in thousands except for share and per share amounts)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2024	2023	2024	2023
Revenue	$ —	$ —	$ —	$ —
Operating expenses:				
Research and development	22,926	18,552	67,943	56,370
General and administrative	7,307	6,070	18,367	17,495
Total operating expenses	30,233	24,622	86,310	73,865
Loss from operations	**(30,233)**	**(24,622)**	**(86,310)**	**(73,865)**
Other income (expense), net:				
Interest income	911	1,369	3,252	4,323
Change in fair value of Contingent Earnout Liability	(8,489)	(1,144)	(38,653)	(11,708)
Interest expense	(2,438)	(1,463)	(6,769)	(4,872)
Change in fair value of derivatives	1,047	(135)	719	(234)
Employee retention credit	—	—	—	3,107
Loss on extinguishment of debt	—	—	—	(2,421)
Total other expense, net	(8,969)	(1,373)	(41,451)	(11,805)
Net loss and comprehensive loss	**$ (39,202)**	**$ (25,995)**	**$ (127,761)**	**$ (85,670)**
Net loss per share attributable to common stockholders, basic and diluted	$ (0.33)	$ (0.25)	$ (1.10)	$ (0.83)
Weighted-average shares outstanding used in computing net loss per share attributable to common stockholders, basic and diluted	119,408,565	103,444,246	115,623,616	103,357,087

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

Humacyte, Inc.
Condensed Consolidated Statements of Changes in Stockholders' Equity (Deficit)
(unaudited)
(in thousands except for share amounts)

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount			
Balance as of December 31, 2023	**103,673,728**	**$ 10**	**$ 550,850**	**$ (537,314)**	**$ 13,546**
Issuance of stock in public offering, net of issuance costs	15,410,000	2	43,044	—	43,046
Proceeds from the exercise of stock options	625	—	2	—	2
Stock-based compensation	—	—	1,454	—	1,454
Net loss	—	—	—	(31,896)	(31,896)
Balance as of March 31, 2024	**119,084,353**	**$ 12**	**$ 595,350**	**$ (569,210)**	**$ 26,152**
Proceeds from the exercise of stock options	263,335	—	787	—	787
Stock-based compensation	—	—	1,437	—	1,437
Net loss	—	—	—	(56,663)	(56,663)
Balance as of June 30, 2024	**119,347,688**	**$ 12**	**$ 597,574**	**$ (625,873)**	**$ (28,287)**
Issuance of commitment shares pursuant to Common Stock Purchase Agreement	115,705	—	708	—	708
Proceeds from sale of stock under Common Stock Purchase Agreement	200,000	—	1,013	—	1,013
Proceeds from the exercise of stock options	179,547	—	495	—	495
Stock-based compensation	—	—	1,552	—	1,552
Net loss	—	—	—	(39,202)	(39,202)
Balance as of September 30, 2024	**119,842,940**	**$ 12**	**$ 601,342**	**$ (665,075)**	**$ (63,721)**

	Common Stock		Additional Paid-in Capital	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount			
Balance as of December 31, 2022	**103,229,013**	**$ 10**	**$ 543,456**	**$ (426,538)**	**$ 116,928**
Proceeds from the exercise of stock options	100,158	—	119	—	119
Stock-based compensation	—	—	1,809	—	1,809
Net loss	—	—	—	(36,969)	(36,969)
Balance as of March 31, 2023	**103,329,171**	**$ 10**	**$ 545,384**	**$ (463,507)**	**$ 81,887**
Proceeds from the exercise of stock options	79,077	—	95	—	95
Stock-based compensation	—	—	1,841	—	1,841
Net loss	—	—	—	(22,706)	(22,706)
Balance as of June 30, 2023	**103,408,248**	**$ 10**	**$ 547,320**	**$ (486,213)**	**$ 61,117**
Proceeds from the exercise of stock options	52,588	—	99	—	99
Stock-based compensation	—	—	1,772	—	1,772
Net loss	—	—	—	(25,995)	(25,995)
Balance as of September 30, 2023	**103,460,836**	**$ 10**	**$ 549,191**	**$ (512,208)**	**$ 36,993**

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

Humacyte, Inc.
Condensed Consolidated Statements of Cash Flows
(unaudited)
(in thousands)

	For the Nine Months Ended September 30,	
	2024	**2023**
Cash flows from operating activities		
Net loss	$ (127,761)	$ (85,670)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation expense	3,819	4,341
Stock-based compensation expense	4,443	5,422
Change in fair value of Contingent Earnout Liability	38,653	11,708
Non-cash interest expense	5,606	1,780
Change in fair value of derivatives	(719)	234
Loss on extinguishment of debt	—	2,421
Loss on disposal of property and equipment	—	9
Amortization expense	1,563	1,545
Non-cash operating lease costs	39	37
Amortization of SVB debt discount	—	482
Changes in operating assets and liabilities:		
Accounts receivable	—	31
Prepaid expenses and other current assets	396	(423)
Accounts payable	475	1,292
Accrued expenses	1,980	2,577
Operating lease obligation	(39)	(37)
Net cash used in operating activities	(71,545)	(54,251)
Cash flows from investing activities		
Purchase of property and equipment	(1,509)	(2,130)
Proceeds from maturity of short-term investments (certificates of deposit)	—	2,107
Net cash used in investing activities	(1,509)	(23)
Cash flows from financing activities		
Proceeds from issuance of stock in public offering, net of underwriting fees	43,396	—
Payments of costs related to public offering	(350)	—
Proceeds from Revenue Interest Purchase Agreement, net of issuance costs	20,000	39,377
Payments of transaction costs related to Revenue Interest Purchase Agreement	(500)	(1,450)
Proceeds from sale of common stock under Common Stock Purchase Agreement	1,013	—
Proceeds from the exercise of stock options	1,284	313
Proceeds from JDRF Agreement	240	80
Payments of finance lease principal	(1,906)	(1,668)
Principal payments on SVB loan	—	(31,500)
Payments for debt prepayment and extinguishment costs	—	(310)
Net cash provided by financing activities	63,177	4,842
Net decrease in cash, cash equivalents and restricted cash	(9,877)	(49,432)
Cash, cash equivalents and restricted cash at the beginning of the period	80,801	149,772
Cash, cash equivalents and restricted cash at the end of the period	**$ 70,924**	**$ 100,340**
Supplemental disclosure:		
Cash paid for interest on SVB loan	$ —	$ 1,613
Supplemental disclosure of noncash activities:		
Debt discount from embedded contingent derivative liability	$ 1,552	$ 2,354
Issuance of commitment shares pursuant to Common Stock Purchase Agreement	$ 708	$ —

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

Humacyte, Inc.
Notes to Condensed Consolidated Financial Statements
(unaudited)

1. Organization and Description of Business

Organization

Humacyte, Inc. and subsidiaries (unless the context indicates otherwise, collectively, the "Company") is pioneering the development and manufacture of off-the-shelf, universally implantable, bioengineered human tissues, advanced tissue constructs and organ systems with the goal of improving the lives of patients and transforming the practice of medicine. The Company is leveraging its regenerative medicine technology platform to develop proprietary product candidates for use in the treatment of diseases and conditions across a range of anatomic locations in multiple therapeutic areas.

On August 26, 2021 (the "Closing Date"), Alpha Healthcare Acquisition Corp. ("AHAC") consummated a merger pursuant to a Business Combination Agreement, dated as of February 17, 2021 (the "Merger Agreement"), by and among Humacyte, Inc. ("Legacy Humacyte"), AHAC and Hunter Merger Sub, Inc. ("Merger Sub"), a wholly owned subsidiary of AHAC. As contemplated by the Merger Agreement, Merger Sub merged with and into Legacy Humacyte, with Legacy Humacyte continuing as the surviving corporation and as a wholly-owned subsidiary of AHAC (such transactions, the "Merger," and, collectively with the other transactions described in the Merger Agreement, the "Reverse Recapitalization"). On the Closing Date, AHAC changed its name to Humacyte, Inc. and Legacy Humacyte changed its name to Humacyte Global, Inc. ("Global"). The Merger was accounted for as a reverse recapitalization in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP"), and under this method of accounting, AHAC was treated as the acquired company for financial reporting purposes and Legacy Humacyte was treated as the acquirer. Operations prior to the Merger are those of Legacy Humacyte.

Liquidity and Going Concern

Since its inception in 2004, the Company has generated no product revenue and has incurred operating losses and negative cash flows from operations in each year. To date, the Company has financed its operations primarily through the sale of equity securities and convertible debt, proceeds from the Reverse Recapitalization, borrowings under loan facilities, proceeds from a revenue interest purchase agreement and, to a lesser extent, through governmental and other grants. At September 30, 2024 and December 31, 2023, the Company had an accumulated deficit of $665.1 million and $537.3 million, respectively. The Company's operating losses were $86.3 million and $73.9 million for the nine months ended September 30, 2024 and 2023, respectively. Net cash flows used in operating activities were $71.5 million and $54.3 million during the nine months ended September 30, 2024 and 2023, respectively. Substantially all of the Company's operating losses resulted from costs incurred in connection with the Company's research and development programs and from general and administrative costs associated with the Company's operations. On August 9, 2024, the FDA informed the Company that the FDA required additional time to complete its review of the Company's BLA for the ATEV in adults as a vascular conduit for extremity arterial injury when urgent revascularization is needed to avoid imminent limb loss, and autologous vein graft is not feasible. The Company will have an additional $40.0 million available for draw under the Purchase Agreement (as defined below) upon the Company receiving FDA approval of the ATEV for the vascular trauma indication on or prior to December 31, 2024. The Company expects to incur substantial operating losses and negative cash flows from operations for the foreseeable future as the Company advances its product candidates.

As further disclosed in Note 6, on May 12, 2023, Humacyte, Inc. and Global entered into a Revenue Interest Purchase Agreement (the "Purchase Agreement") with two purchasers, both affiliates of Oberland Capital Management LLC (the "Purchasers"), and another affiliate of Oberland Capital Management LLC, as agent for the Purchasers, to obtain financing with respect to the further development and commercialization of the Company's ATEV, to repay the Company's then-existing credit facility with Silicon Valley Bank ("SVB"), and for other general corporate purposes. As of September 30, 2024, $62.1 million was recorded as a revenue interest liability on the condensed consolidated balance sheet.

The Purchase Agreement contains customary representations and warranties and affirmative covenants for transactions of this type, including, among others, the provision of financial and other information to the Purchaser, notice to the Purchaser upon the occurrence of certain material events, and compliance with applicable laws. The Purchase Agreement also contains customary negative covenants, including certain restrictions on the ability to incur indebtedness and grant liens or security interests on assets. On February 18, 2024, the Company reached an agreement with the Purchasers and the Agent to waive certain breaches related to, and extend the deadline for certain post-closing obligations under, the Purchase Agreement, including the requirement for the Company to deliver a leasehold mortgage in favor of the Agent over the Company's headquarters. On May 8, 2024, the Company agreed with the Purchasers to amend the Purchase Agreement to remove requirements related to the leasehold mortgage. In exchange for removing this requirement, the Company agreed to fund an account in the amount of $54.0 million over which the Agent has certain consent and other rights to $50.0 million of the funds. The Company funded an account with the required $54.0 million on August 14, 2024. As of September 30, 2024, the $50.0 million was classified as restricted cash on the accompanying condensed consolidated balance sheet.

The Company is required to evaluate whether there are conditions and events, considered in the aggregate, that raise substantial doubt about its ability to continue as a going concern for at least one year from the issuance date of its financial statements. As of September 30, 2024, the Company had cash and cash equivalents of $20.6 million and restricted cash of $50.4 million.

As further disclosed in Note 8, on September 24, 2024, the Company entered into a common stock purchase agreement with Lincoln Park Capital Fund, LLC ("Lincoln Park") for an equity line financing (the "Common Stock Purchase Agreement"). The Common Stock Purchase Agreement provides that, subject to the terms and conditions set forth therein, the Company has the sole right, but not the obligation, to sell to Lincoln Park shares of the Company's common stock, par value $0.0001 per share ("Common Stock"), having an aggregate value of up to $50.0 million (the "Purchase Shares") over a 24-month period. The Company controls the timing and amount of any sales of Purchase Shares to Lincoln Park pursuant to the Common Stock Purchase Agreement in its sole discretion. As of September 30, 2024, the Company had $49.0 million in remaining availability for sales of Common Stock under the Common Stock Purchase Agreement. As of September 30, 2024, the Company had completed sales of shares under the Common Stock Purchase Agreement that provided $1.0 million in gross proceeds, and as further disclosed in Note 13, from September 30, 2024 through November 8 2024, the Company completed sales of shares to Lincoln Park that provided $1.5 million in additional gross proceeds.

As further disclosed in Note 13, on October 7, 2024, the Company received net proceeds of approximately $28.1 million in connection with the closing of the Registered Direct Offering (as defined in Note 13).

As noted above, the Company funded the restricted cash account, in accordance with the amended Purchase Agreement, of which $50.0 million is not subject to the Company's unilateral control. Based on current plans and assumptions, which exclude this $50.0 million of cash and the potential approval of the BLA from its forecasted liquidity, the Company will not have sufficient cash and cash equivalents to fund its operations beyond one year from the issuance of these financial statements if the Company is unable to achieve approval of the ATEV and generate sufficient cash flows from commercial sales on a timely basis and/or obtain additional capital. These factors raise substantial doubt about the Company's ability to continue as a going concern. Accordingly, the Company will, over the course of the next year, require additional financing to continue its operations. Adequate additional capital may not be available to the Company when needed or on acceptable terms. If the Company is unable to raise sufficient capital when required, the Company may be required to reduce or discontinue its operations, sell assets, or cease all operations. The accompanying unaudited condensed consolidated financial statements have been prepared assuming that the Company will continue as a going concern and contemplate the realization of assets and the satisfaction of liabilities in the normal course of business. The accompanying financial statements do not include any adjustments related to the recoverability and classification of assets or the amounts and classification of liabilities or any other adjustments that might be necessary should the Company be unable to continue as a going concern.

2. Summary of Significant Accounting Policies

Basis of Presentation

The Company has prepared the accompanying financial statements in conformity with U.S. GAAP. The Company's condensed consolidated financial statements reflect the operations of the Company and its wholly owned subsidiaries. All intercompany accounts and transactions have been eliminated in consolidation.

Humacyte, Inc.
Notes to Condensed Consolidated Financial Statements
(unaudited)

Use of Estimates

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

Unaudited Interim Condensed Consolidated Financial Statements

The accompanying interim condensed consolidated financial statements and the related footnote disclosures are unaudited. These unaudited interim financial statements have been prepared on the same basis as the audited financial statements and, in management's opinion, include all adjustments, consisting of only normal recurring adjustments, necessary for the fair statement of the Company's financial position as of September 30, 2024 and its results of operations for the three and nine months ended September 30, 2024 and 2023, and cash flows for the nine months ended September 30, 2024 and 2023. The results of operations for the three and nine months ended September 30, 2024 are not necessarily indicative of the results to be expected for the year ending December 31, 2024 or any other period. The December 31, 2023 year-end condensed consolidated balance sheet was derived from audited annual financial statements but does not include all disclosures from the annual financial statements.

Certain information and footnote disclosures normally included in consolidated financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to such rules and regulations. Accordingly, these condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements for the year ended December 31, 2023 and the related notes included in the Company's Annual Report on Form 10-K, filed with the SEC on March 28, 2024 (the "Annual Report"), which provides a more complete discussion of the Company's accounting policies and certain other information. There have been no significant changes to the significant accounting policies disclosed in Note 2 of the audited consolidated financial statements as of and for the years ended December 31, 2023 and 2022 included in the Company's Annual Report.

Reclassifications

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

Segments

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

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents, including amounts classified as restricted cash. Total cash balances exceeded insured balances by the Federal Deposit Insurance Corporation as of September 30, 2024 and December 31, 2023. The Company believes it mitigates this risk by monitoring the financial stability of the institutions holding material cash and cash equivalents balances. The Company maintains the majority of these balances at a Global Systemically Important Bank, as designated by the Financial Stability Board. As of both September 30, 2024 and December 31, 2023, the Company had cash equivalents held in highly rated money market funds that are invested only in obligations of the U.S. government and its agencies. The Company has not experienced any credit loss relating to its cash and cash equivalents.

Restricted Cash

The Company classifies as restricted cash all cash pledged as collateral to secure long-term obligations and all cash whose use is otherwise limited by contractual provisions. As of September 30, 2024, restricted cash includes $50.0 million maintained in an account that is not subject to the Company's unilateral control, in accordance with the amended Purchase Agreement. As of September 30, 2024 and December 31, 2023, the Company classified $0.2 million in funds maintained in a separate deposit account to secure a letter of credit for the benefit of the lessor of the Company's headquarters lease, and $0.1 million in cash balances held as collateral for the Company's employee credit card program as restricted cash.

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported within the condensed consolidated balance sheets to the total of the amounts shown in the condensed consolidated statements of cash flows as of September 30, 2024 and December 31, 2023.

($ in thousands)	September 30, 2024	December 31, 2023
Cash and cash equivalents	$ 20,571	$ 80,448
Restricted cash included in prepaid expenses and other current assets	144	144
Restricted cash included in long-term assets	50,209	209
Total cash, cash equivalents and restricted cash	$ 70,924	$ 80,801

Employee Retention Credit

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

Net Loss per Share Attributable to Common Stockholders

Basic net loss per share attributable to common stockholders is computed by dividing net loss attributable to common stockholders by the weighted-average number of shares of Common Stock outstanding during the period without consideration of potentially dilutive shares of Common Stock. Diluted net loss per share attributable to common stockholders reflects the potential dilution that could occur if securities or other contracts to issue Common Stock were exercised or converted into Common Stock or resulted in the issuance of Common Stock that then shared in the earnings of the Company unless inclusion of such shares would be anti-dilutive. As the Company has incurred losses for the three and nine months ended September 30, 2024 and 2023, basic and diluted net loss per share is the same for each period.

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

	Three and Nine Months Ended September 30,	
	2024	2023
Exercise of options under stock plan	12,287,369	7,170,891
Warrants to purchase Common Stock	5,588,506	5,588,506

The 15,000,000 Contingent Earnout Shares, as defined in Note 8, are excluded from the anti-dilutive table for all periods presented, as such shares are contingently issuable until the share price of the Company exceeds specified thresholds that have not yet been achieved, or upon the occurrence of a change in control. The Option Agreement, as defined in Note 6 — Revenue Interest Purchase Agreement, is excluded from the anti-dilutive table for all periods presented based on the Company's assumption that the Option Agreement will not be exercised unless the Company's stock price exceeds $7.50 per share, the minimum purchase price under the Option Agreement.

Other Risks and Uncertainties

The Company is subject to risks and uncertainties common to early-stage companies in the biotechnology industry, including, but not limited to, successful discovery and development of its product candidates, the success of clinical trials and other studies for its product candidates, including its ongoing V007 and V012 Phase 3 clinical trials, the regulatory approval and commercialization of its ATEVs and other product candidates, the expected size of the target populations for the Company's product candidates, the degree of market acceptance of the ATEVs, if approved, the availability of third-party coverage and reimbursement, development by competitors of new technological innovations, the ability to manufacture ATEVs and other product candidates in sufficient quantities, expectations regarding the Company's strategic partnerships, dependence on third parties, key personnel and the ability to attract and retain qualified employees, protection of proprietary technology and confidentiality of trade secrets, compliance with governmental regulations, the Company's implementation and maintenance of effective internal controls, and the ability to secure additional capital to fund operations and the commercial success of its product candidates.

Product candidates currently under development will require extensive preclinical and clinical testing and regulatory approval prior to commercialization. These efforts require significant amounts of additional capital, adequate personnel, and infrastructure and extensive compliance-reporting capabilities. Even if the Company's commercialization efforts are successful, it is uncertain when, if ever, the Company will realize significant revenue from product sales, and the Company may depend on certain strategic relationships to distribute its products, including the Company's strategic partnership with Fresenius Medical Care, to sell, market and distribute its 6 millimeter ATEV for certain specified indications outside the United States.

Recent Accounting Pronouncements

In November 2023, the FASB issued ASU No. 2023-07, "Segment Reporting (Topic 280), Improvements to Reportable Segment Disclosures" ("ASU 2023-07"). The FASB issued this update to improve the disclosures about an entity's reportable segments, including providing more detailed information about a reportable segment's expenses, enhancing interim disclosure requirements and providing new segment disclosure requirements for entities with a single reportable segment. This standard is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024, with early adoption permitted. Entities should apply the amendments retrospectively to all prior periods presented in the financial statements. This ASU is applicable to the Company's Annual Report on Form 10-K for the fiscal year ending December 31, 2024, and subsequent interim periods. The Company is currently evaluating the impact of adopting ASU 2023-07 on its disclosures included in the notes to the consolidated financial statements.

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

3. Fair Value Measurements

Fair value is defined as the price that would be received to sell an asset or paid to transfer a liability in the principal or most advantageous market in an orderly transaction between market participants at the measurement date. ASC 820, *Fair Value Measurement and Disclosures*, establishes a hierarchy whereby inputs to valuation techniques used in measuring fair value are prioritized, or the fair value hierarchy. There are three levels to the fair value hierarchy based on reliability of inputs, as follows:

- Level 1 — Observable inputs that reflect unadjusted quoted prices for identical assets or liabilities in active markets.
- Level 2 — Inputs other than quoted prices included in Level 1 that are observable for the asset or liability, such as quoted prices for similar assets or liabilities, quoted prices in markets that are not active, or other inputs that are observable or can be corroborated by observable market data for substantially the full term of the assets or liabilities.
- Level 3 — Unobservable inputs in which little or no market data exists, therefore requiring the Company to develop its own assumptions.

The Company's money market funds are classified within Level 1 of the fair value hierarchy because they are valued using quoted market prices. The carrying values of cash, prepaid expenses and other current assets, accounts payable and accrued expenses as of September 30, 2024 and December 31, 2023 approximated their fair values due to the short-term nature of these items.

The Company evaluates assets and liabilities subject to fair value measurements on a recurring basis to determine the appropriate level at which to classify them for each reporting period, utilizing valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible. The determination requires significant judgments to be made by the Company.

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

	Fair Value Measured as of September 30, 2024			
($ in thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets:				
Cash equivalents (money market funds)	$ 13,465	$ —	$ —	$ 13,465
Common Stock Purchase Agreement derivative asset	—	694	—	694
Total financial assets	$ 13,465	$ 694	$ —	$ 14,159
Liabilities:				
Contingent Earnout Liability	$ —	$ —	$ 76,569	$ 76,569
Contingent derivative liability	—	—	3,105	3,105
Private Placement Warrants liability	—	—	374	374
Option Agreement liability	—	—	86	86
JDRF Agreement derivative liability	—	—	126	126
Total financial liabilities	$ —	$ —	$ 80,260	$ 80,260

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

The fair value of the Contingent Earnout Liability, Private Placement Warrants liability (each as defined in Note 8 — Stockholders' Equity (Deficit)), contingent derivative liability related to the Put Option (as defined in Note 6 — Revenue Interest Purchase Agreement and discussed below), Option Agreement liability (as defined in Note 6 — Revenue Interest Purchase Agreement), and the derivative liability associated with the JDRF Agreement Disposition Payment are based on significant unobservable inputs, which represent Level 3 measurements within the fair value hierarchy. The fair values of the Private Placement Warrants liability, the Option Agreement liability and the derivative liability associated with the JDRF Agreement Disposition Payment, are included in other long-term liabilities on the condensed consolidated balance sheets.

Common Stock Purchase Agreement

The Company evaluated the Common Stock Purchase Agreement and determined that the agreement should be accounted for in accordance with ASC 815-40, "*Derivatives and Hedging — Contracts on an Entity's Own Equity*". Accordingly, the Company recorded a derivative asset with an initial fair value based on the 115,705 shares of Common Stock issued to Lincoln Park as consideration for its irrevocable commitment to purchase up to $50.0 million in shares of Common Stock. The initial fair value of $0.7 million was based on the closing price of the Common Stock on September 24, 2024, which was $6.12 per share, and the derivative asset is reported as a component of long-term assets on the condensed consolidated balance sheets. Subsequent changes in the fair value of the derivative asset are dependent upon, among other things, changes in the closing share price of Common Stock, the quantity and purchase price of the shares purchased by Lincoln Park during the reporting period and the unused capacity under the Common Stock Purchase Agreement. The Common Stock Purchase Agreement is subsequently remeasured at each reporting date with changes in fair value recorded as a component of other income (expense), net in the condensed consolidated statements of operations and comprehensive loss. The change in fair value of the derivative asset between the September 24, 2024 issuance date and September 30, 2024 was insignificant.

Contingent Earnout Liability

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

	Contingent Earnout Liability			
	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in thousands)	2024	2023	2024	2023
Fair value as of beginning of period	$ (68,080)	$ (38,457)	$ (37,916)	$ (27,893)
Change in fair value included in other income (expense), net	(8,489)	(1,144)	(38,653)	(11,708)
Fair value as of end of period	$ (76,569)	$ (39,601)	$ (76,569)	$ (39,601)

In determining the fair value of the Contingent Earnout Liability, the Company used the Monte Carlo simulation value model using a distribution of potential outcomes on a monthly basis over a 10-year period prioritizing the most reliable information available. The assumptions utilized in the calculation were based on the achievement of certain stock price milestones, including the current Common Stock price, expected volatility, risk-free rate, expected term and expected dividend yield (see Note 8 — Stockholders' Equity (Deficit)). Contingent earnout payments involve certain assumptions requiring significant judgment and actual results can differ from assumed and estimated amounts.

Private Placement Warrants Liability

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

	Private Placement Warrants			
	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in thousands)	2024	2023	2024	2023
Fair value as of beginning of period	$ (285)	$ (158)	$ (78)	$ (80)
Change in fair value included in other income (expense), net	(89)	9	(296)	(69)
Fair value as of end of period	$ (374)	$ (149)	$ (374)	$ (149)

In determining the fair value of the Private Placement Warrants liability, the Company used the Monte Carlo simulation valuation model to estimate the fair value utilizing assumptions including the current Company stock price, expected volatility, risk-free rate, expected term and expected dividend yield (see Note 8 — Stockholders' Equity (Deficit)).

Derivative liabilities

Contingent derivative liability

The debt pursuant to the Purchase Agreement, as defined in Note 6, contains an embedded derivative related to the Put Option, as defined in Note 6, requiring bifurcation as a single compound derivative instrument. The Company estimated the fair value of the derivative liability using a "with-and-without" methodology. The "with-and-without" methodology involves valuing the whole instrument on an as-is basis and then valuing the instrument without the individual embedded derivative. The difference between the entire instrument with the embedded derivative compared to the instrument without the embedded derivative was the fair value of the derivative liability at issuance and each subsequent reporting period. In determining the fair value of the contingent derivative liability, the Company used the Monte Carlo simulation value model using a distribution of potential outcomes on a monthly basis over a 10-year period. The estimated probability and timing of underlying events triggering the exercisability of the Put Option contained within the Purchase Agreement, forecasted cash flows and the discount rates are significant unobservable inputs used to determine the estimated fair value of the entire instrument with the embedded derivative.

As of September 30, 2024, the discount rates used to calculate the value of the contingent derivative liability were 14.0% to calculate the present-value of the revenue forecast and 18.4% to calculate the present-value of the payoff of the Put Option. As of December 31, 2023, the discount rates used to calculate the value of the contingent derivative liability were 14.5% to calculate the present-value of the revenue forecast and 17.1% to calculate the present-value of the payoff of the Put Option. Changes in fair value of the contingent derivative liability are recognized as other income (expense) in the condensed consolidated statements of operations and comprehensive loss, classified in change in fair value of derivative liabilities.

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

	Contingent Derivative Liability			
	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in thousands)	2024	2023	2024	2023
Fair value as of beginning of period	$ (4,266)	$ (2,392)	$ (2,636)	$ —
Fair value of embedded derivative upon issuance of debt	—	—	(1,552)	(2,354)
Change in fair value included in other income (expense), net	1,161	(144)	1,083	(182)
Fair value as of end of period	$ (3,105)	$ (2,536)	$ (3,105)	$ (2,536)

4. Property and Equipment, Net

Property and equipment, net consisted of the following:

($ in thousands)	September 30, 2024	December 31, 2023
Scientific and manufacturing equipment	$ 29,271	$ 28,400
Computer equipment	125	125
Software	1,032	682
Furniture and fixtures	1,066	1,066
Leasehold improvements	27,901	27,844
	59,395	58,117
Accumulated depreciation	(35,145)	(31,326)
Property and equipment, net	$ 24,250	$ 26,791

Depreciation expense totaled $1.3 million and $3.8 million for the three and nine months ended September 30, 2024, respectively, and $1.3 million and $4.3 million for the three and nine months ended September 30, 2023, respectively. All long-lived assets are maintained in the United States.

5. Accrued Expenses

Accrued expenses consisted of the following:

($ in thousands)	September 30, 2024	December 31, 2023
Accrued external research, development and manufacturing costs	$ 4,370	$ 3,845
Accrued employee compensation and benefits	6,341	5,238
Accrued professional fees	440	257
Total	$ 11,151	$ 9,340

6. Revenue Interest Purchase Agreement

Revenue Interest Purchase Agreement

On May 12, 2023, the Company and Global entered into the Purchase Agreement with the Purchasers, and another affiliate of Oberland Capital Management LLC, as agent for the Purchasers, to obtain financing with respect to the further development and commercialization of the Company's ATEV, to repay the Company's then-existing credit facility with SVB, and for other general corporate purposes. Pursuant to the Purchase Agreement, on May 12, 2023, the Purchasers purchased certain revenue interests (the "Revenue Interests") from Global in exchange for an aggregate investment amount of up to $150.0 million (the "Investment Amount") to be paid in multiple tranches. On May 12, 2023, the Company received an initial payment of $40.0 million, less certain transaction expenses, which was used to repay in full the Company's then-existing obligations under the Loan Agreement with SVB, as defined in Note 7 — Debt. In February 2024, the FDA accepted the Company's BLA for an indication in vascular trauma, and in accordance with the Purchase Agreement, on March 11, 2024, the Company received a subsequent installment of $20.0 million.

As of September 30, 2024, the Company is entitled to receive up to approximately $90.0 million in subsequent installments subject to the terms and conditions set forth in the Purchase Agreement, as follows: (i) $40.0 million, at the Company's option, upon the Company receiving FDA approval of the ATEV for the vascular trauma indication on or prior to December 31, 2024 and (ii) $50.0 million, at the Company's option, upon reaching $35.0 million trailing worldwide three-month net sales any time prior to December 31, 2025. Each tranche is dependent on the satisfaction of the conditions and receipt of funds from the previous tranche.

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

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

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

The Purchase Agreement contains customary representations and warranties and affirmative covenants for transactions of this type, including, among others, the provision of financial and other information to the Purchaser, notice to the Purchaser upon the occurrence of certain material events, and compliance with applicable laws. The Purchase Agreement also contains customary negative covenants, including certain restrictions on the ability to incur indebtedness and grant liens or security interests on assets. On February 18, 2024, the Company reached an agreement with the Purchasers and the Agent to waive certain breaches related to, and extend the deadline for certain post-closing obligations under, the Purchase Agreement, including the requirement for the Company to deliver a leasehold mortgage in favor of the Agent over the Company's headquarters. On May 8, 2024, the Company agreed with the Purchasers to amend the Purchase Agreement, the effect of which was to remove requirements related to the leasehold mortgage. In exchange for the removal of these requirements, the Company funded an account in an amount of $54.0 million on August 14, 2024, over which the Agent has certain consent and other rights to $50.0 million of the funds. As of September 30, 2024, $50.0 million of the funded account was classified as long-term restricted cash on the accompanying condensed consolidated balance sheets.

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

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

The Company recorded a revenue interest liability related to the Purchase Agreement on the accompanying condensed consolidated balance sheet on the date the Company entered into the Purchase Agreement, net of a debt discount comprised of $2.1 million issuance costs and transaction costs, $0.1 million fair value allocated to the Option Agreement, defined below, and the $2.4 million initial fair value of the bifurcated contingent derivative liability related to the Put Option. The revenue interest liability is based on the Company's contractual repayment obligation to the Purchasers, based on the current estimates of future revenues, over the life of the Purchase Agreement. The Company imputes interest expense associated with this liability using the interest method. The effective interest rate is calculated based on the rate that would enable the debt to be repaid in full over the anticipated life of the arrangement. The interest rate on this liability may vary during the term of the agreement depending on a number of factors, including the level and expected timing of forecasted net sales. The Company evaluates the interest rate quarterly based on its current net sales forecasts. If the level and timing of any forecasted net sales and related payments change, the Company prospectively adjusts the effective interest and the related amortization of the liability and related issuance costs on a quarterly basis.

As of September 30, 2024 and December 31, 2023, $62.1 million and $38.6 million, respectively, was recorded as a revenue interest liability. The estimated effective annual interest rate as of September 30, 2024 and December 31, 2023 was 13.6% and 14.1%, respectively. The Company recorded $2.0 million and $5.6 million in interest expense related to the Purchase Agreement for the three and nine months ended September 30, 2024, respectively, and recorded $1.0 million and $1.8 million in interest expense related to the Purchase Agreement for the three and nine month ended September 30, 2023, respectively. The Company incurred and paid $0.5 million of transaction costs during the nine months ended September 30, 2024 in connection with the Purchase Agreement. The transaction costs were capitalized to debt discount and are being amortized to interest expense over the estimated term of the debt, consistent with the issuance and transaction costs incurred in 2023 discussed above.

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

Revenue Interest Payments made as a result of the Company's net product sales will reduce the revenue interest liability. During the three and nine months ended September 30, 2024 and 2023, the Company did not record any product sales revenue.

The following table summarizes the revenue interest liability activity during the three and nine months ended September 30, 2024:

($ in thousands)		
Revenue interest liability at December 31, 2023	$	38,600
Proceeds from revenue interest purchase agreement		20,000
Debt discount from embedded contingent derivative liability		(1,552)
Interest expense recognized		1,411
Transaction costs accrued at March 31, 2024		(500)
Revenue interest liability at March 31, 2024	$	57,959
Interest expense recognized		2,119
Revenue interest liability at June 30, 2024	$	60,078
Interest expense recognized		2,039
Revenue interest liability at September 30, 2024	$	62,117

Option Agreement

In connection with the Purchase Agreement, the Company also entered into an option agreement with TPC Investments III LP and TPC Investment Solutions LP (the "Option Agreement"), which gave TPC Investments III LP and TPC Investment Solutions LP (the "Holders") the right to purchase, in the aggregate, up to $10.0 million worth of shares of Common Stock (the "Option") at a purchase price per share equal to the greater of $7.50, or the 15 day volume-weighted average price as of the exercise date, exercisable in cash only at any time prior to the earlier of (i) December 31, 2026 and (ii) the closing date of a corporate reorganization. The Holders also received certain registration rights relating to the shares underlying the Option pursuant to the Option Agreement. The Holders purchased $1,950,000 of shares of Common Stock in the February 29, 2024 Offering, as defined in Note 8, and the Holders have the right to purchase up to $8,050,000 of shares of Common Stock under the Option Agreement.

The Option granted to the Holders represents a freestanding instrument separate from the purchaser commitments outlined in the Purchase Agreement. The Option Agreement does not qualify for the equity contract scope exception under ASC 815-40 and the Company recorded the Option as a liability ("Option Agreement liability") on the condensed consolidated balance sheet at an initial fair value of $55 thousand, with subsequent changes in the fair value to be recognized in the condensed consolidated statements of operations and comprehensive loss at each reporting date. The fair value of the Option Agreement liability as of September 30, 2024 and December 31, 2023 was $86 thousand and $35 thousand, respectively.

7. Debt

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

In connection with the termination of the Loan Agreement, the Company paid a prepayment premium of $0.3 million and recorded a loss on extinguishment of debt of $2.4 million during the nine months ended September 30, 2023 in other income (expense), net in the condensed consolidated statements of operations and comprehensive loss.

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8. Stockholders' Equity (Deficit)

Public Offering

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

Equity Line Financing

On September 24, 2024, the Company entered into the Common Stock Purchase Agreement with Lincoln Park for an equity line financing, which provides that, subject to the terms and conditions set forth therein, the Company has the sole right, but not the obligation, to sell to Lincoln Park shares of Common Stock having an aggregate value of up to $50.0 million over a 24-month period. The Company controls the timing and amount of any sales of Purchase Shares to Lincoln Park pursuant to the Common Stock Purchase Agreement in its sole discretion. In consideration for entering into the Common Stock Purchase Agreement, the Company issued 115,705 shares of Common Stock (the "Commitment Shares") to Lincoln Park. The Company did not receive any cash proceeds from the issuance of the Commitment Shares. The fair value of the Common Stock Purchase Agreement was measured on the issuance date based on the fair value of the Commitment Shares, which was the consideration given to Lincoln Park in exchange for entering into the agreement. The fair value of the Commitment Shares on the issuance date was determined to be $0.7 million based on the closing price of the Common Stock on September 24, 2024, which was $6.12 per share. The Company recognized the fair value of the Commitment Shares as a non-current asset as a component of long-term assets on the condensed consolidated balance sheets. The Common Stock Purchase Agreement is subsequently remeasured at each reporting date with changes in fair value recorded as a component of other income (expense), net in the condensed consolidated statements of operations and comprehensive loss. As of September 30, 2024, the Company has sold 200,000 shares to Lincoln Park for aggregate gross proceeds of $1.0 million, and the Company had $49.0 million in remaining availability for sales of Common Stock under the Common Stock Purchase Agreement. From September 30, 2024 through November 8 2024, the Company sold 300,000 shares to Lincoln Park for aggregate gross proceeds of $1.5 million.

Common Stock

As of September 30, 2024, the Company's Second Amended and Restated Certificate of Incorporation authorized the Company to issue 250,000,000 shares of Common Stock. The number of authorized shares of Common Stock may be increased or decreased (but not below the number of shares then outstanding or reserved for issuance) by the affirmative vote of the holders of a majority in interest of the Common Stock.

The holders of Common Stock are entitled to receive dividends from time to time as may be declared by the Company's board of directors. Through September 30, 2024, no dividends have been declared. The Purchase Agreement limits the Company's ability to pay cash dividends to the holders of Common Stock.

The holders of Common Stock are entitled to one vote for each share held with respect to all matters voted on by the common stockholders of the Company.

In the event of a reorganization of the Company, after payment to any preferred stockholders of their liquidation preferences, holders of Common Stock are entitled to share ratably in all remaining assets of the Company.

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As of September 30, 2024, the Company had reserved Common Stock for future issuances as follows:

	September 30, 2024
Common stock reserved for Contingent Earnout Shares	15,000,000
Common stock reserved for Common Stock Purchase Agreement	12,300,000
Common stock reserved for Option Agreement	1,073,333 (1)
Exercise of options outstanding under stock plans	12,287,369
Options available for issuance under stock plans	5,864,288
Shares available for grant under ESPP	1,030,033
Warrants to purchase Common Stock	5,588,506
	53,143,529

(1) Assumes the exercise of the $8,050,000 of shares of Common Stock remaining under the Option as provided for in the Option Agreement at the minimum purchase price of $7.50 per share.

See Note 13 — Subsequent Events for a summary of Common Stock and warrants issued as part of the Registered Direct Offering that closed on October 7, 2024.

Preferred Stock

The Company's Second Amended and Restated Certificate of Incorporation provides the Company's board of directors with the authority to issue preferred stock, par value $0.0001 per share, in one more series and to establish from time to time the number of shares to be included in each such series, by adopting a resolution and filing a certificate of designations. Voting powers, designations, powers, preferences and relative, participating, optional, special and other rights shall be stated and expressed in such resolutions. There were 20,000,000 shares designated as preferred stock and none were outstanding as of September 30, 2024 and December 31, 2023.

Warrants

The Company had the following Common Stock warrants outstanding as of September 30, 2024 and December 31, 2023:

	Common Stock Warrants Outstanding
Legacy Humacyte Common Stock Warrants	411,006
Private Placement Warrants	177,500
Public Warrants	5,000,000
Total Common Stock Warrants	5,588,506

In connection with the Company's Loan Agreement, in 2021 the Company granted warrants to the lenders to purchase 411,006 shares of Common Stock at an exercise price of $10.28 per share (such warrants, "Legacy Humacyte Common Stock Warrants"). The Company recognized the fair value of the warrants within stockholders' equity using a Black-Scholes valuation model, as the settlement of the warrants is indexed to the Common Stock. There were no issuances, exercises or expirations of warrants during the nine months ended September 30, 2024 or September 30, 2023. In connection with the Registered Direct Offering, the Company issued warrants to purchase 5,681,820 shares of Common Stock. See Note 13 — Subsequent Events for additional information.

In connection with the Merger, the Company assumed 5,000,000 publicly-traded warrants ("Public Warrants") and 177,500 private placement warrants issued to AHAC Sponsor LLC (the "Sponsor"), Oppenheimer & Co. Inc. and Northland Securities, Inc., in connection with AHAC's initial public offering ("Private Placement Warrants" and, together with the Public Warrants, the "Common Stock Warrants"). The Common Stock Warrants entitle the holder to purchase one share of Common Stock at an exercise price of $11.50 per share. The Company evaluated the Common Stock Warrants to determine the appropriate financial statement classification upon the consummation of the Merger. The Common Stock Warrants are not mandatorily redeemable and are considered to be freestanding instruments as they are separately exercisable into Common Stock. As such, the Common Stock Warrants were not classified as liabilities under FASB ASC Topic 480, *Distinguishing Liabilities from Equity*. The Company then evaluated the Common Stock Warrants under FASB ASC Topic 815, *Derivatives and Hedging*.

Public Warrants

The Public Warrants are publicly traded and are exercisable for cash unless certain conditions occur, such as the failure to have an effective registration statement related to the shares issuable upon exercise or redemption by the Company under certain conditions, at which time the Public Warrants may be eligible for a cashless exercise. The Public Warrants may only be exercised for a whole number of shares and will expire five years after the completion of the Merger.

The Public Warrants are considered to be "indexed to the Company's own stock." The agreement provides that in the event of a tender or exchange offer made to and accepted by holders of more than 50% of the outstanding shares of the Company's Common Stock, all holders of the Common Stock Warrants (both the Public Warrants and the Private Placement Warrants) would be entitled to receive cash for all of their Common Stock Warrants. As the Company has a single class of Common Stock, a qualifying cash tender offer of more than 50% of the Common Stock will always result in a change in control and would not preclude permanent equity classification of the Public Warrants. Based on this evaluation, the Company concluded that the Public Warrants meet the criteria to be classified within stockholders' equity. The Public Warrants were initially recognized as equity on the Closing Date at a fair value of $2.80 per share.

Private Placement Warrants

The Private Placement Warrants are non-redeemable for cash so long as they are held by the initial purchasers or their permitted transferees. If the Private Placement Warrants are held by someone other than the initial purchasers or their permitted transferees, the Private Placement Warrants are redeemable by the Company and exercisable by such holders on the same basis as the Public Warrants.

The agreement governing the Common Stock Warrants includes a provision, the application of which could result in a different settlement value for the Private Placement Warrants depending on their holder. Because the holder of an instrument is not an input into the pricing of a fixed-for-fixed option on the Common Stock, the Private Placement Warrants are not considered to be "indexed to the Company's own stock" and therefore are not classified in stockholders' equity. As the Private Placement Warrants meet the definition of a derivative, the Company recorded these warrants as liabilities on the condensed consolidated balance sheet at fair value, with subsequent changes in their respective fair values recognized in the condensed consolidated statements of operations and comprehensive loss at each reporting date.

The Private Placement Warrants were initially recognized as a liability on the Closing Date, at a fair value of $0.6 million. See Note 3 — Fair Value Measurements for a summary of the change in the fair value of the Private Placement Warrants during the three and nine months ended September 30, 2024 and 2023. The remeasurement of the Private Placement Warrant liability to a fair value of $0.4 million as of September 30, 2024 from $0.1 million as of December 31, 2023 resulted in non-cash losses of $0.1 million and $0.3 million for the three and nine months ended September 30, 2024, respectively, compared to an insignificant non-cash gain for the three months ended September 30, 2023 and a non-cash loss of $0.1 million for the nine months ended September 30, 2023. The remeasurement of the Private Placement Warrant liability is classified within Change in fair value of derivatives in the condensed consolidated statements of operations and comprehensive loss.

The Private Placement Warrants were valued using the following assumptions under the Monte Carlo simulation value model:

	September 30, 2024	December 31, 2023
Market price of public stock	$ 5.44	$ 2.84
Exercise price	$ 11.50	$ 11.50
Expected term (years)	1.90	2.65
Expected share price volatility	108.0 %	75.0 %
Risk-free interest rate	3.69 %	4.09 %
Estimated dividend yield	0 %	0 %

Contingent Earnout Liability

Following the closing of the Merger (the "Closing"), former holders of Legacy Humacyte common and preferred shares are eligible to receive up to 15,000,000 additional shares of Common Stock (the "Contingent Earnout Shares") in the aggregate, in two equal tranches of 7,500,000 shares of Common Stock per tranche. The first and second tranches are issuable if the closing volume weighted average price ("VWAP") per share of Common Stock quoted on The Nasdaq Stock Market LLC ("Nasdaq") (or the exchange on which the shares of Common Stock are then listed), is greater or equal to $15.00 and $20.00, respectively, over any 20 trading days within any 30 consecutive trading day period.

Upon the Closing, the contingent obligation to issue Contingent Earnout Shares was accounted for as a liability because the triggering events that determine the number of Contingent Earnout Shares required to be issued include events that are not solely indexed to the Common Stock. The Contingent Earnout Shares are subsequently remeasured at each reporting date with changes in fair value recorded as a component of other income (expense), net in the condensed consolidated statements of operations and comprehensive loss. The estimated fair value of the total Contingent Earnout Shares at the Closing on August 26, 2021 was $159.4 million based on a Monte Carlo simulation valuation model using a distribution of potential outcomes on a monthly basis over a 10-year period using the most reliable information available.

See Note 3 — Fair Value Measurements for a summary of the change in the fair value of the Contingent Earnout Liability during the three and nine months ended September 30, 2024 and 2023. The remeasurement of the Contingent Earnout Liability to a fair value of $76.6 million as of September 30, 2024, from a fair value of $37.9 million as of December 31, 2023, resulted in non-cash losses of $8.5 million and $38.7 million for the three and nine months ended September 30, 2024, respectively, compared to non-cash losses of $1.1 million and $11.7 million for the three and nine months ended September 30, 2023, respectively, related to the remeasurement of the Contingent Earnout Liability. The remeasurement of the Contingent Earnout Liability is classified within Change in fair value of Contingent Earnout Liability in the condensed consolidated statements of operations and comprehensive loss. The assumptions utilized in the calculations of fair value were based on the achievement of certain stock price milestones, including the current Common Stock price, expected volatility, risk-free rate, expected term and expected dividend yield.

Assumptions used in the valuations are described below:

	September 30, 2024	December 31, 2023
Current stock price	$ 5.44	$ 2.84
Expected share price volatility	84.2 %	86.7 %
Risk-free interest rate	3.81 %	3.88 %
Estimated dividend yield	0 %	0 %
Expected term (years)	10.00	10.00

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9. Stock-based Compensation

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

The 2021 Plan and ESPP provide that on January 1 of each year commencing January 1, 2022, the 2021 Plan and the ESPP reserve will automatically increase in an amount equal to the lesser of (a) 5% and 1%, respectively, of the number of shares of Common Stock outstanding on December 31 of the preceding year and (b) a number of shares of Common Stock determined by the Company's board of directors. The Company's board of directors determined that there would be no automatic increase in the number of shares reserved under the 2021 Plan on either January 1, 2022 or January 1, 2023. The 2021 Plan share reserve automatically increased on January 1, 2024 by 5,183,686 shares, which was equivalent to 5% of the number of shares of Common Stock outstanding on December 31, 2023. Since the inception of the ESPP, the Company's board of directors has determined that there would be no automatic increase in the number of shares reserved under the ESPP. As of September 30, 2024, 5,864,288 and 1,030,033 shares of Common Stock were available under the 2021 Plan and ESPP, respectively.

Prior to the Closing, Legacy Humacyte had two equity incentive plans, the 2015 Omnibus Incentive Plan, as amended (the "2015 Plan"), and the 2005 Stock Option Plan (the "2005 Plan"). As a result of the Merger, no further awards will be granted under either the 2015 Plan or the 2005 Plan. All awards previously granted and outstanding as of the effective date of the Merger were adjusted to reflect the impact of the Merger as set forth in the Merger Agreement, but otherwise retained their original terms. The shares underlying any award granted under the 2021 Plan or the 2015 Plan that are forfeited, cancelled or reacquired by the Company prior to vesting, that expire or that are paid out in cash rather than shares will become available for grant and issuance under the 2021 Plan. As of September 30, 2024, 8,558,936, 3,726,781 and 1,652 shares of Common Stock remain reserved for outstanding options issued under the 2021 Plan, the 2015 Plan and the 2005 Plan, respectively. The Company has sufficient authorized and unissued shares to issue Common Stock in satisfaction of any outstanding awards and any awards available for grant under the 2021 Plan.

The Company's stock option plans allow for the grant of awards that the Company believes aid in aligning the interests of award recipients with those of its stockholders. The Company's board of directors or compensation committee determines the specific terms of equity incentive grants, including the exercise price per share and vesting period for option awards. Option awards are granted with an exercise price equal to the fair market value of the Common Stock at the date of grant.

The Company has granted options that include either a service-based or performance-based vesting condition, or both, and a 10-year contractual term. The service-based vesting condition for the plans is generally satisfied over 36 to 48 months from the date of grant. The performance-based vesting conditions are satisfied upon the attainment of certain product development milestones. The Company recognizes stock-based compensation expense based on the grant date fair value of the awards measured using the Black-Scholes option pricing model. Compensation expense related to awards with service-based vesting conditions is recognized on a straight-line basis over the requisite service period. Option valuation models, including the Black-Scholes option-pricing model, require the input of highly subjective assumptions, and changes in the assumptions used can materially affect the grant-date fair value of an award. These assumptions include the risk-free rate of interest, expected dividend yield, expected volatility, the expected term of the award, and the fair value of the underlying Common Stock on the date of grant. Forfeitures are accounted for as they occur.

Compensation expense related to awards with performance-based vesting conditions is recognized over the requisite service period using the accelerated attribution method to the extent achievement of the performance-based condition is probable. The Company does not recognize compensation expense related to awards with performance-based vesting conditions until it is probable that the performance-based vesting condition will be achieved. Forfeitures are accounted for as they occur.

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Option awards under the Company's option plans generally provide for accelerated vesting of the unvested portions of any option award in the event of an involuntary termination, as such term is defined in the relevant stock option agreement, of a grantee's employment during the period that commences 30 days prior to the effective date of a corporate transaction and that ends 12 months following the effective date of such transaction. Additionally, the Company's board of directors may, in its sole discretion, accelerate the vesting of any unvested stock options in the event of a corporate transaction.

The Company estimated the fair value of the stock options on the date of grant using the following assumptions in the Black-Scholes option-pricing model:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Estimated dividend yield	0 %	0 %	0 %	0 %
Expected share price volatility (weighted average and range, if applicable)	92.8%	89.8%	91.8% (90.8% to 92.8%)	89.0% (88.6% to 89.8%
Risk-free interest rate (weighted average and range, if applicable)	3.54%	4.39%	4.12% (3.54% to 4.41%)	3.91% (3.58% to 4.39%)
Expected term of options (in years)	6.25	6.25	6.25	6.25

- *Fair Value of Common Stock.* The fair value of the Common Stock has been determined based on the closing price of the shares on Nasdaq.
- *Expected Term.* The expected term represents the period that stock options are expected to be outstanding. The Company calculated the expected term using the simplified method for options, which is available where there is insufficient historical data about exercise patterns and post-vesting employment termination behavior. The simplified method is based on the vesting period and the contractual term for each grant, or for each vesting-tranche for awards with graded vesting. The mid-point between the vesting date and the maximum contractual expiration date is used as the expected term under this method. For awards with multiple vesting-tranches, the times from grant until the mid-points for each of the tranches may be averaged to provide an overall expected term.
- *Expected Volatility.* The expected volatility was determined based on a blended approach using the historical share volatility of the Common Stock and that of several publicly traded peer companies over a period of time equal to the expected term of the options, as the Company has a limited trading history. For purposes of identifying these peer companies, the Company considered the industry, stage of development, size and financial leverage of potential comparable companies.
- *Risk-Free Interest Rate.* The risk-free interest rate was based on the yields of U.S. Treasury zero-coupon securities with maturities similar in duration to the expected term of the options.
- *Expected Dividend Yield.* The Company has not paid dividends on its Common Stock nor does it expect to pay dividends in the foreseeable future. Accordingly, the Company has estimated the dividend yield to be zero.

The following table shows a summary of stock-based compensation expense included in the condensed consolidated statements of operations and comprehensive loss for the three and nine months ended September 30, 2024 and 2023:

	Three Months Ended September 30,		Nine Months Ended September 30,	
($ in thousands)	**2024**	**2023**	**2024**	**2023**
Research and development	$ 635	$ 361	$ 2,110	$ 1,262
General and administrative	917	1,411	2,333	4,160
Total	$ 1,552	$ 1,772	$ 4,443	$ 5,422

As of September 30, 2024, unrecognized stock-based compensation cost for options was $19.3 million and is expected to be recognized over a weighted-average period of 2.9 years.

A summary of option activity under the Company's stock option plans during the nine months ended September 30, 2024 is presented below:

	Number of Shares	Weighted Average Exercise Price Per Share	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value (in thousands)
Options outstanding at December 31, 2023	11,919,421	$ 4.64	8.3	$ 383
Granted	1,497,350	$ 6.36		
Exercised	(443,507)	$ 2.90		
Forfeited	(685,895)	$ 3.64		
Options outstanding at September 30, 2024	12,287,369	$ 4.97	7.9	$ 19,310
Vested and exercisable, September 30, 2024	4,453,743	$ 7.22	5.7	$ 3,338
Vested and expected to vest, September 30, 2024	12,287,369	$ 4.97	7.9	$ 19,310

10. Income Taxes

The Company's tax provision for interim periods is determined using an estimate of its annual effective tax rate, adjusted for discrete items, if any, that arise during the period. Each quarter, the Company updates its estimate of the annual effective tax rate and, if the estimated annual effective tax rate changes, the Company makes a cumulative adjustment in such period. No such adjustment was made as of September 30, 2024. The Company's effective federal and state tax rate for the three and nine months ended September 30, 2024 and 2023 was 0%, primarily as a result of estimated net operating losses for the fiscal year to date offset by the increase in the valuation allowance against its deferred tax asset.

The Company did not record any income tax expense or benefit during the three and nine months ended September 30, 2024 and 2023. The Company has a net operating loss and has provided a valuation allowance against net deferred tax assets due to uncertainties regarding the Company's ability to realize these assets. All losses before income taxes arose in the United States.

11. Commitments and Contingencies

Patent License Agreements

Duke University

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

In connection with the Company's entry into the license agreement, the Company granted equity consideration to Duke in the form of 52,693 shares of Common Stock. Under the license agreement, the Company also agreed to pay Duke:

- a low single-digit percentage royalty on eligible sales of licensed products and licensed services, plus a low double-digit percentage of any sublicensing revenue;
- an annual minimum royalty beginning in 2012, which increases in the calendar year immediately following the first commercial sale of licensed products or licensed services (whichever occurs first); and
- an additional amount in license fees, as certain milestones are met.

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

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

Yale University

In August 2019, the Company entered into a license agreement with Yale University ("Yale") that granted the Company a worldwide license to the patents related to the biovascular pancreas ("BVP") product candidate (the "BVP License Agreement"). The license granted under the BVP License Agreement is exclusive in the field of engineered vascular tissues that deliver pancreatic islet cells to patients, except that it is subject to Yale's non-exclusive right, on behalf of itself and all other non-profit academic institutions, to use the licensed products for research, teaching, and other non-commercial purposes. The Company has agreed to pay to Yale an annual maintenance fee, increasing between the first and fourth anniversaries of the BVP License Agreement up to a maximum of less than $0.1 million per year for this license.

In August 2019, the Company entered into a license agreement with Yale that granted the Company a worldwide license to the patents related to tubular prostheses (the "Tubular Prosthesis License Agreement"). The license granted under the Tubular Prosthesis License Agreement is exclusive in the field of engineered urinary conduits, engineered tracheas/airways, and engineered esophagi, except that it is subject to Yale's non-exclusive right, on behalf of itself and all other non-profit academic institutions, to use the licensed products for research, teaching, and other non-commercial purposes. The Company has agreed to pay to Yale an annual maintenance fee, increasing between the first and fourth anniversaries of the Tubular Prosthesis License Agreement up to a maximum of less than $0.1 million per year for this license.

The Company has agreed to use reasonable commercial efforts to develop and commercialize the licensed patents and any licensed products and methods, and to use reasonable efforts to make the licensed products available to patients in low and low-middle income countries. The Company is also obligated to provide Yale periodically an updated and revised copy of its plan for each license, which must indicate progress of its development and commercialization. The Company may also sublicense the Company's rights without Yale's prior written consent, but such sublicense is subject to certain conditions.

In connection with its entry into the Tubular Prosthesis License Agreement, the Company paid Yale upfront cash fees. The Company has also agreed to pay Yale:

- annual maintenance fees, increasing annually until the fifth anniversary for the BVP License Agreement and until the fourth anniversary for the Tubular Prostheses License Agreement up to a maximum of less than $0.1 million per year;
- milestone payments upon achievement of certain regulatory and commercial milestones of $0.2 million and $0.6 million, respectively;
- a low single-digit percentage royalty on worldwide net sales, subject to reductions for third-party license fees; and
- a low double-digit percentage of sublicensing income.

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

The BVP License Agreement and Tubular Prosthesis License Agreement expire on a country-by-country basis on the date on which the last of the patents in such country expires, lapses or is declared invalid. Yale may terminate the BVP License Agreement and Tubular Prosthesis License Agreement if the Company fails to (i) provide written diligence reports, (ii) provide commercially reasonable diligence plans, (iii) implement the plans in accordance with the obligations under the agreements, or (iv) reach certain research and development milestones within the scheduled timeframe set forth in the agreements; however, any such termination right would be limited in scope to the country to which such failure relates. Yale may also terminate for the Company's non-payment, uncured material breach, failure to obtain adequate insurance, bringing or assisting in bringing of a patent challenge against Yale, abandonment of the research and development of the Company's products or insolvency. The Company may terminate the BVP License Agreement and Tubular Prosthesis License Agreement (i) on 90 days' prior written notice to Yale, provided the Company is not in breach of the license agreements and has made all required payments to Yale thereunder and (ii) on written notice to Yale following an uncured material breach. With respect to the BVP License Agreement, the Company's rights under the agreement will also terminate automatically with respect to a patent application or patent within the licensed patents in a specified country if, upon receipt of written notice from Yale, the Company does not agree to pay the patent filing, prosecution and maintenance fees incurred by Yale for such patent applications or patents in the specified country. Under certain circumstances, Yale may, at its option, convert the exclusive licenses to non-exclusive licenses if the Company declines to initiate certain infringement or interference proceedings with respect to the licensed patents. The Company has agreed to indemnify Yale against certain third-party claims. Payments to Yale under the BVP License Agreement and Tubular Prosthesis License Agreement were immaterial during the periods presented.

JDRF Agreement

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

The Company received the first milestone payment of $80 thousand in April 2023 upon execution of the JDRF Agreement. In May 2024, the Company received the second milestone payment of $90 thousand and the third milestone payment of $150 thousand, based upon the achievement of certain research and development milestones specified in the JDRF Agreement. As of September 30, 2024, the Actual Award totaled $320 thousand.

The Company determined that the JDRF Actual Award payments are to be classified as long-term debt under ASC 470, *Debt* in the condensed consolidated balance sheets. The JDRF liability related to the Actual Award payments is reported at amortized cost and is included in other long-term liabilities in the condensed consolidated balance sheets. As of September 30, 2024 and December 31, 2023, the carrying value of the JDRF liability is $251 thousand and $69 thousand, respectively. There was an insignificant amount of interest expense related to the JDRF liability recorded in each period presented.

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

- a one-time royalty in an amount equal to four times the Actual Award, to be paid in three equal installments following the first commercial sale of any product containing the Company's technology identified in the JDRF Agreement;
- an additional royalty equal to the Actual Award at a specified payment date after net sales exceed $250 million; and
- in the event of a license, sale or transfer of the Company's rights to the product's technology identified in the JDRF Agreement or a change of control transaction, a payment equal to 10% of any license or purchase price payments received by the Company up to an amount equal to four times the Actual Award (the "Royalty Cap"), less any previous royalty payments paid towards the Royalty Cap (the "Disposition Payment"). The Disposition Payment was determined to meet the definition of an embedded derivative requiring bifurcation and is measured at fair value each reporting period with changes in fair value recognized as other income (expense) in the condensed consolidated statements of operations and comprehensive loss, classified in change in fair value of derivatives.

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

Legal Matters

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

Indemnification

To the extent permitted under Delaware law, the Company has agreed to indemnify its directors and officers for certain events or occurrences while the director or officer is, or was serving, at the Company's request in such capacity. The indemnification period covers all pertinent events and occurrences during the director's or officer's service. The maximum potential amount of future payments the Company could be required to make under these indemnification arrangements is not specified in such arrangements; however, the Company has director and officer insurance coverage that is intended to reduce its exposure and enable the Company to recover a portion of any potential future amounts the Company could be required to make. To date, the Company has not incurred any costs as a result of such obligations and has not accrued any liabilities related to such obligations in the condensed consolidated financial statements.

12. Related Party Transactions

Fresenius Medical Care investments and distribution agreement

In June 2018, the Company completed a $150 million financing transaction pursuant to which Fresenius Medical Care purchased shares of series D redeemable convertible preferred stock that at the Closing Date converted into 15,812,735 shares of Common Stock. In August 2021, Fresenius Medical Care invested $25 million as part of a private placement offering related to the Merger (the "PIPE Financing") and received an additional 2.5 million shares of Common Stock.

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

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

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

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

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

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

Agreements with Frenova Renal Research

In May 2022 and June 2023, the Company entered into three services agreements with Frenova Renal Research ("Frenova"), a subsidiary of Fresenius Medical Care, to conduct a study to review the outcomes of 178,575 adult patients who received in-center dialysis at Fresenius Kidney Care dialysis centers. The Company expensed an insignificant amount and approximately $0.2 million for clinical research services performed by Frenova during the three and nine months ended September 30, 2023, respectively, related to these agreements. As of September 30, 2023, the clinical research services contracted for under these agreements with Frenova were fully complete and no further expenses have been incurred related to these agreements.

In June 2024, the Company entered into a master services agreement with Frenova that sets forth the terms by which the Company may engage Frenova to provide certain services for projects, with the services for each project being described in a separate statement of work. As of September 30, 2024, Frenova was engaged to perform clinical research services related to the Company's V012 Phase 3 clinical trial. During the three and nine months ended September 30, 2024, amounts expensed in relation to this agreement with Frenova were insignificant.

In July 2024, the Company entered into a service agreement with Fresenius Medical Care Deutschland GmbH ("Fresenius GmbH"), which provides medical scientific research services through Frenova. Frenova agreed to conduct a study to review patient data of adult hemodialysis patients who received treatment in certain European countries at dialysis centers that are part of Fresenius Medical Care AG. Fresenius Medical Care AG is the German parent company of Fresenius GmbH and ultimately of Fresenius Medical Care. During each of the three and nine months ended September 30, 2024, amounts expensed in relation to this agreement with Fresenius GmbH were approximately $0.1 million. As of September 30, 2024, there was $0.1 million payable to Fresenius GmbH included in accounts payable on the Company's consolidated balance sheets. During the three and nine months September 30, 2023, there was no and $0.1 million of expense recognized, respectively, for services performed by Fresenius GmbH.

Arrangements with Yale University

The Company's President and Chief Executive Officer, Laura Niklason M.D., PhD., serves as an Adjunct Professor in Anesthesia at Yale University. As of September 30, 2024 and December 31, 2023, the Company was a party to license agreements with Yale University as described in Note 11 — Commitments and Contingencies above. Amounts expensed in relation to the license agreements with Yale University were insignificant during the three months ended September 30, 2024 and 2023. Amounts expensed in relation to the license agreements with Yale University were $0.1 million during each of the nine months ended September 30, 2024 and 2023.

Humacyte, Inc.
Notes to Condensed Consolidated Financial Statements
(unaudited)

13. Subsequent Events

Proceeds from Sales of Shares

On October 4, 2024, the Company entered into a securities purchase agreement with an institutional investor pursuant to which the investor purchased 5,681,820 shares of Common Stock and warrants to purchase up to 5,681,820 shares of Common Stock (the "Registered Direct Warrants") in a registered direct offering (the "Registered Direct Offering"). The Registered Direct Warrants are immediately exercisable. Registered Direct Warrants to purchase 2,840,910 shares of Common Stock have an exercise price of $5.28 per share, and will expire 180 days from the date of issuance. The remaining Registered Direct Warrants to purchase 2,840,910 shares of Common Stock have an exercise price of $5.28 per share, and will expire 1,640 days from the date of issuance. The purchase price for one share of Common Stock and one Registered Direct Warrant was $5.28. The net proceeds to the Company from the Registered Direct Offering were approximately $28.1 million after deducting placement agent's fees and offering expenses of approximately $1.9 million. The Registered Direct Offering closed on October 7, 2024.

From September 30, 2024 through November 8 2024, the Company sold 300,000 shares to Lincoln Park for aggregate gross proceeds of $1.5 million.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our unaudited condensed consolidated financial statements and related notes appearing elsewhere in this Quarterly Report on Form 10-Q ("Quarterly Report") and with our audited financial statements and the notes thereto included in our Annual Report. In addition, you should read the "Risk Factors" and "Information Regarding Forward-Looking Statements" sections of this Quarterly Report and our Annual Report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Unless the context indicates otherwise, references in this Quarterly Report to the "Company," "Humacyte," "we," "us," "our" and similar terms refer to Humacyte, Inc. (formerly known as Alpha Healthcare Acquisition Corp.) and its consolidated subsidiary (Humacyte Global, Inc.) following the Merger (defined below); references to "Legacy Humacyte" refer to Humacyte, Inc. prior to the Merger; and references to "AHAC" refer to Alpha Healthcare Acquisition Corp. prior to the Merger.

Overview

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

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

For the ATEV, we believe there is substantial clinical demand for safe and effective vascular conduits to replace and repair blood vessels throughout the body. Vascular injuries resulting from trauma are common in civilian and military populations, frequently resulting in the loss of either life or limb. Existing treatment options in the vascular repair, reconstruction and replacement market include the use of autologous vessels and synthetic grafts, which we believe suffer from significant limitations. For example, the use of autologous veins to repair traumatic vascular injuries can lead to significant morbidity associated with the surgical wounds created for vein harvest and prolonged times to restore blood flow to injured limbs, leading to an increased risk of complications such as amputation and reperfusion injury. In addition, in many instances of vascular trauma the patient may not have adequate vein available, or the time between injury and treatment is too long, to make autologous graft repair feasible. Synthetic grafts are often contraindicated in the setting of vascular trauma due to higher infection risk that can lead to prolonged hospitalization and limb loss. Given the competitive advantages our ATEVs are designed to have over existing vascular substitutes, we believe that ATEVs have the potential to become the standard of care and lead to improved patient outcomes and lower healthcare costs.

We and our collaborators are currently conducting Phase 3 and Phase 2 trials of our 6 millimeter ATEV across three therapeutic indications: vascular trauma, AV access for hemodialysis, and PAD. We were granted Fast Track designation by the FDA for our 6 millimeter ATEV for use in AV access for hemodialysis in 2014. We also received the first Regenerative Medicine Advanced Therapy ("RMAT") designation from the FDA, for the creation of vascular access for performing hemodialysis, in March 2017. In May 2023, we were granted the RMAT designation for the ATEV for urgent arterial repair following extremity vascular trauma, and in June 2024, we were granted the RMAT designation for the ATEV for patients with advanced PAD. In addition, in 2018 our ATEV product candidate was assigned a priority designation by the Secretary of Defense under Public Law 115-92, enacted to expedite the FDA's review of products that are intended to diagnose, treat or prevent serious or life-threatening conditions facing American military personnel.

In September 2023, we announced positive topline results from our V005 Phase 2/3 trial in vascular trauma, and in December 2023, we filed a BLA for urgent arterial repair following extremity vascular trauma when synthetic graft is not indicated, and when autologous vein use is not feasible. In February 2024, the FDA accepted the BLA filing and granted priority review and set a Prescription Drug User Fee Act date of August 10, 2024. On August 9, 2024, the FDA informed us that it required additional time to complete its review of the BLA for the vascular trauma indication.

In April 2023, we announced completion of enrollment of our V007 Phase 3 trial of the ATEV for use in AV access for hemodialysis. In July 2024, we announced positive topline results from our V007 Phase 3 trial in which the ATEV met the primary endpoints in the study. We expect to discuss a potential market authorization pathway for the ATEV with the FDA for an indication in AV access for hemodialysis.

We have generated no product revenue and incurred operating losses and negative cash flows from operations in each year since our inception in 2004. As of September 30, 2024 and December 31, 2023, we had an accumulated deficit of $665.1 million and $537.3 million, respectively, and working capital of $2.1 million and $64.8 million, respectively. Our operating losses were approximately $30.2 million and $86.3 million for the three and nine months ended September 30, 2024, respectively, and $24.6 million and $73.9 million for the three and nine months ended September 30, 2023, respectively.

Net cash flows used in operating activities were $71.5 million and $54.3 million during the nine months ended September 30, 2024 and 2023, respectively. Substantially all of our operating losses resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect to incur substantial operating losses and negative cash flows from operations for the foreseeable future as we advance our product candidates.

As of September 30, 2024, we had cash and cash equivalents of $20.6 million and restricted cash of $50.4 million. Subsequent to September 30, 2024, we received an additional $29.6 million in net proceeds from the Registered Direct Offering and sales of shares to Lincoln Park under the Common Stock Purchase Agreement. The extension of time required by the FDA to review our vascular trauma BLA, and the delay in potential approval, has delayed, among other items, our ability to draw an additional $40.0 million in Purchase Agreement proceeds. Accordingly, we do not believe our available cash and cash equivalents on hand will be sufficient to fund operations, including clinical trial expenses and capital expenditure requirements, for at least one year from the date of this Quarterly Report without achieving approval of the ATEV for vascular trauma and generating sufficient cash flows from commercial sales on a timely basis and/or obtaining additional capital. See Note 1 — Organization and Description of Business in the notes to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report for additional information regarding this assessment.

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

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

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

Components of Results of Operations

Revenue

To date, we have not generated revenue from the sale of any products. All of our revenue has been derived from government and other grants. From inception through September 30, 2024 we have been awarded grants, including grants from the California Institute of Regenerative Medicine ("CIRM"), the National Institutes of Health ("NIH"), and the Department of Defense, to support our development, production scaling and clinical trials of our product candidates. We may generate revenue in the future from government and other grants, payments from future license or collaboration agreements and, if any of our product candidates receive marketing approval, from product sales. We expect that any revenue we generate will fluctuate from quarter to quarter. If we fail to complete the development of, or obtain marketing approval for, our product candidates in a timely manner, our ability to generate future revenue, and our results of operations and financial position, would be materially adversely affected.

Research and Development Expenses

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

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

The majority of our research and development resources are currently focused on our Phase 2 and 3 clinical trials for our 6 millimeter ATEV and other work needed to obtain marketing approval for our 6 millimeter ATEV for use for 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.

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 and refinement of clinical and commercial manufacturing capabilities or making arrangements with third-party manufacturers in order to ensure that it or its third-party manufacturers are able to successfully manufacture our product;
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;
- significant and changing government regulations;
- launching commercial sales of our product candidates, if approved, whether alone or in collaboration with others;
- the degree of market acceptance of any product candidates that obtain marketing approval; and
- maintaining a continued acceptable safety profile following approval, if any, of our product candidates.

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

General and Administrative Expenses

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

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

Other Income (Expense), Net

Total other income (expense), net consists of (i) the change in fair value of the Contingent Earnout Liability that was accounted for as a liability as of the date of the Merger, and is remeasured to fair value at each reporting period, resulting in a non-cash gain or loss, (ii) interest income earned on our cash and cash equivalents and short-term investments, (iii) interest expense incurred on the Purchase Agreement (defined above), finance leases, and our former loan agreement with SVB, during the periods each were outstanding, (iv) the change in fair value of our derivative liabilities and asset including the private placement Common Stock warrant liabilities related to the Private Placement Warrants, which we assumed in connection with the Merger; the contingent derivative liability related to the Purchase Agreement; a liability related to the Option Agreement; a derivative liability related to our agreement with JDRF; and a derivate asset related to our Common Stock Purchase Agreement, all of which are subject to remeasurement to fair value at each balance sheet date resulting in a non-cash gain or loss, (v) a loss on debt extinguishment related to the prepayment of our loan agreement with SVB in May 2023, and (vi) an employee retention credit we recognized in June 2023.

Results of Operations

Comparison of the Three Months Ended September 30, 2024 and 2023

	Three Months Ended September 30,		Change	
($ in thousands)	**2024**	**2023**	**$**	**%**
Revenue	$ —	$ —	$ —	— %
Operating expenses:				
Research and development	22,926	18,552	4,374	24 %
General and administrative	7,307	6,070	1,237	20 %
Total operating expenses	30,233	24,622	5,611	23 %
Loss from operations	**(30,233)**	**(24,622)**	**(5,611)**	**23 %**
Other income (expense), net				
Interest income	911	1,369	(458)	(33) %
Change in fair value of Contingent Earnout Liability	(8,489)	(1,144)	(7,345)	642 %
Interest expense	(2,438)	(1,463)	(975)	67 %
Change in fair value of derivatives	1,047	(135)	1,182	(876) %
Total other expense, net	(8,969)	(1,373)	(7,596)	553 %
Net loss	**$ (39,202)**	**$ (25,995)**	**$ (13,207)**	**51 %**

Research and Development Expenses

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

	Three Months Ended September 30,		Change	
($ in thousands)	2024	2023	$	%
Direct Expenses				
Vascular Trauma	$ 439	$ 941	$ (502)	(53) %
AV Access	1,927	2,248	(321)	(14) %
PAD	22	88	(66)	(75) %
Total	2,388	3,277	(889)	(27) %
Unallocated Expenses				
External services	1,915	1,008	907	90 %
Materials and supplies	5,451	3,301	2,150	65 %
Payroll and personnel expenses	9,621	7,665	1,956	26 %
Other research and development expenses	3,551	3,301	250	8 %
Total	20,538	15,275	5,263	34 %
Total research and development expenses	**$ 22,926**	**$ 18,552**	**$ 4,374**	**24 %**

Research and development expenses were $22.9 million for the three months ended September 30, 2024, representing an increase of $4.4 million, or 24%, from $18.6 million for the three months ended September 30, 2023. The increase was primarily driven by expenses incurred to support our expanded research and development initiatives, including increased product manufacturing and development and support of the FDA review of the BLA in vascular trauma. Expense increases were primarily comprised of a $2.2 million increase in the purchase of materials and supplies and $2.0 million in additional payroll and personnel expenses.

General and Administrative Expenses

General and administrative expenses were $7.3 million and $6.1 million for the three months ended September 30, 2024 and 2023, respectively. The increase in general and administrative expenses during this period of $1.2 million, or 20%, was primarily driven by preparation for the planned commercial launch of the ATEV in vascular trauma. Major changes in expenses included a $1.1 million increase in salaries and benefits and a $0.8 million increase in external services, partially offset by a $0.5 million decrease in non-cash stock compensation expense and a $0.4 million decrease in insurance expense.

Total Other Income (Expense), net

Total other expense, net was $9.0 million for the three months ended September 30, 2024 compared to $1.4 million for the three months ended September 30, 2023. The increase in net expense of $7.6 million during the three months ended September 30, 2024 compared to the three months ended September 30, 2023 primarily resulted from a $7.3 million increase in the non-cash loss resulting from the remeasurement of the Contingent Earnout Liability during each period.

Comparison of the Nine Months Ended September 30, 2024 and 2023

($ in thousands)	Nine Months Ended September 30, 2024	2023	Change $	Change %
Revenue	$ —	$ —	—	— %
Operating expenses:				
Research and development	67,943	56,370	11,573	21 %
General and administrative	18,367	17,495	872	5 %
Total operating expenses	86,310	73,865	12,445	17 %
Loss from operations	**(86,310)**	**(73,865)**	**(12,445)**	**17 %**
Other income (expense), net:				
Interest income	3,252	4,323	(1,071)	(25) %
Change in fair value of Contingent Earnout Liability	(38,653)	(11,708)	(26,945)	230 %
Interest expense	(6,769)	(4,872)	(1,897)	39 %
Change in fair value of derivatives	719	(234)	953	(407) %
Employee retention credit	—	3,107	(3,107)	(100) %
Loss on extinguishment of debt	—	(2,421)	2,421	(100) %
Total other expense, net	(41,451)	(11,805)	(29,646)	251 %
Net loss	**$ (127,761)**	**$ (85,670)**	**$ (42,091)**	**49 %**

Research and Development Expenses

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

($ in thousands)	Nine Months Ended September 30, 2024	2023	Change $	Change %
Direct Expenses				
Vascular Trauma	$ 1,904	$ 3,030	$ (1,126)	(37) %
AV Access	4,952	7,653	(2,701)	(35) %
PAD	161	230	(69)	(30) %
Total	7,017	10,913	(3,896)	(36) %
Unallocated Expenses				
External services	5,340	3,669	1,671	46 %
Materials and supplies	17,470	9,053	8,417	93 %
Payroll and personnel expenses	27,763	22,804	4,959	22 %
Other research and development expenses	10,353	9,931	422	4 %
Total	$ 60,926	$ 45,457	$ 15,469	34 %
Total research and development expenses	**$ 67,943**	**$ 56,370**	**$ 11,573**	**21 %**

Research and development expenses were $67.9 million for the nine months ended September 30, 2024, representing an increase of $11.6 million, or 21%, from $56.4 million for the nine months ended September 30, 2023. The increase was primarily driven by expenses incurred to support our expanded research and development initiatives, including increased product manufacturing and development and support of the FDA review of the BLA in vascular trauma. Expense increases were primarily comprised of a $8.4 million increase in the purchase of materials and supplies and $5.0 million in additional payroll and personnel expenses.

General and Administrative Expenses

General and administrative expenses were $18.4 million and $17.5 million for the nine months ended September 30, 2024 and 2023, respectively. The increase in general and administrative expenses during this period of $0.9 million, or 5%, was primarily driven by preparation for the planned commercial launch of the ATEV in vascular trauma. Major changes in expenses included (i) a $1.5 million increase in salaries and benefits expense, (ii) a $0.9 million increase in external services and (iii) a $0.9 million increase in professional fees, partially offset by a $1.8 million decrease in non-cash stock compensation expense and a $0.6 million decrease in insurance expense.

Total Other Income (Expense), net

Total other expense, net was $41.5 million for the nine months ended September 30, 2024, compared to expense of $11.8 million for the nine months ended September 30, 2023. The increase in net expense of $29.6 million during the nine months ended September 30, 2024 compared to the nine months ended September 30, 2023 primarily resulted from a $26.9 million increase in the non-cash loss resulting from the remeasurement of the Contingent Earnout Liability during each period.

Liquidity and Capital Resources

Sources of Liquidity

We have historically financed our operations primarily through the sale of equity securities and convertible debt, including pursuant to the Offering, proceeds from the Merger and related PIPE Financing, borrowings under loan facilities, the Purchase Agreement, and, to a lesser extent, through grants from governmental and other agencies. Since our inception, we have incurred significant operating losses and negative cash flows. As of September 30, 2024 and December 31, 2023, we had an accumulated deficit of $665.1 million and $537.3 million, respectively.

As of September 30, 2024 and December 31, 2023, we had working capital of $2.1 million and $64.8 million, respectively. As of September 30, 2024 and December 31, 2023, we had cash and cash equivalents of $20.6 million and $80.4 million, respectively, and restricted cash of $50.4 million and $0.4 million, respectively. We are required to evaluate whether there are conditions and events, considered in the aggregate, that raise substantial doubt about our ability to continue as a going concern for at least one year from the issuance date of our financial statements. We funded the restricted cash account on August 14, 2024, in accordance with our amended Purchase Agreement, of which $50.0 million is not subject to our unilateral control.

As disclosed in Note 13 — Subsequent Events to our accompanying unaudited condensed consolidated financial statements, on October 7, 2024, we received net proceeds of approximately $28.1 million in connection with the closing of the Registered Direct Offering. From September 30, 2024 through November 8 2024, we sold 300,000 shares to Lincoln Park under our Common Stock Purchase Agreement for aggregate gross proceeds of $1.5 million. As of November 8 2024, we had $47.5 million in remaining availability for sales of Common Stock under our Common Stock Purchase Agreement with Lincoln Park.

Based on current plans and assumptions, which excludes the $50.0 million of restricted cash and the potential approval of the BLA from our forecasted liquidity, we will not have sufficient cash and cash equivalents to fund our operations beyond one year from the issuance of these financial statements if we are unable to achieve approval of the ATEV and generate sufficient cash flows from commercial sales on a timely basis and/or obtain additional capital. These factors raise substantial doubt about our ability to continue as a going concern. We will, over the course of the next year, require additional financing to continue our operations. Adequate additional capital may not be available to us when needed or on acceptable terms. If we are unable to raise sufficient capital when required, we may be required to reduce or discontinue our operations, sell assets, or cease all operations. The accompanying unaudited condensed consolidated financial statements have been prepared assuming that we will continue as a going concern and contemplate the realization of assets and the satisfaction of liabilities in the normal course of business. The accompanying financial statements do not include any adjustments related to the recoverability and classification of assets or the amounts and classification of liabilities or any other adjustments that might be necessary should we be unable to continue as a going concern. See Note 1 — Organization and Description of Business to our accompanying unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report for additional information regarding our assessment. We believe that our longer-term working capital, planned research and development, capital expenditures and other general corporate funding requirements may be satisfied through the sale of equity, debt, borrowings under credit facilities or through potential

collaborations with other companies, other strategic transactions or government or other grants. Our liquidity plans are subject to a number of risks and uncertainties, including those described in the sections entitled "Forward-Looking Statements" and "Risk Factors" in this Quarterly Report and our Annual Report. If we are unable to raise sufficient capital, we could be forced to further 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.

On May 12, 2023, we entered into the Purchase Agreement with the Purchasers and another affiliate of Oberland Capital Management LLC, as agent for the Purchasers, to obtain financing in respect to the further development and commercialization of our ATEV, to repay the Loan Agreement, and for other general corporate purposes. Pursuant to the Purchase Agreement and subject to customary closing conditions, the Purchasers have agreed to pay us an aggregate investment amount of up to $150.0 million. Under the terms of the Purchase Agreement, $40.0 million of the Investment Amount, less certain transaction expenses, was funded on May 12, 2023, which was used to repay in full and retire our indebtedness under the Loan Agreement, with the remaining proceeds funded to the Company. On March 11, 2024, $20.0 million of the Investment Amount was funded to the Company. See Note 6 — Revenue Interest Purchase Agreement to the condensed consolidated financial statements for additional details about this financing transaction.

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

On February 29, 2024, we entered into the Underwriting Agreement in connection with the Offering. The net proceeds to us from the Offering were approximately $43.0 million, after deducting underwriting discounts and commissions and Offering expenses. The Offering closed on March 5, 2024.

On September 24, 2024, we entered into the Common Stock Purchase Agreement with Lincoln Park for an equity line financing, which provides that, subject to the terms and conditions set forth in the Common Stock Purchase Agreement, we have the sole right, but not the obligation, to sell to Lincoln Park shares of Common Stock having an aggregate value of up to $50.0 million over a 24-month period. We control the timing and amount of any sales to Lincoln Park. As of September 30, 2024, we had completed sales of shares under the Common Stock Purchase Agreement that provided $1.0 million in gross proceeds, and as further disclosed in Note 13 — Subsequent Events, from September 30, 2024 through November 8 2024, we completed sales of shares that provided $1.5 million in additional gross proceeds. As of November 8 2024, we had $47.5 million in remaining availability for sales of our Common Stock under our Common Stock Purchase Agreement with Lincoln Park.

On October 4, 2024, we entered into a securities purchase agreement with an institutional investor pursuant to which the investor purchased approximately $30.0 million worth of Common Stock and Registered Direct Warrants in the Registered Direct Offering. The net proceeds to us from the Registered Direct Offering were approximately $28.1 million, after deducting placement agent's fees and offering expenses of approximately $1.9 million. The Registered Direct Offering closed on October 7, 2024.

Material Cash Requirements

Our known material cash requirements include: (1) the purchase of supplies and services that are primarily for research and development; (2) repayments pursuant to the Purchase Agreement; (3) employee wages, benefits, and incentives; (4) financing and operating lease payments (for additional information see below), and (5) payments under our JDRF Agreement (see Note 11 — Commitments and Contingencies to our unaudited condensed consolidated financial statements contained elsewhere in this Quarterly Report). We have also entered into contracts with CROs primarily for clinical trials. These contracts generally provide for termination upon limited notice, and therefore we believe that our non-cancellable obligations under these agreements are not material. Moreover, we may be subject to additional material cash requirements that are contingent upon the occurrence of certain events, for example, legal contingencies, uncertain tax positions, and other matters.

As of September 30, 2024, we had non-cancellable purchase commitments of $23.0 million for supplies and services that are primarily for research and development. We have existing license agreements with Duke University and Yale University, a distribution agreement with Fresenius Medical Care and our JDRF Agreement. The amount and timing of any potential milestone payments, license fee payments, royalties and other payments that we may be required to make under these agreements are unknown or uncertain at September 30, 2024. For additional information regarding our agreement with Fresenius Medical Care, see Note 12 — Related Party Transactions to our unaudited condensed consolidated financial statements contained elsewhere in this Quarterly Report. For additional information regarding our agreements with Duke University, Yale University and JDRF, see Note 11 — Commitments and Contingencies to our unaudited condensed consolidated financial statements contained elsewhere in this Quarterly Report.

Revenue Interest Purchase Agreement

On May 12, 2023, we entered into the Purchase Agreement and repaid in full all of the outstanding obligations under our Loan Agreement with SVB and SVB Innovation Credit Fund VIII, L.P. Under the Purchase Agreement, as of September 30, 2024, we had $62.1 million recorded as a revenue interest liability on our condensed consolidated financial statements. For additional information regarding repayment, see Note 6 — Revenue Interest Purchase Agreement to our unaudited condensed consolidated financial statements contained elsewhere in this Quarterly Report.

Leases

Our finance leases relate to our headquarters facility containing our manufacturing, research and development and general and administrative functions, which was substantially completed in June 2018 and is being leased through May 2033, and our operating lease relates to the land lease associated with our headquarters. Our future contractual obligations under our lease agreements as of September 30, 2024 are as follows:

($ in thousands)	Total	Less than 1 year	1 – 3 years	3 – 5 years	More than 5 years
Finance leases	$ 22,465	$ 4,186	$ 7,524	$ 4,414	$ 6,341
Operating lease	810	105	210	210	285

ATM Facility

On September 1, 2022, we entered into an agreement for the sale from time to time up to $80.0 million of shares of Common Stock pursuant to a sales agreement (the "ATM Facility"). As of September 30, 2024, we have not conducted any sales of Common Stock under the ATM Facility.

Future Funding Requirements

We expect to incur significant expenses in connection with our ongoing activities as we seek to (i) continue clinical development of our 6 millimeter ATEV for use in vascular trauma and hemodialysis AV access and submit a BLA for FDA approval of an indication in hemodialysis AV access, (ii) to launch and commercialize our ATEVs for vascular repair and hemodialysis AV access, if marketing approval is obtained, in the U.S. market, as well as subsequent launches in key international markets, (iii) advance our pipeline in major markets, including PAD Phase 3 trials and continue preclinical development and advance to planned clinical studies in CABG and BVP for diabetes, and (iv) scale out our manufacturing facility as required to satisfy market demand. We will need additional funding in connection with these activities.

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

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

Until such time, if ever, as we are able to successfully develop and commercialize one or more of our product candidates, we expect to continue financing our operations through the sale of equity, debt, borrowings under credit facilities or through potential collaborations with other companies, other strategic transactions or government or other grants. Adequate capital may not be available to us when needed or on acceptable terms. Other than the Purchase Agreement, we do not currently have any committed external source of funds. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of stockholders. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making acquisitions or capital expenditures. Debt financing would also result in fixed payment obligations. If we are unable to raise capital, we 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.

Our principal use of cash in recent periods has been primarily to fund our operations, including the clinical and preclinical development of our product candidates. Our future capital requirements, both short-term and long-term, will depend on many factors, including the progress and results of our clinical trials and preclinical development, timing and extent of spending to support development efforts, cost and timing of future commercialization activities, and the amount and timing of revenues, if any, that we receive from commercial sales.

See the section of this Quarterly Report entitled “Risk Factors” for additional risks associated with our substantial capital requirements.

Cash Flows

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

($ in thousands)	Nine Months Ended September 30, 2024	2023
Net loss	$ (127,761)	$ (85,670)
Non-cash adjustments to reconcile net loss to net cash used in operating activities[(1)]:	53,404	27,979
Changes in operating assets and liabilities:	2,812	3,440
Net cash used in operating activities	(71,545)	(54,251)
Net cash used in investing activities	(1,509)	(23)
Net cash provided by financing activities	63,177	4,842
Net decrease in cash, cash equivalents and restricted cash	$ (9,877)	$ (49,432)
Cash, cash equivalents and restricted cash at the beginning of the period	$ 80,801	$ 149,772
Cash, cash equivalents and restricted cash at the end of the period	$ 70,924	$ 100,340

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

Cash Flow from Operating Activities

The increase in net cash used in operating activities from the nine months ended September 30, 2023 to the nine months ended September 30, 2024 was primarily due to increased spending on pre-clinical, clinical and pre-commercial activities as well as payroll and personnel expenses, expansion of clinical development of the ATEV for use in AV access, and preparation for the planned commercial launch of the ATEV for an indication in vascular trauma, if approved by the FDA.

Cash Flow from Investing Activities

Net cash used in investing activities for the nine months ended September 30, 2024 consisted of purchases of property and equipment. Net cash used in investing activities for the nine months ended September 30, 2023 consisted of purchases of property and equipment, which fully offset proceeds from the maturity of our short-term investments (certificates of deposit).

Cash Flow from Financing Activities

Net cash provided by financing activities for the nine months ended September 30, 2024 consisted primarily of $43.0 million of net proceeds from our Offering and $19.5 million of net proceeds from our Purchase Agreement. Net cash provided by financing activities for the nine months ended September 30, 2023 consisted primarily of $37.9 million of net proceeds from our Purchase Agreement, partially offset by $31.8 million of cash payments related to the repayment of our Loan Agreement.

Off-Balance Sheet Arrangements

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

Critical Accounting Estimates

Our discussion and analysis of our financial condition and results of operations are based upon our unaudited condensed consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States of America. The preparation of our unaudited condensed consolidated financial statements requires us to make estimates, assumptions and judgments that affect the reported amounts of assets, liabilities, revenues, and expenses, and disclosure of contingent liabilities. We base our estimates and assumptions on historical experience and other factors that we believe to be reasonable under the circumstances. We evaluate our estimates and assumptions on an ongoing basis. Although we believe that our estimates, assumptions, and judgments are reasonable, they are based upon information presently available. Actual results may differ significantly from these estimates based on different assumptions, judgments, or conditions.

An accounting estimate or assumption is considered critical if both (a) the nature of the estimate or assumption involves a significant level of estimation uncertainty, and (b) the impact within a reasonable range of outcomes of the estimate and assumption is material to our financial condition. There have been no material changes to our critical accounting policies and estimates as compared to those disclosed in our audited consolidated financial statements as of and for the years ended December 31, 2023 and 2022, included in our Annual Report.

Emerging Growth Company and Smaller Reporting Company Status

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

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

Item 3. Quantitative and Qualitative Disclosures About Market Risk

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

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures are designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is (i) recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms and (ii) accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow timely decisions regarding required disclosure.

As of September 30, 2024, our management, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures were effective as of September 30, 2024.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting (as defined in Rule 13a-15(f) and 15d-15(f) under the Exchange Act) during the three months ended September 30, 2024 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations on Effectiveness of Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, believes that our disclosure controls and procedures and internal control over financial reporting are designed to provide reasonable assurance of achieving their objectives and are effective at the reasonable assurance level. However, our management does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent or detect all error and fraud. Any control system, no matter how well designed and operated, is based upon certain assumptions and can provide only reasonable, not absolute, assurance that its objectives will be met. Further, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, within our company have been detected.

PART II – OTHER INFORMATION

Item 1. Legal Proceedings

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

Item 1A. Risk Factors

Our risk factors are disclosed in Part I, Item 1A of our Annual Report. Except as set forth below, there have been no material changes during the nine months ended September 30, 2024 from or updates to the risk factors discussed in Part I, Item 1A, Risk Factors of our Annual Report.

We have concluded that a substantial doubt is deemed to exist concerning our ability to continue as a going concern.

As further discussed in Note 1 — Organization and Description of Business in the notes to our unaudited condensed consolidated financial statements, substantial doubt is deemed to exist about the company's ability to continue as a going concern through November 8, 2025. Our financial statements do not include any adjustment relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern. Our ability to continue as a going concern will require us to generate positive cash flow from operations, obtain additional financing, enter into strategic alliances, or sell assets. Our cash resources and our potential inability to continue as a going concern may materially adversely affect our share price and our ability to raise new capital, enter into strategic alliances on a timely basis or at all. If we become unable to continue as a going concern, we may have to liquidate our assets and the values we receive for our assets in liquidation or dissolution could be significantly lower than the values reflected in our financial statements.

Our near-term prospects are dependent on the commercial success of our product candidates, if approved, and if we are unable to successfully commercialize them, our business, operating results and financial condition will be materially harmed.

Our business currently depends heavily on our ability to successfully commercialize our ATEVs in the United States and in other jurisdictions where we may obtain marketing approval. We may never be able to successfully commercialize our ATEVs or meet our expectations with respect to revenues for a number of reasons, including:

- a lack of acceptance of our ATEVs by physicians, patients, third-party payors and other members of the medical community;
- our limited experience in marketing, selling and distributing our ATEVs or any other product;
- our limited experience in the commercial manufacturing of our ATEVs or any other product;
- reimbursement and coverage policies of government and private payors such as Medicare, Medicaid, group purchasing organizations, insurance companies, health maintenance organizations and other plan administrators;
- changed or increased regulatory restrictions in the United States, EU and other foreign territories; and
- a lack of adequate financial or other resources to commercialize our ATEVs successfully.

There is no guarantee that the infrastructure, systems, processes, policies, relationships, and materials we have built for the launch and commercialization of our approved product in the United States will be sufficient for us to achieve success at the levels we expect. If we are not able to commercialize our ATEVs successfully for these or other reasons, our ability to generate revenue from product sales and achieve profitability will be adversely affected and the market price of our common stock could decline significantly.

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

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

We currently manufacture the 6 millimeter ATEVs for our clinical trials and for planned initial commercial distribution, 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 ATEVs, 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. We have limited years of experience manufacturing our ATEVs in-house with the LUNA200 system, and no experience manufacturing the volume of ATEVs 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 have experienced interruptions in the supply of the raw materials required to manufacture our product candidates, 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 ATEVs 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 ATEVs in sufficient volumes that also satisfy the legal, regulatory, quality, price, durability, engineering, design and production standards required to commercialize our ATEVs successfully.

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

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

Our estimates of the market opportunity for our ATEVs, if approved, and certain of our other 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.

Our product candidates, if approved, may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success.

The commercial success of our ATEVs will depend, in part, on the acceptance of physicians, patients and health care payors as medically necessary, cost-effective and safe. Our ATEVs and any other product that we commercialize may not gain acceptance by physicians, patients, health care payors and others in the medical community due to ethical, social, medical 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 our ATEVs or any of our other product candidates that receives marketing approval will depend on a number of factors, including:

- the efficacy and potential advantages of our ATEVs or our other 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 ATEVs or our other products, if approved.

There is uncertainty with respect to third-party coverage and reimbursement of our ATEVs, if approved, and our other product candidates. 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. In the United States, third-party payors, including government payors such as the Medicare and Medicaid programs, play an important role in determining the extent to which medical products and biologics will be covered and reimbursed. The Medicare and Medicaid programs increasingly are used as models for how private payors and government payors develop their coverage and reimbursement policies. Currently, no RMAT tissue engineered product has established coverage and reimbursement by the CMS. It is difficult to predict what CMS or any comparable foreign regulatory agency will decide with respect to coverage and reimbursement for novel products such as our ATEVs and our other product candidates, as there is no body of established practices and precedents for these types of products.

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

On August 16, 2022, President Biden signed the Inflation Reduction Act ("IRA") into law, which sets forth meaningful changes to drug product reimbursement by Medicare. Among other actions, the IRA permits the Department of Health and Human Services ("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.

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

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

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 ATEVs 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 ATEVs and our other product candidates in human clinical trials and will face an even greater risk, when we commercially sell our ATEVs and any other product candidates. If we cannot successfully defend ourselves against claims that our ATEVs or our other product candidates caused injuries, we will incur substantial liabilities. Regardless of merit or eventual outcome, product liability claims may result in:

- decreased demand for our ATEVs or any other product candidates that we develop or sell, leading to loss of revenue;
- injury to our reputation and significant negative media attention;
- withdrawal, or slower enrollment, of clinical trial participants;
- significant costs to defend the related litigation and reduced resources of our management to pursue our business strategy;
- substantial monetary awards to trial participants or patients; and
- inability to further develop or commercialize our ATEVs or our other 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.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

Director and Officer Trading Arrangements

On August 16, 2024, Shamik Parikh, the Company's Chief Medical Officer, adopted a trading arrangement for the sale of Common Stock that is intended to satisfy the affirmative defense conditions provided by Rule 10b5-1(c) under the Exchange Act. (the "Parikh 10b5-1 Plan"). The Parikh 10b5-1 Plan provides for a first possible trade date of November 21, 2024 and terminates automatically on the earlier of the execution of all trades contemplated by the Parikh 10b5-1 Plan, or August 25, 2025. The Parikh 10b5-1 Plan provides for the sale of up to 181,512 shares of Common Stock pursuant to its terms.

On September 13, 2024, Dale Sander, the Company's Chief Financial Officer, adopted a trading arrangement for the sale of Common Stock that is intended to satisfy the affirmative defense conditions provided by Rule 10b5-1(c) under the Exchange Act. (the "Sander 10b5-1 Plan"). The Sander 10b5-1 Plan provides for a first possible trade date of December 12, 2024 and terminates automatically on the earlier of the execution of all trades contemplated by the Sander 10b5-1 Plan, or September 12, 2025. The Sander 10b5-1 Plan provides for the sale of up to 189,860 shares of Common Stock pursuant to its terms.

Other than as disclosed above, during the three months ended September 30, 2024, no director or officer (as defined in Rule 16a-1(f) under the Exchange Act) of the Company adopted or terminated any "Rule 10b5-1 trading arrangement" or any "non Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

Item 6. Exhibits

The following exhibits are filed as part of, or incorporated by reference into, this Quarterly Report on Form 10-Q.

Exhibit Number	Description
4.1	Form of Common Stock Purchase Warrant (incorporated by reference to Exhibit 4.1 to Humacyte, Inc.'s Current Report on Form 8-K, filed with the SEC on October 7, 2024).
10.1	Purchase Agreement, dated as of September 24, 2024, by and between Humacyte, Inc. and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.1 to Humacyte Inc.'s Current Report on Form 8-K, filed with the SEC on September 25, 2024).
10.2	Registration Rights Agreement, dated as of September 24, 2024, by and between Humacyte, Inc. and Lincoln Park Capital Fund, LLC (incorporated by reference to Exhibit 10.2 to Humacyte Inc.'s Current Report on Form 8-K, filed with the SEC on September 25, 2024).
10.3	Securities Purchase Agreement, dated as of October 4, 2024, by and between Humacyte, Inc. and the investor (incorporated by reference to Exhibit 10.1 to Humacyte Inc.'s Current Report on Form 8-K, filed with the SEC on October 7, 2024).
31.1*	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) under the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1**	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2**	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	The following materials from Humacyte, Inc.'s Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, formatted in Inline XBRL (Inline eXtensible Business Reporting Language): (i) Condensed Consolidated Balance Sheets (unaudited), (ii) Condensed Consolidated Statements of Operations and Comprehensive Loss (unaudited), (iii) Condensed Consolidated Statements of Changes in Stockholders' Equity (Deficit) (unaudited), (iv) Condensed Consolidated Statements of Cash Flows (unaudited), (v) Notes to Condensed Consolidated Financial Statements (unaudited), and (vi) Cover Page.
104	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Filed herewith.

** This exhibit is being furnished rather than filed, and shall not be deemed incorporated by reference into any filing, in accordance with Item 601 of Regulation S-K.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized on this 8th day of November, 2024.

HUMACYTE, INC.

Date: November 8, 2024

By: /s/ Laura E. Niklason, M.D., Ph.D.

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

Title: President and Chief Executive Officer

By: /s/ Dale A. Sander

Name: Dale A. Sander

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

Exhibit 31.1

CERTIFICATION

I, Laura E. Niklason, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Humacyte, Inc. for the quarter ended September 30, 2024;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 8, 2024

By: /s/ Laura E. Niklason

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

Title: President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION

I, Dale A. Sander, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Humacyte, Inc. for the quarter ended September 30, 2024;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

    c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 8, 2024

By: /s/ Dale A. Sander

Name: Dale A. Sander

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

Exhibit 32.1

CERTIFICATION

In connection with the Quarterly Report on Form 10-Q of Humacyte, Inc. (the "Company") for the quarter ended September 30, 2024 (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, I, Laura E. Niklason, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 8, 2024

By: /s/ Laura E. Niklason

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

Title: President and Chief Executive Officer

Exhibit 32.2

CERTIFICATION

In connection with the Quarterly Report on Form 10-Q of Humacyte, Inc. (the "Company") for the quarter ended September 30, 2024 (the "Report"), as filed with the Securities and Exchange Commission on the date hereof, I, Dale A. Sander, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 8, 2024

By: /s/ Dale A. Sander

Name: Dale A. Sander

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