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

FORM 10-Q

☒ **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: 001-40060

Longeveron Inc.

(Exact name of registrant as specified in its charter)

Delaware	**47-2174146**
(State or Other Jurisdiction of Incorporation)	**(IRS Employer Identification No.)**
1951 NW 7th Avenue, Suite 520, Miami, Florida	**33136**
(Address of principal executive offices)	**(Zip Code)**

(305)

909-0840

(Registrant's telephone number, including area code)

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

Title of each class	Trading Symbol	Name of each exchange on which registered
Class A common stock, par value $0.001 per share	LGVN	The Nasdaq Capital Market

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	☐

	☒	Smaller reporting company	
Non-accelerated filer			☒
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 8, 2024, the registrant had

13,352,770
shares of Class A common stock, $0.001 par value per shares, and

1,484,005
shares of Class B common stock, $0.001 par value per share, outstanding.

LONGEVERON INC.

TABLE OF CONTENTS

PART I. FINANCIAL INFORMATION		1
ITEM 1.	Condensed Financial Statements	1
	Condensed Balance Sheets as of September 30, 2024 (unaudited) and December 31, 2023	1
	Condensed Statements of Operations for the three and nine months ended September 30, 2024 and 2023 (unaudited)	2
	Condensed Statements of Comprehensive Loss for the three and nine months ended September 30, 2024 and 2023 (unaudited)	3
	Condensed Statements of Changes in Stockholders' Equity for the three and nine months ended September 30, 2024 and 2023 (unaudited)	4
	Condensed Statements of Cash Flows for the nine months ended September 30, 2024 and 2023 (unaudited)	8
	Notes to Unaudited Condensed Financial Statements	9
ITEM 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	25
ITEM 3.	Quantitative and Qualitative Disclosures About Market Risk	38
ITEM 4.	Controls and Procedures	39
PART II. OTHER INFORMATION		40
ITEM 1.	Legal Proceedings	40
ITEM 1A.	Risk Factors	40
ITEM 2.	Unregistered Sales of Equity Securities and Use of Proceeds	40
ITEM 3	Defaults Upon Senior Securities	40
ITEM 4	Mine Safety Disclosures	40
ITEM 5	Other Information	40
ITEM 6.	Exhibits	41
SIGNATURES		42

PART I. FINANCIAL INFORMATION

Item 1. Condensed Financial Statements.

Longeveron Inc.
Condensed Balance Sheets
(In thousands, except share and per share data)

	September 30, 2024 (Unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 22,778	$ 4,949
Marketable securities	–	412
Prepaid expenses and other current assets	609	376
Accounts and grants receivable	380	111
Total current assets	23,767	5,848
Property and equipment, net	2,622	2,529
Intangible assets, net	2,347	2,287
Operating lease asset	970	1,221
Other assets	203	193
Total assets	$ 29,909	$ 12,078
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 887	$ 638
Accrued expenses	1,479	2,152
Current portion of lease liability	616	593
Deferred revenue	118	506
Total current liabilities	3,100	3,889
Long-term liabilities:		

Lease liability	983	1,448
Other liabilities	199	–
Total long-term liabilities	1,182	1,448
Total liabilities	4,282	5,337
Commitments and contingencies (Note 9)		
Stockholders' equity:		
Preferred stock, $ 0.001 par value per share, 5,000,000 shares authorized, no shares issued and outstanding at September 30, 2024, and December 31, 2023	–	–
Class A common stock, $ 0.001 par value per share, 84,295,000 shares authorized, 13,352,770 shares issued and outstanding at September 30, 2024; 1,025,183 issued and outstanding at December 31, 2023	13	1
Class B common stock, $ 0.001 par value per share, 15,705,000 shares authorized, 1,484,005 shares issued and outstanding at September 30, 2024; 1,485,560 issued and outstanding at December 31, 2023	1	1
Additional paid-in capital	131,139	91,823

Stock subscription receivable	–	(100)
Accumulated deficit	(105,525)	(84,984)
Accumulated other comprehensive loss	(1)	–
Total stockholders' equity	25,627	6,741
Total liabilities and stockholders' equity	$ 29,909	$ 12,078

See accompanying notes to unaudited condensed financial statements.

Longeveron Inc.
Condensed Statements of Operations
(In thousands, except per share data)
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2024	**2023**	**2024**	**2023**
Revenues				
Clinical trial revenue	$ 210	$ 150	$ 1,012	$ 605
Contract manufacturing revenue	563	-	777	-
Grant revenue	-	-	-	41
Total revenues	773	150	1,789	646
Cost of revenues	91	96	435	423
Gross profit	682	54	1,354	223
Operating expenses				
General and administrative	3,125	3,372	7,447	8,902
Research and development	2,206	1,843	6,148	6,910
Total operating expenses	5,331	5,215	13,595	15,812
Loss from operations	(4,649)	(5,161)	(12,241)	(15,589)
Other income				
Other income, net	230	55	349	204
Total other income, net	230	55	349	204
Net loss	$ (4,419)	$ (5,106)	$ (11,892)	$ (15,385)
Deemed dividend – warrant inducement offers	(149)	(798)	(8,650)	(798)
Net loss attributable to common stockholders	$ (4,568)	$ (5,904)	$ (20,542)	$ (16,183)
Basic and diluted net loss per share	$ (0.34)	$ (2.79)	$ (2.71)	$ (7.29)

Basic and diluted weighted average common shares outstanding	13,627,793	2,117,877	7,572,601	2,110,646

See accompanying notes to unaudited condensed financial statements.

Longeveron Inc.
Condensed Statements of Comprehensive Loss
(In thousands)
(Unaudited)

	Three months ended September 30,		Nine months ended September 30,	
	2024	**2023**	**2024**	**2023**
Net loss	($ 4,419)	($ 5,106)	($ 11,892)	($ 15,385)
Other comprehensive loss:				
Net unrealized gain (loss) on available-for-sale securities	-	26	(1)	48
Total comprehensive loss	($ 4,419)	($ 5,080)	($ 11,893)	($ 15,337)

See notes to unaudited condensed financial statements.

Longeveron Inc.
Condensed Statements of Changes in Stockholders' Equity
(In thousands, except share amounts)
(Unaudited)

	Class A Common Stock		Class B Common Stock		Subscription	Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Total Stockholders'
	Number	Amount	Number	Amount	Receivable	Capital	Deficit	Loss	Equity
Balance at December 31, 2023	1,025,183	$ 1	1,485,560	$ 1	$ (100)	$ 91,822	$ (84,983)	$ -	$ 6,741
Conversion of Class B common stock for Class A common stock	1,555	-	(1,555)	-	-	-	-	-	-
Class A common stock, issued for RSUs vested	482,246	-	-	-	-	-	-	-	-
Class A common stock, held for taxes on RSUs vested	(109,461)	-	-	-	-	(296)	-	-	(296)
Class A common stock, issued for PSUs vested	8,002	-	-	-	-	-	-	-	-
Class A common stock, held for taxes on PSUs vested	(3,268)	-	-	-	-	(17)	-	-	(17)
Collection of stock subscription receivable	-	-	-	-	100	-	-	-	100
Equity-based compensation	-	-	-	-	-	1,938	-	-	1,938
Unrealized gain attributable to change in market value of available for sale investments	-	-	-	-	-	-	-	(1)	(1)
Class A common stock issued in public offering, net of issuance cost of $ 2,064	4,448,792	4				12,862	-	-	12,866
Class A common stock issue for warrants exercised, net of issuance cost of $ 1,855	7,432,751	8	-	-	-	16,180	-	-	16,188
Deemed dividend – warrant inducement offers	-	-	-	-	-	8,650	(8,650)	-	-
Reverse stock split rounding adjustment	66,970	-	-	-	-	-	-	-	-
Net loss	-	-	-	-	-	-	(11,892)	-	(11,892)

Balance at September 30, 2024	13,352,770	$ 13	1,484,005	$ 1	$ -	$ 131,139	(105,525)	($ 1)	$ 25,627

See notes to unaudited condensed financial statements.

Longeveron Inc.
Condensed Statements of Changes in Stockholders' Equity
(In thousands, except share amounts)
(Unaudited)

	Class A Common Stock		Class B Common Stock		Subscription Receivable	Additional Paid-In Capital	Accumulated Deficit	Accumulated Other Comprehensive (Loss) Gain	Total Stockholders' Equity
	Number	Amount	Number	Amount					
Balance at December 31, 2022	612,732	$ 1	1,489,109	$ 1	$ (100)	$ 83,731	$ (62,773)	$ (357)	$ 20,503
Conversion of Class B common stock into Class A common stock	3,555	-	(3,555)	-	-	-	-	-	-
Class A common stock, issued for RSUs vested	22,703	-	-	-	-	-	-	-	-
Class A common stock, held for taxes on RSUs vested	(4,305)	-	-	-	-	(153)	-	-	(153)
Class A common stock issued for stock rights offering	10,850	-	-	-	-	-	-	-	-
Equity-based compensation	-	-	-	-	-	1,619	-	-	1,619
Unrealized gain attributable to change in market value of available for sale investments	-	-	-	-	-	-	-	48	48
Dividend attributable to down round feature of 2021 warrants	-	-	-	-	-	798	(798)	-	-
Reverse stock split rounding adjustment	-	-	6	-	-	-	-	-	-
Net loss	-	-	-	-	-	-	(15,385)	-	(15,385)
Balance at September 30, 2023	645,535	$ 1	1,485,560	$ 1	$ (100)	$ 85,995	$ (78,956)	$ (309)	$ 6,632

See notes to unaudited condensed financial statements.

Longeveron Inc.
Condensed Statements of Changes in Stockholders' Equity
(In thousands, except share amounts)
(Unaudited)

	Class A Common Stock		Class B Common Stock		Subscription	Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Total Stockholder's
	Number	Amount	Number	Amount	Receivable	Capital	Deficit	Loss	Equity
Balance at June 30, 2024	8,116,909	$ 8	1,484,005	$ 1	$ -	$ 115,858	$ (100,957)	$ (1)	$ 14,909
Class A Common Stock, issued for RSUs vested	472,532	-	-	-	-	-	-	-	-
Class A Common Stock, held for taxes on RSUs vested	(105,960)	-	-	-	-	(270)	-	-	(270)
Equity-based compensation	-	-	-	-	-	1,413	-	-	1,413
Class A common stock issued in public offering, net of issuance costs of $ 919	2,236,026	2	-	-	-	8,142	-	-	8,144
Class A common stock issued for warrants exercised, net of issuance costs of $ 494	2,633,263	3	-	-	-	5,847	-	-	5,850
Deemed dividend – warrant inducement offers	-	-	-	-	-	149	(149)	-	-
Net loss	-	-	-	-	-	-	(4,419)	-	(4,419)
Balance at September 30, 2024	13,352,770	$ 13	1,484,005	$ 1	$ -	$ 131,139	$ (105,525)	$ (1)	$ 25,627

See accompanying notes to unaudited condensed financial statements.

Longeveron Inc.
Condensed Statements of Changes in Stockholders' Equity
(In thousands, except share amounts)
(Unaudited)

	Class A Common Stock		Class B Common Stock		Subscription	Additional Paid-In	Accumulated	Accumulated Other Comprehensive	Total Stockholder's
	Number	Amount	Number	Amount	Receivable	Capital	Deficit	(Loss) Gain	Equity
Balance at June, 2023	631,423	$ 1	1,485,560	$ 1	$ (100)	$ 84,748	$ (73,052)	$ (335)	$ 11,263
Class A Common Stock, issued for RSUs vested	4,731	-	-	-	-	-	-	-	-
Class A Common Stock, held for taxes on RSUs vested	(1,469)	-	-	-	-	(50)	-	-	(50)
Class A common stock issued for stock rights offering	10,850	-	-	-	-		-	-	-
Equity-based compensation	-	-	-	-	-	499	-	-	499
Unrealized gain attributable to change in market value of available-for-sale securities	-	-	-	-	-	-	-	26	26
Dividend attributable to down round feature of 2021 warrants	-	-	-	-	-	798	(798)	-	-
Net loss	-	-	-	-	-	-	(5,106)	-	(5,106)
Balance at September 30, 2023	645,535	$ 1	1,485,560	$ 1	$ (100)	$ 85,995	$ (78,956)	$ (309)	$ 6,632

See accompanying notes to unaudited condensed financial statements.

Longeveron Inc.
Condensed Statements of Cash Flows
(In thousands)
(Unaudited)

	Nine months ended September 30,	
	2024	**2023**
Cash flows from operating activities		
Net loss	$ (11,892)	$ (15,385)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	716	710
Interest earned on marketable securities	60	180
Equity-based compensation	1,938	1,619
Changes in operating assets and liabilities:		
Accounts and grants receivable	(269)	122
Prepaid expenses and other current assets	(233)	(611)
Other assets	(10)	47
Accounts payable	248	(922)
Deferred revenue	(387)	–
Nonoperating lawsuit liability	–	(1,398)
Accrued expenses	(674)	823
Operating lease asset and lease liability	(191)	(190)
Other liabilities	199	–
Net cash used in operating activities	(10,495)	(15,005)
Cash flows from investing activities		
Proceeds from the sale of marketable securities	352	7,057
Acquisition of property and equipment	(642)	(137)

Acquisition of intangible assets	(227)	(298)
Net cash (used in) provided by investing activities	(517)	6,622
Cash flows from financing activities		
Proceeds from the issuance of common stock, net of issuance cost	12,866	–
Proceeds from warrants exercised, net of issuance cost	16,188	–
Proceeds from stock subscription receivable	100	–
Payments for taxes on RSUs vested and PSUs vested	(313)	(153)
Net cash provided by (used in) financing activities	28,841	(153)
Change in cash and cash equivalents	17,829	(8,536)
Cash and cash equivalents at beginning of the period	4,949	10,503
Cash and cash equivalents at end of the period	$ 22,778	$ 1,967
Supplement Disclosure of Non-cash Investing and Financing Activities:		
Vesting of RSUs and PSUs into Class A common stock	$ (978)	$ (717)
Deemed dividend – warrant inducement offers	$ 8,650	$ 798

See accompanying notes to unaudited condensed financial statements.

Longeveron Inc.
Notes to Unaudited Condensed Financial Statements
Nine Month Periods Ended September 30, 2024 and 2023

1. Nature of Business, Basis of Presentation, and Liquidity

Nature of business:

Longeveron was formed as a Delaware limited liability company on October 9, 2014, and was authorized to transact business in Florida on December 15, 2014. On February 12, 2021, Longeveron, LLC converted its corporate form (the "Corporate Conversion") from a Delaware limited liability company (Longeveron, LLC) to a Delaware corporation, Longeveron Inc. (the "Company," "Longeveron" or "we," "us," or "our"). The Company is a clinical stage biotechnology company developing cellular therapies for specific aging-related and life-threatening conditions. The Company operates out of its leased facilities in Miami, Florida.

The Company's product candidates are currently in development. There can be no assurance that the Company's research and development will be successfully completed, that adequate protection for the Company's intellectual property will be obtained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. Even if the Company's product development efforts are successful, it is uncertain when, if ever, the Company will generate significant revenue from product sales. The Company operates in an environment of rapid technological change and substantial competition from, among others, existing pharmaceutical and biotechnology companies. In addition, the Company is dependent upon the services of its employees, partners, and consultants.

The accompanying interim condensed balance sheet as of September 30, 2024, and the condensed statements of operations, statements of comprehensive loss, and statements of changes in stockholders' equity for the three and nine months ended September 30, 2024 and 2023 and the condensed statements of cash flows for the nine months ended September 30, 2024 and 2023 are unaudited. The unaudited condensed financial statements have been prepared according to the rules and regulations of the Securities and Exchange Commission ("SEC") and, therefore, certain information and disclosures normally included in financial statements prepared in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") have been omitted. In the opinion of management, the accompanying unaudited condensed financial statements for the periods presented reflect all adjustments which are normal and recurring, and necessary to fairly state the financial position, results of operations, and cash flows of the Company. These unaudited condensed financial statements and notes should be read in conjunction with the audited financial statements and notes thereto in the Company's 2023 Annual Report on Form 10-K filed with the SEC on February 27, 2024.

Liquidity:

Since inception, the Company has primarily been engaged in organizational activities, including raising capital, and research and development activities. The Company does not yet have a product that has been approved by the U.S. Food and Drug Administration ("FDA"), and has only generated revenues from grants, clinical trials and contract manufacturing. The Company has not yet achieved profitable operations or generated positive cash flows from operations. The Company intends to continue its efforts to raise additional funds via equity financing, develop its intellectual property, and secure regulatory approvals to commercialize its products. There is no assurance that profitable operations, if achieved, could be sustained on a continuing basis. Further, the Company's future operations are dependent on the success of the Company's efforts to raise additional capital, its research and commercialization efforts, regulatory approval, and, ultimately, the market acceptance of the Company's approved products, if any. These condensed financial statements do not include adjustments that might result from the outcome of these uncertainties.

The Company has incurred recurring losses from operations since its inception, including a net loss of $

11.9
million and $

15.4
million for the nine months ended September 30, 2024 and 2023, respectively. In addition, as of September 30, 2024, the Company had an accumulated deficit of $

105.5
million. The Company expects to continue to generate operating losses in the foreseeable future.

As of September 30, 2024, the Company had cash and cash equivalents of $

22.8
million. The Company currently believes that its cash and cash equivalents as of September 30, 2024 will enable it to fund its operating expenses and capital expenditure requirements through the fourth quarter of 2025 based on its current operating budget and cash flow forecast. However, as a result of its successful Type C meeting with the U.S. FDA in August 2024 with respect to the HLHS regulatory pathway, the Company has started to ramp up Biologics License Application (BLA) enabling activities as the Company currently anticipates a potential filing with the FDA in 2026 if the current ELPIS II trial is successful. To the extent that the Company's operating expenses and capital expenditure requirements accelerate in calendar 2025 as a result of these activities, including CMC (Chemistry, Manufacturing, and Controls) and manufacturing readiness, there will be a need to increase the Company's current proposed spend and further increase its capital investments. The Company intends to seek additional financing/capital raises/non-dilutive funding options to support these activities, and current cash projections may be impacted by these ramped up activities and any financing transactions entered into.

2. Summary of Significant Accounting Policies

Basis of presentation:

The condensed financial statements of the Company were prepared in accordance with U.S. GAAP.

Certain reclassifications have been made to prior year condensed financial statements to conform to classifications used in the current year. These reclassifications had no impact on net loss, stockholders' equity or cash flows as previously reported.

Reverse Stock Split:

On March 26, 2024, the Company effected a reverse stock split of the outstanding shares of its Class A common stock and Class B common stock on a one-for-10 (1:10) basis (the "Reverse Stock Split"). The Reverse Stock Split became effective at 11:59 p.m. Eastern Time on March 26, 2024 via a certificate of amendment to the Company's Certificate of Incorporation filed with the Secretary of State of the State of Delaware. At the effective time of the Reverse Stock Split, every 10 shares of the Company's Class A common stock and Class B common stock, whether issued and outstanding or held by the Company as treasury stock, were automatically combined and converted (without any further act) into one fully paid and nonassessable share of Class A common stock or Class B common stock, respectively, subject to rounding up of fractional shares to the nearest whole number of shares resulting from the Reverse Stock Split without any change in the par value per share. All share, per share, option, warrant, equity award, and other derivative security numbers and exercise prices appearing in this Quarterly Report on Form 10-Q and the accompanying condensed financial statements have been adjusted to give effect to the Reverse Stock Split for all prior periods presented. However, the Company's annual, other periodic, and current reports, and all other information and documents incorporated by reference into this Quarterly Report on Form 10-Q that were filed prior to March 19, 2024, do not give effect to the Reverse Stock Split.

Use of estimates:

The presentation of condensed 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 condensed financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results could differ from those estimates.

Accounting Standard Updates:

A variety of proposed or otherwise potential accounting standards are currently under consideration by standard-setting organizations and certain regulatory agencies. Because of the tentative and preliminary nature of such proposed standards, management has not yet determined the effect, if any, that the implementation of such proposed standards would have on the Company's condensed financial statements.

In December 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2023-09, "Improvements to Income Tax Disclosures". The amendments in this ASU change disclosure requirements for various items, including effective tax rate reconciliations and cash taxes paid. This ASU is effective for public companies for the financial reporting periods beginning on January 1, 2025, with early adoption permitted. The Company has not adopted ASU 2023-09 for its financial reporting period ending December 31, 2023, and will continue to evaluate early adoption for its financial reporting period ending December 31, 2024.

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2023-07, "Improvements to Reportable Segment Disclosures". The amendments in this ASU are intended to improve reportable segment disclosure requirements, primarily through enhanced disclosures about significant segment expenses and by extending the disclosure requirements to entities with a single reportable segment. This ASU 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. ASU 2023-07 is to be applied retrospectively to all prior periods presented in the financial statements. ASU 2023-07 will be effective for the Company for the annual period of its fiscal year ending December 31, 2024. The Company does not anticipate the adoption of this ASU will have a material impact on its consolidated financial statements.

Cash and cash equivalents:

The Company considers cash to consist of cash on hand and temporary investments having an original maturity of 90 days or less that are readily convertible into cash.

Marketable securities:

The Company has

no

marketable securities at September 30, 2024. Marketable securities December 31, 2023 consisted of marketable fixed income securities, primarily corporate bonds which are categorized as available for sale securities and are thus marked to market and stated at fair value in accordance with Accounting Standards Codification ("ASC") 820 *Fair Value Measurement*. These investments are considered Level 1 and Level 2 investments within the ASC 820 fair value hierarchy. The fair value of Level 1 investments, including cash equivalents, money funds and U.S. government securities, are substantially based on quoted market prices in active markets. The fair value of corporate bonds is determined using standard market valuation methodologies, including discounted cash flows, matrix pricing and/or other similar techniques. The inputs to these valuation techniques include but are not limited to market interest rates, credit rating of the issuer or counterparty, industry sector of the issuer, coupon rate, call provisions, maturity, estimated duration and assumptions regarding liquidity and estimated future cash flows. In addition to bond characteristics, the valuation methodologies incorporate market data, such as actual trades completed, bids and actual dealer quotes, where such information is available. Accordingly, the estimated fair values are based on available market information and judgments about financial instruments categorized within Level 1 and Level 2 of the fair value hierarchy. Interest and dividends are recorded when earned. Realized gains and losses on investments are determined by specific identification and are recognized as incurred in the condensed statement of operations. Changes in net unrealized gains and losses are reported in other comprehensive loss and represent the change in the fair value of investment holdings during the reporting period. Changes in net unrealized losses were less than $

0.1

million for the nine months ended September 30, 2024 and 2023, respectively.

Accounts and grants receivable:

Accounts and grants receivable include amounts due from customers, granting institutions and others. The amounts as of September 30, 2024 and December 31, 2023 are certain to be collected, and no amount has been recognized for expected credit losses. In addition, for the clinical trial revenue, most participants pay in advance of treatment. Advanced grant funds and prepayments for the clinical trial revenue are recorded to deferred revenue. Advance contract manufacturing payments are recorded to deferred revenue.

Accounts and grants receivable by source, as of (in thousands):

	September 30, 2024	December 31, 2023
Accounts receivable from customers	$ 321	$ 15
National Institutes of Health – Grant	59	96
Total	$ 380	$ 111

Deferred offering costs:

The Company recorded certain legal, professional and other third-party fees that were directly associated with in-process equity financings as deferred offering costs until the applicable equity financing was consummated. After consummation of an equity financing, these costs are recorded in stockholders' equity as a reduction of proceeds generated as a result of the offering.

Property and equipment:

Property and equipment, including improvements that extend the useful lives of related assets, are recorded at cost, while maintenance and repairs are charged to operations as incurred. Depreciation is calculated using the straight-line method based on the estimated useful lives of the assets. Leasehold improvements are amortized over the shorter of the estimated useful life of the asset or the original term of the lease. Depreciation expense is recorded in the research and development line of the condensed statements of operations as the assets are primarily related to the Company's clinical programs.

Intangible assets:

Intangible assets include payments on license agreements with the Company's co-founder and Chief Scientific Officer ("CSO") and the University of Miami ("UM") (see Note 9) and legal costs incurred related to patents and trademarks. License agreements have been recorded at the value of cash consideration, common stock and membership units transferred to the respective parties when acquired.

Payments for license agreements are amortized using the straight-line method over the estimated term of the agreements, which range from 5 - 20 years. Patents are amortized over their estimated useful life, once issued. The Company considers trademarks to have an

indefinite useful life and evaluates them for impairment on an annual basis. Amortization expense is recorded in the research and development line of the condensed statements of operations as the assets are primarily related to the Company's clinical programs.

Impairment of Long-Lived Assets:

The Company evaluates long-lived assets for impairment, including property and equipment and intangible assets, when events or changes in circumstances indicate that the carrying value of such assets may not be recoverable. Upon the occurrence of a triggering event, the asset is reviewed to assess whether the estimated undiscounted cash flows expected from the use of the asset plus the residual value from the ultimate disposal exceeds the carrying value of the asset. If the carrying value exceeds the estimated recoverable amounts, the asset is written down to the estimated fair value. Any resulting impairment loss is reflected in the condensed statements of operations. Upon evaluation, management determined that there was no impairment of long-lived assets during the three and nine months ended September 30, 2024 and 2023.

Deferred revenue:

The unearned portion of advanced grant funds and prepayments for clinical trial and contract manufacturing revenues, which will be recognized as revenue when the Company meets the respective performance obligations, has been presented as deferred revenue in the accompanying condensed balance sheets. For the nine months ended September 30, 2024 and 2023, the Company recognized less than $

0.1

million, respectively, of funds that were previously classified as deferred revenue. Due to the Maryland Stem Cell Research Fund ("MSCRF") – Technology Development Corporation ("TEDCO") – grant Acute Respiratory Distress Syndrome ("ARDS") program being discontinued, $

0.4

million recorded as deferred revenue was reversed when the funds were returned to MSCRF – TEDCO. As of September 30, 2024 and December 31, 2023, the Company had $

0.1

million and $

0.5

million, respectively, recorded in deferred revenue on the condensed balance sheets.

Revenue recognition:

The Company recognizes revenue when performance obligations related to respective revenue streams are met. For grant revenue, the Company considers the performance obligation met when the grant related expenses are incurred or supplies and materials are received. The Company is paid in tranches pursuant to terms of the related grant agreements, and then applies payments based on regular expense reimbursement submissions to grantors. There are no remaining performance obligations or variable consideration once grant expense reporting to the grantor is complete. For clinical trial revenue, the Company considers the performance obligation met when the participant has received the treatment. The Company usually receives prepayment for these services or receives payment at the time the treatment is provided, and there are no remaining performance obligations or variable consideration once the participant receives the treatment. For contract manufacturing revenue, the Company considers the performance obligation met when the contractual obligation and/or statement of work has been satisfied. Payment terms may vary depending on specific contract terms. There are no significant judgments affecting the determination of the amount and timing of revenue recognition.

Revenue by source (in thousands):

	Three months ended September 30,		Nine months ended September 30,	
	2024	2023	2024	2023
Clinical trial revenue	$ 210	$ 150	$ 1,012	$ 605
Contract manufacturing	563	-	777	-
NIH - grant	-	-	-	41
Total	$ 773	$ 150	$ 1,789	$ 646

The Company records cost of revenues based on expenses directly related to revenue. For grants, the Company records allocated expenses for research and development costs to a grant as a cost of revenues. For the clinical trial revenue, directly related expenses for that program are expensed as incurred. These expenses are similar to those described under "Research and development expense" below. For the contract manufacturing, the Company records costs incurred under the contract as cost of revenues.

Research and development expense:

Research and development costs are charged to expense when incurred in accordance with ASC 730 *Research and Development*. ASC 730 addresses

the proper accounting and reporting for research and development costs. It identifies: 1) those activities that should be identified as research and development; 2) the elements of costs that should be identified with research and development activities, and the accounting for these costs; and 3) the financial statement disclosures related to them. Research and development costs include

costs such as clinical trial expenses, contracted research and license agreement fees with no alternative future use, supplies and materials, salaries, share-based compensation, employee benefits, property and equipment depreciation and allocation of various corporate costs. The Company accrues for costs incurred by external service providers, including contract research organizations and clinical investigators, based on its estimates of service performed and costs incurred. These estimates include the level of services performed by the third parties, patient enrollment in clinical trials, administrative costs incurred by the third parties, and other indicators of the services completed. Based on the timing of amounts invoiced by service providers, the Company may also record payments made to those providers as prepaid expenses that will be recognized as expenses in future periods as the related services are rendered.

Concentrations of credit risk:

Financial instruments which potentially subject the Company to credit risk consist principally of cash and cash equivalents, marketable securities and accounts and grants receivable. Cash and cash equivalents are held in U.S. financial institutions. At times, the Company may maintain balances in excess of the federally insured amounts.

Income taxes:

The Company's tax provision consists of taxes currently payable or receivable, plus any change during the period in deferred tax assets and liabilities. The Company uses the asset and liability method of accounting for income taxes. Under this method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of assets and liabilities and their respective tax basis. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. In addition, a valuation allowance is established to reduce any deferred tax asset for which it is determined that it is more likely than not that some portion of the deferred tax asset will not be realized. The Company's tax provision was $

0

for the three and nine months ended September 30, 2024 and 2023 due to net operating losses. The Company has not recorded any tax benefit for the net operating losses incurred due to the offset created by the Company's valuation allowance.

The Company recognizes the tax benefits from uncertain tax positions that the Company has taken or expects to take on a tax return. In the unlikely event an uncertain tax position exists in which the Company could incur income taxes, the Company would evaluate whether there is a probability that the uncertain tax position taken would be sustained upon examination by a taxing authority. Reserves for uncertain tax positions would then be recorded if the Company determined it is probable that either a position would not be sustained upon examination, or a payment would have to be made to a taxing authority and the amount was reasonably estimable. As of September 30, 2024 and December 31, 2023, the Company does not believe it has any uncertain tax positions that would result in the Company having a liability to a taxing authority. It is the Company's policy to expense any interest and penalties associated with its tax obligations when they are probable and estimable.

Equity-based compensation:

The Company accounts for equity-based compensation expense by the measurement and recognition of compensation expense for stock-based awards based on estimated fair values on the date of grant. The fair value of the stock options is estimated at the date of the grant using the Black-Scholes option-pricing model.

The Black-Scholes option-pricing model requires the input of highly subjective assumptions, the most significant of which are the expected share price volatility, the expected life of the stock option award, the risk-free rate of return, and dividends during the expected term. Because the option-pricing model is sensitive to changes in the input assumptions, different determinations of the required inputs may result in different fair value estimates of the stock options.

Neither the Company's stock options nor its restricted stock units ("RSUs") trade on an active market. Volatility is a measure of the amount by which a financial variable, such as a stock price, has fluctuated (historical volatility) or is expected to fluctuate (expected volatility) during a period. Given the Company's limited historical data, the Company utilizes the average historical volatility of similar publicly traded companies that are in the same industry. The risk-free interest rate is the average U.S. treasury rate (having a term that most closely approximates the expected life of the option) for the period in which the stock option was granted. The expected life is the period of time that the stock options granted are expected to remain outstanding. Stock options granted have a maximum term of ten years . The Company has insufficient historical data to utilize in determining its expected life assumptions and, therefore, uses the simplified method for determining expected life.

The Company accounts for the cost of services performed by vendors in exchange for an award of stock options based on the grant-date fair value of the award. The Company recognizes the expense consistent with the contractual vesting period and in the same manner as if the Company had paid cash for the services.

3. Marketable securities

The following is summary of marketable securities that the Company measures at fair value (in thousands):

	Fair Value at September 30, 2024			
	Level 1	Level 2	Level 3	Total
Money market funds[1]	$ 6,799	$ -	$ -	$ 6,799
Accrued income	26	-	-	26
Total marketable securities	$ 6,825	$ -	$ -	$ 6,825

(1) Money market funds are included in cash and cash equivalents in the condensed balance sheets.

	Fair Value at December 31, 2023			
	Level 1	Level 2	Level 3	Total
Corporate bonds	$ -	$ 412	$ -	$ 412
Money market funds[1]	3,948	-	-	3,948
Accrued income	16	-	-	16
Total marketable securities	$ 3,964	$ 412	$ -	$ 4,376

(1) Money market funds are included in cash and cash equivalents in the condensed balance sheets.

As of September 30, 2024 and December 31, 2023, the Company reported accrued interest receivable related to marketable securities of less than $

0.1

million. These amounts are recorded in other assets on the condensed balance sheets and are not included in the carrying value of the marketable securities.

4. Property and equipment, net

Major components of property and equipment are as follows (in thousands):

	Useful Lives	September 30, 2024	December 31, 2023
Leasehold improvements	10 years	$ 4,398	$ 4,328
Furniture/Lab equipment	7 years	3,054	2,483
Computer equipment	5 years	120	120

Software/Website	3 years	38	38
Total property and equipment		7,610	6,969
Less accumulated depreciation		4,988	4,440
Property and equipment, net		$ 2,622	$ 2,529

Depreciation expense amounted to approximately $ 0.2 million for the three-month periods ended September 30, 2024 and 2023, and $ 0.5 million for the nine months ended September 30, 2024 and 2023.

5. Intangible assets, net

Major components of intangible assets as of September 30, 2024, are as follows (in thousands):

	Useful Lives	Cost	Accumulated Amortization	Total
License agreements	20 years	$ 2,043	$ (1,076)	$ 967
Patent costs		1,170	-	1,170
Trademark costs		210	-	210
Total		$ 3,423	$ (1,076)	$ 2,347

Major components of intangible assets as of December 31, 2023, are as follows (in thousands):

	Useful Lives	Cost	Accumulated Amortization	Total
License agreements	20 years	$ 2,043	$ (909)	$ 1,134
Patent costs		959	-	959
Trademark costs		194	-	194
Total		$ 3,196	$ (909)	$ 2,287

Amortization expense related to intangible assets amounted to approximately $ 0.1 million and $ 0.2 million for each of the three and nine month periods ended September 30, 2024 and 2023.

Future amortization expense for intangible assets as of September 30, 2024 is as follows (in thousands):

Years Ending December 31,	Amount
2024 (remaining three months)	$ 56
2025	224
2026	224
2027	224
2028	224
Thereafter	15
Total	$ 967

6. Leases

The Company records a right-of-use operating lease asset and a lease liability related to its operating leases (there are no finance leases). The Company's corporate office lease expires in March 2027. As of September 30, 2024, the operating lease asset and lease liability were approximately $ 1.0 million and $ 1.6 million, respectively. As of December 31, 2023, the operating lease asset and lease liability were approximately $ 1.2

million and $

2.0
million, respectively.

Future minimum payments under the operating leases as of September 30, 2024, are as follows (in thousands):

Years Ending December 31,	Amount
2024 (remaining three months)	$ 170
2025	682
2026	682
2027	170
Total	1,704
Less: Interest	105
Present value of operating lease liability	$ 1,599

During each of the three months ended September 30, 2024 and 2023, the Company incurred approximately $

0.2

million of total lease costs and for the nine month periods ended September 30, 2024 and 2023, the Company incurred approximately $

0.6
million and $

0.7
million of total lease costs, respectively, that are included in the general and administrative expenses in the condensed statements of operations.

7. Stockholders' Equity

Class A Common Stock

RSUs are taxable upon vesting based on the market value on the date of vesting. The Company is required to make mandatory tax withholding for the payment and satisfaction of income tax, social security tax, payroll tax, or payment on account of other tax related to withholding obligations that arise by reason of vesting of an RSU. The taxable income is calculated by multiplying the number of vested RSUs for each individual by the closing share price as of the vesting date and a tax liability is calculated based on each individual's tax bracket. The shares withheld are available for reissuance pursuant to the Company's Second Amended and Restated 2021 Incentive Award Plan (the "Equity Plan").

During the nine months ended September 30, 2024,

no
stock options were exercised for Class A common stock shares.

Class B Common Stock

Holders of Class A common stock generally have rights identical to holders of Class B common stock, except that holders of Class A common stock are entitled to one (1) vote per share and holders of Class B common stock are entitled to five (5) votes per share. The holders of Class B common stock may convert each share of Class B common stock into one share of Class A common stock at any time at the holder's option. Class B common stock is not publicly tradable.

During the nine months ended September 30, 2024, stockholders converted

1,555
shares of Class B common stock into

1,555
shares of Class A common stock. During the year ended December 31, 2023, stockholders converted

3,555
shares of Class B common stock into

3,555
shares of Class A common stock.

Warrants

Summary of Warrant Issuances

As part of the Company's initial public offering ("IPO"), the underwriter received warrants to purchase up to

10,640
shares of Class A common stock. The warrants are exercisable at any @time and from time to time, in whole or in part, during the four and a half-year period commencing August 12, 2021 , at a price of $

120.00
per share and the fair value of warrants was approximately $

0.5
million. During 2021, the underwriters assigned

9,576
of the warrants to its employees.

As part of the Company's 2021 private placement offering, the Company issued warrants to investors to purchase up to an aggregate of

116,935
shares of Class A common stock, equal to the number of shares of Class A common stock purchased by such investor in the offering, at an exercise price of $

175.00
per share , which were immediately exercisable, were set to expire five years from the date of issuance, and had certain downward pricing adjustment mechanisms, subject to a floor, as set forth in greater detail therein (the "Purchaser Warrants"). In addition, the Company granted the underwriters warrants, under similar terms, to purchase

4,679
shares of Class A common stock, at an exercise price of $

175.00
per share. On August 16, 2023, the Company announced its Stock Rights Offering, which triggered the downward pricing mechanism on the Purchaser Warrants, at which time these warrants were adjusted downward to an exercise price of $

52.50
for the period remaining through expiration. This resulted in a deemed dividend to common stockholders of approximately $

0.8
million for the change in the fair value of the warrants using a Black-Scholes pricing model.

As part of an October 2023 registered direct offering, the Company issued Series A warrants and Series B warrants to purchase up to

242,425
and

242,425
, respectively, shares of Class A common stock. Each series of warrants had an exercise price of $

16.50
per share, with the Series A warrants having a term of five and one-half (5.5) years from the date of issuance, and the Series B warrants having a term of eighteen (18) months from the date of issuance. Both the Series A and Series B warrants became exercisable as of December 26, 2023, following stockholder approval. In addition, the Company granted the placement agent warrants, under similar terms, to purchase

16,971
shares of Class A common stock, at an exercise price of $

20.625
per share. In April 2024, the Series A Warrants and Series B Warrants were amended to reduce the exercise price to $

2.35
per share . The Series A Warrants and Series B Warrants were subsequently exercised in full in April 2024.

As part of a December 2023 registered direct offering, the Company issued warrants to purchase an aggregate of

135,531
shares of Class A common stock. These warrants have an exercise price of $

16.20
per share, became immediately issuable upon issuance, and expire on June 22, 2029. In addition, the Company granted the placement agent warrants, under similar terms, to purchase

9,489
shares of Class A common stock, at an exercise price of $

21.813
per share.

On April 8, 2024, the Company commenced a public offering of up to

639,872
shares of the Company's Class A common stock, along with pre-funded warrants to purchase up to an aggregate

1,572,894
shares of Class A common stock (the "Pre-Funded Warrants"). The shares and Pre-Funded Warrants were sold together with warrants to purchase up to an aggregate of

2,212,766
shares of Common Stock (the "Common Warrants"). The combined public offering price was $

2.35
per share and related Common Warrant and $

2.349
per Pre-Funded Warrant and related Common Warrant. Subject to certain limitations, the Pre-Funded Warrants were immediately exercisable and could be exercised at a nominal consideration of $

0.001
per share of Class A common stock at any time until all of the Pre-Funded Warrants were exercised in full. The Common Warrants were immediately exercisable and expire on April 10, 2029 .

As compensation to the placement agent the Company also issued to designees of the placement agent warrants to purchase up to

154,894
shares of Class A common stock, which had substantially the same terms as the Common Warrants, and with an exercise price of $

2.9375
per share and a term of five years from the commencement of sales in the offering.

In connection with the offering, the Company also entered into an agreement with a holder of existing warrants to amend the holder's existing Series A warrants and Series B warrants to reduce the exercise price to $

2.35

per share and (ii) amend the expiration date of the Series A Warrants to five and one-half (5.5) years following the closing of the public offering and the Series B warrants to eighteen (18) months following the closing of the public offering, in each case for a payment to the Company of $

0.125

per amended warrant.

On April 16, 2024, the Company entered into inducement letter agreements with certain holders of its existing Series A warrants and Series B warrants, and Common Warrants issued on April 10, 2024, whereby the holders agreed to exercise the warrants for cash at the exercise price of $

2.35

per share in consideration for payment of $

0.125

per new warrant and for the Company's agreement to issue new unregistered Class A common stock warrants to purchase up to

4,799,488

shares of Class A common stock at an exercise price of $

2.35

per share, and which were immediately exercisable upon issuance. The warrants to purchase up to

2,399,744

shares of Class A common stock (the "Series C Warrants") have a term of five (5) years from the issuance date, and the warrants to purchase up to

2,399,744

shares of Class A common stock (the "Series D Warrants") have a term of twenty-four (24) months from the issuance date, with all of the Series C Warrants and Series D Warrants being immediately exercisable. All of the Series D Warrants were exercised in June 2024, pursuant to ordinary course exercise as well as a subsequent inducement transaction.

Additionally, the Company issued to the placement agent or its designees as compensation, warrants to purchase up to

167,982

shares of Class A common stock, equal to

7.0

% of the aggregate number of shares of Class A common stock issued upon exercise of the warrants pursuant to the inducement transaction, which had the same terms as the Series C Warrants, except that the placement agent warrants have an exercise price of $

3.25

per share.

Furthermore, upon exercise, if any, of the Series D Warrants for cash, the Company agreed to issue the placement agent or its designees, within five (5) business days of the Company's receipt of the exercise price, warrants to purchase the number of shares of Class A common stock equal to

7.0

% of the aggregate number of shares underlying such Series D Warrants that have been exercised, with such warrants to be in the same form and terms as the prior placement agent warrants.

On June 17, 2024, the Company entered into additional inducement letter agreements with the holders of its existing Series D Warrants to exercise the remaining

1,697,891

shares of Class A common stock underlying Series D Warrants that remained outstanding for cash at the exercise price of $

2.35

per share in consideration for the Company's agreement to issue new unregistered Class A common stock warrants (the "June Inducement Warrants"), for payment of $

0.125

per new warrant, to purchase up to an aggregate of

3,395,782

shares of Class A common stock at an exercise price of $

2.50

per share and which were immediately exercisable upon issuance and have a term of twenty-four (24) months from the issuance date.

The Company also issued to the placement agent or its designees as compensation, (i) warrants to purchase up to

118,852

shares of Class A common stock, equal to

7.0

% of the aggregate number of shares of Class A common stock issued upon exercise of the warrants pursuant to the June inducement transaction and (ii) warrants to purchase up to an aggregate of

49,130

shares of Common Stock, equal to

7.0
% of the aggregate number of shares of Common Stock issued upon exercise of certain Series D warrants prior to the inducement transaction, which had substantially the same terms as the June Inducement Warrants, had an exercise price of $

3.25
per share and $

2.9375
per share, respectively (the "June placement agent warrants").

Upon exercise, if any, of the June Inducement Warrants for cash, the Company agreed to issue within five (5) business days to the placement agent or its designees, warrants to purchase the number of shares of Class A common stock equal to

7.0
% of the aggregate number of shares of Class A common stock underlying such June Inducement Warrants that have been exercised, with such warrants to be in the same form and terms as the June placement agent warrants.

The issuance under the inducement offers represented $

8.5
million in additional value provided to the investors, which was recorded as a deemed dividend to common stockholders. The June Inducement Warrants expire on June 18, 2026 .

On July 10, 2024, a holder exercised Series C warrants for

50,000
shares of Class A common stock for cash (the “July Series C warrant exercise”).

On July 10, 2024, certain holders of warrants issued in June of 2024 exercised warrants to purchase an aggregate of

150,000
shares of Class A common stock for cash (the “July 10 warrant exercise”). In addition, on July 17, 2024, we issued to the placement agent warrants to purchase up to

10,500
shares of Class A common stock, equal to

7.0
% of the aggregate number of shares of Class A common stock issued in the July 10 warrant exercise (the “first tranche July ordinary course placement agent warrants”). The first tranche July ordinary course placement agent warrants have substantially the same terms as the June placement agent warrants, except that the first tranche July ordinary course placement agent warrants (i) have an exercise price of $

3.125
per share and (ii) expire July 17, 2026 .

On July 17, 2024, a holder of the June Inducement Warrants exercised the same to purchase

2,319,186

shares of Class A common stock for cash (the “July 17 warrant exercise” and together with the July 10 warrant exercise and the July Series C warrant exercise, collectively, the “July warrant exercises”). Accordingly, on July 24, 2024, we issued to the placement agent warrants to purchase up to

162,344

shares of Class A common stock, equal to

7.0

% of the aggregate number of shares of Class A common stock issued in the July 17 warrant exercise (the “second tranche July ordinary course placement agent warrants”, and together with the first tranche July ordinary course placement agent warrants, the “July ordinary course placement agent warrants”, and collectively with the July offering placement agent warrants, the “July placement agent warrants”). The second tranche July ordinary course placement agent warrants have substantially the same terms as the first tranche July ordinary course placement agent warrants, except that the second tranche July ordinary course placement agent warrants expire July 24, 2026 .

The gross proceeds to the Company from the July warrant exercises, inclusive of the payment consideration for such Series C warrants and June Inducement Warrants, were approximately $

6.3

million, inclusive of the payment consideration for such warrants, before deducting placement agent fees payable by the Company.

On July 18, 2024, we entered into a securities purchase agreement with institutional and accredited investors relating to the registered direct offering and sale of an aggregate of

2,236,026

shares of our Class A common stock at a purchase price of $

4.025

per share of Class A common stock and associated warrant (the “July registered direct offering”). The securities issued in the July registered direct offering were offered pursuant to a prospectus supplement, dated July 18, 2024, and accompanying prospectus, in connection with a takedown from our shelf registration statement on Form S-3 (File No. 333-264142), which was declared effective by the SEC on April 14, 2022.

In a concurrent private placement (the “July private placement” and together with the July registered direct offering, the “July offering”), we also sold unregistered Class A common stock warrants to purchase up to an aggregate of

2,236,026

shares of our Class A common stock (the “July private placement warrants”). The unregistered July private placement warrants have an exercise price of $

3.90

per share, became exercisable on July 19, 2024, and expire on July 20, 2026 . In addition, the Company granted the placement agent warrants, under similar terms, to purchase

156,522

shares of Class A common stock, at an exercise price of $

5.0313

(the “July offering placement agent warrants”). The gross proceeds to the Company from the July offering were approximately $

9.0

million, before deducting placement agent fees and other offering expenses payable by the Company.

On August 6, 2024, the Company filed a registration statement with the SEC on Form S-1 registering the resale of an aggregate of

2,565,392

shares of Class A common stock issuable upon exercise of certain warrants, of which (i) up to

2,236,026

shares are issuable upon the exercise of the July private placement warrants issued to the purchasers upon the closing of the July private placement; (ii)

156,522

shares are issuable upon exercise of the July offering placement agent warrants issued to Wainwright, or its designees, pursuant to the terms of the current engagement Letter with Wainwright; and (iii)

172,844

shares are issuable upon exercise of the July ordinary course placement agent warrants issued to Wainwright, or its designees, pursuant to the terms of a then-applicable engagement letter with Wainwright, in connection with previously exercised June Inducement Warrants. The Form S-1 was declared effective by the SEC on August 12, 2024.

In September 2024, the Company entered into additional inducement letter agreements with certain holders of its existing Purchaser Warrants issued as part of the Company’s 2021 private placement offering to amend and reduce the exercise price of the Purchaser Warrants to $

1.00

per share in consideration for the holders’ cash exercise of all Purchaser Warrants held by such holder on or before September 27, 2024. In connection with the September 2024 inducement transaction, Purchaser Warrants were exercised for

114,077

shares of Class A common stock, resulting in gross proceeds to the Company of $

114,077

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Summary of Warrants Outstanding

As of September 30, 2024, warrants exercisable for an aggregate of up to

6,805,526
shares of the Company's Class A common stock remain outstanding. This includes:

- IPO underwriter warrants exercisable for up to

  5,536
  shares of Class A common stock at an exercise price of $

  120.00
  per share, which expire February 12, 2026 .

- Purchaser Warrants issued in connection with the 2021 private placement offering exercisable for up to

  2,858
  shares of Class A common stock at an exercise price of $

  52.50
  per share, which expire December 3, 2026 .

- Underwriter warrants issued in connection with the 2021 private placement offering exercisable for up to

  4,679
  shares of Class A common stock at an exercise price of $

  175.00
  per share, which expire December 1, 2026 .

• Placement agent warrants issued in connection with the October 2023 registered direct offering exercisable for up to

16,971
shares of Class A common stock at an exercise price of $

20.625
per share, which expire October 11, 2028 .

• Investor warrants issued in connection with the December 2023 registered direct offering exercisable for up to

135,531
shares of Class A common stock at an exercise price of $

16.20
per share, which expire June 22, 2029 .

• Placement agent warrants issued in connection with the December 2023 registered direct offering exercisable for up to

9,489
shares of Class A common stock at an exercise price of $

21.813
per share, which expire December 20, 2028 .

• Common Warrants issued in connection with the April 2024 public offering exercisable for up to

297,872
shares of Class A common stock at an exercise price of $

2.35
per share, which expire April 10, 2029 .

• Placement agent warrants issued in connection with the April 2024 public offering exercisable for up to

154,894
shares of Class A common stock at an exercise price of $

2.9375
per share, which expire April 8, 2029 .

• Series C Warrants issued in connection with the April 2024 inducement transaction exercisable for up to

2,349,744
shares of Class A common stock at an exercise price of $

2.35
per share, which expire April 18, 2029 .

• Placement agent warrants issued in connection with the April 2024 inducement transaction exercisable for up to

167,982
shares of Class A common stock at an exercise price of $

3.25
per share, which expire April 18, 2029 .

• June placement agent warrants issued in the ordinary course prior to the June 2024 inducement transaction exercisable for up to

49,130
shares of Class A common stock at an exercise price of $

2.9375
per share, which expire June 18, 2026 .

• June Inducement Warrants exercisable for up to

926,596
shares of Class A common stock at an exercise price of $

2.50
per share, which expire June 18, 2026 .

• Placement agent warrants issued in connection with the June 2024 inducement transaction exercisable for up to

118,852
shares of Class A common stock at an exercise price of $

3.25
per share, which expire June 18, 2026 .

• First tranche July ordinary course placement agent warrants exercisable for up to

10,500
shares of Class A common stock at an exercise price of $

3.125
per share, which expire July 17, 2026 .

- Second tranche July ordinary course placement agent warrants exercisable for up to

162,344
shares of Class A common stock at an exercise price of $

3.125
per share, which expire July 24, 2026 .

- July private placement warrants exercisable for up to

2,236,026
shares of Class A common stock at an exercise price of $

3.90
per share, which expire July 20, 2026 .

- July offering placement agent warrants exercisable for up to

156,522
shares of Class A common stock at an exercise price of $

5.0313
per share, which expire July 20, 2026 .

8. Equity-based compensation

As part of the Company's IPO, the Company adopted and approved the 2021 Incentive Award Plan, which has been subsequently amended and restated twice (as accordingly amended and restated, the "2021 Incentive Plan"). Under the 2021 Incentive Plan, the Company may grant cash and equity incentive awards to eligible service providers in order to attract, motivate and retain the talent for which the Company competes.

RSUs

As of September 30, 2024 and December 31, 2023, the Company had

752,666
and

11,239
, respectively of RSUs outstanding (unvested).

RSU activity for the nine months ended September 30, 2024, was as follows:

	Number of RSUs
Outstanding (unvested) at December 31, 2023	11,239
RSU granted	1,235,324
RSUs vested	(485,997)
RSU expired/forfeited	(7,900)
Outstanding (unvested) at September 30, 2024	752,666

Stock Options

Stock options may be granted under the 2021 Incentive Plan. The exercise price of stock options is equal to the fair market value of the Company's Class A common stock as of the grant date. Stock options historically granted have generally become exercisable over four years and expire ten years from the date of grant. The 2021 Incentive Plan provides for equity grants to be granted up to

5
% of the outstanding common stock shares.

As of September 30, 2024, there have been

88,625
stock options granted during 2024 under the 2021 Incentive Plan. The fair value of the options issued during 2024 were estimated using the Black-Scholes option-pricing model and had the following assumptions: a dividend yield of

0
%; an expected life of 10 years ; volatility ranging from

79
%-

95
%; and risk-free interest rate based on the grant date ranging from of

3.79
% -

4.52
%. Each stock option grant made during 2024 will be expensed ratably over the option vesting periods, which approximates the service period.

As of September 30, 2024 and December 31, 2023, the Company has recorded issued and outstanding options to purchase a total of

121,186
and

43,786
shares of Class A common stock, respectively, pursuant to the 2021 Incentive Plan, at a weighted average exercise price of $

15.09
and $

49.60
per share, respectively.

For the nine months ended September 30, 2024:

	Number of Stock Options
Stock options vested (based on ratable vesting)	21,143

Stock options unvested	100,043
Total stock options outstanding at September 30, 2024	121,186

For the year ended December 31, 2023:

	Number of Stock Options
Stock options vested (based on ratable vesting)	16,091
Stock options unvested	27,695
Total stock options outstanding at December 31, 2023	43,786

Stock option activity for the nine months ended September 30, 2024, was as follows:

	Number of Stock Options	Weighted Average Exercise Price
Outstanding at December 31, 2023	43,786	$ 49.60
Options granted	88,625	2.46
Options exercised	-	-
Options expired/forfeited	(11,225)	50.20
Outstanding at September 30, 2024	121,186	$ 15.09

For the three months ended September 30, 2024 and 2023, the equity-based compensation expense amounted to approximately $

1.4
million and $

0.5
million, respectively, and for the nine months ended September 30, 2024 and 2023, the equity-based compensation expense amounted to approximately $

1.9
million and $

1.6
million, respectively, which is included in the research and development

and general and administrative expenses in the condensed statements of operations for the three and nine months ended September 30, 2024 and 2023, respectively.

As of September 30, 2024, the remaining unrecognized RSUs compensation of approximately $

1.4

million will be recognized over approximately 2.01 years. The remaining unrecognized stock options compensation of approximately $

0.4

million will be recognized over approximately 1.94 years.

Share-based payments to third-party service provider

In April 2024, the Company agreed to issue stock options to a third-party service provider for future services exercisable for up to

50,000

shares of Class A common stock at an exercise price of $

2.15

, the grant date fair value, with the options vesting quarterly over 36 months. The Company recorded general and administrative expenses of less than $

0.1

million for the three and nine months ended September 30, 2024.

9. Commitments and Contingencies

Master Services Agreements:

As of September 30, 2024, the Company terminated its active master services agreements with third parties that were previously engaged to conduct its clinical trials and manage clinical research programs and clinical development services. This termination was due to the Company's decision in April 2024 to discontinue trial activities in Japan.

Consulting Services Agreement:

On November 20, 2014, the Company entered into a ten-year consulting services agreement with Dr. Joshua Hare, its CSO. Under the agreement, the Company has agreed to pay the CSO $

265,000

annually. The compensation payments are for scientific knowledge, medical research, technical knowledge, skills, and abilities to be provided by the CSO to further develop the intellectual property rights assigned by the CSO to the Company. This agreement requires the CSO to also assign to the Company the exclusive right, title, and interest in any work product developed from his efforts during the term of this agreement. On November 16, 2022, the Company accounted for but had not issued

4,814

RSUs convertible to unregistered shares of Class A common stock, with an aggregate value of $

0.2

million as payment for accrued expenses under the consulting agreement with the CSO. These shares were issued on May 24, 2023. As of September 30, 2024 and December 31, 2023, the Company had accrued balances due to the CSO of approximately $

0.1

million and $

0.1

million, respectively, which are included in accrued expenses and an additional less than $

0.1

million and $

0.1

million, respectively, which are included in accounts payable in the accompanying condensed balance sheets.

The Company entered into a deferred compensation agreement with the CSO to defer payment of the consulting fees earned for services rendered during 2024. The 2024 consulting fees will be paid in the form of a lump sum distribution in February 2027. As of September 30, 2024, the Company had an accrued balance of $

0.2

million which are included in other long-term liabilities in the accompanying condensed balance sheets.

Technology Services Agreement:

On March 27, 2015, the Company entered into a technology services agreement with Optimal Networks, Inc. (a related company owned by Dr. Joshua Hare's brother-in-law) for use of information technology services. The technology services agreement was terminated as of April 14, 2023. As of September 30, 2024 and December 31, 2023, the Company owed $

0

pursuant to this agreement.

Manufacturing Services Agreement:

On February 21, 2024, the Company entered into a five-year Supply Agreement with Secretome Therapeutics, Inc. (“Secretome”), a biotechnology company developing multiple, novel secretomes to address a spectrum of diseases driven by pathological processes , to manufacture, test, release, and supply Secretome with cardiac stem cells (the “Product”) to be used in Phase 1 and Phase 2 clinical trials (the “Secretome Agreement”). The Company received an initial start-up payment of $

242,000

upon signing of the Secretome Agreement, which was comprised of (a) technology transfer, documentation preparation, training, and testing costs of $

210,000

, (b) a ten-hour prepayment of project management fees of $

2,400

, and (c) a first month suite reservation fee of $

30,000

. The Company will bill Secretome on a variable fee basis for quality control, in process, release, and stability testing service items. For each Product lot, Secretome will pay the Company $

55,000

per lot as well as a $

30,000

for each additional Product lot in excess of two initial “training run” lots. Secretome will also pay a $

30,000

monthly manufacturing suite reservation fee to the Company as well as a $

240

per hour hourly fee for project management services.

Secretome has also agreed to compensate the Company for the value of all materials involved in manufacturing and quality control testing the Product, plus a

20

percent markup on these materials. For any outsourced testing, Secretome will be billed directly by the laboratory conducting the testing, plus a fee of $

500

per batch payable to the Company. Furthermore, Secretome will pay the Company $

2,000

monthly for storage of in process samples, vialed harvests for training, and in process samples for Product lots. The Company will receive certain variable payments related to product packing, handling and shipping, with a standard fee of $

750

, with an increased fee of $

1,500

for expedited or special hour service.

Following the initial five-year term, the Secretome Agreement may be renewed for additional successive two-year terms upon the mutual written agreement of the parties. Either party may terminate the agreement for cause and upon notice in the event of a material breach, within (i) 30 days of an uncured material breach that is not a payment default or (ii) 10 days for an uncured payment default. The Secretome Agreement further provides that either party may terminate the agreement at any time upon 90 days' notice to the other party. In addition, either party may terminate the agreement immediately in the event the other party seeks the protection of any bankruptcy court, becomes insolvent, makes an assignment for the benefit of creditors, or any debarment activity occurs with respect to that party. A force majeure provision also permits termination of the Secretome Agreement upon written notice to the other party as a result of a delay or interference of performance continuing for more than 60 days.

For the three and nine months ended September 30, 2024, the Company has earned revenues of $

0.6

million and $

0.8

million under the Secretome Agreement, respectively.

The Company is also a party to a Mutual Nondisclosure Agreement with Secretome, signed and effective as of October 24, 2023 (the "Nondisclosure Agreement"), by which both parties have agreed to maintain the strict confidentiality of, restrict access to, and not to disclose any intellectual property, trade secrets, business dealings, customers, operations, products, research, clinical data, or other competitively sensitive or proprietary confidential information shared between them, subject to certain customary carve-outs for disclosures pursuant to applicable law or filings with regulatory or governmental agencies including the SEC. The Nondisclosure Agreement has a term of ten years from the later of (i) the effective date of the Nondisclosure Agreement, (ii) the date of the last disclosure of information under the Secretome Agreement, any "Quality Agreement" which may be entered into between the parties, or any scope of work; or (iii) the expiration of any patents issued arising out of or resulting from the confidential information. The Nondisclosure Agreement will not terminate with respect to trade secrets.

Exclusive Licensing Agreements:

UM Agreement

On November 20, 2014, the Company entered into an Exclusive License Agreement with UM (the "UM License") for the use of certain Aging-related Frailty Mesenchymal Stem Cell ("MSC") technology rights developed by our CSO at UM. The UM License is a worldwide, exclusive license, with right to sublicense, with respect to any and all know-how specifically related to the development of the culture-expanded MSCs for Aging-related Frailty used at the Human-induced pluripotent stem cell-derived MSCs ("IMSCs"), all standard operating procedures used to create the IMSCs, and all data supporting isolation, culture, expansion, processing, cryopreservation and management of the IMSCs. The Company is required to pay UM (i) a license issue fee of $

5,000

, (ii) a running royalty in an amount equal to three percent of annual net sales on products or services developed from the technology, payable on a country-by-country basis beginning on the date of first commercial sale through termination of the UM License Agreement, and which may be reduced to the extent we are required to pay royalties to a third party for the same product or process, (iii) escalating annual cash payments of up to $

50,000

, subject to offset. The agreement extends for up to 20 years from the last date a product or process is commercialized from the technology and was amended in 2017 to modify certain milestone completion dates as detailed below. In 2021 the license fee was increased by an additional $

100,000

, to defray patent costs. In addition, the Company issued

11,039

unregistered shares of Class A common stock to UM.

The milestone payment amendments shifted the triggering payments to three payments of $

500,000

, to be paid within six months of: (a) the completion of the first Phase 3 clinical trial of the products (based upon the final data unblinding); (b) the receipt by the Company of approval for the first new drug application ("NDA"), biologics application ("BLA"), or other marketing or licensing application for the product; and (c) the first sale following product approval. "Approval" refers to product approval, licensure, or other marketing authorization by the U.S. Food and Drug Administration, or any successor agency. The amendments also provided for the Company's license of additional technology, to the extent not previously included in the UM License and granted the Company an exclusive option to obtain an exclusive license for (a) the HLHS investigational new drug application ("IND") with ckit+ cells; and (b) UMP-438 titled "Method of Determining Responsiveness to Cell Therapy in Dilated Cardiomyopathy."

The Company has the right to terminate the UM License upon 60 days' prior written notice, and either party has the right to terminate upon a breach of the UM License. To date, the Company has made payments totaling $

365,000
to UM, and as of September 30, 2024

and December 31, 2023, the Company had accrued $

37,500
and $

50,000
in milestone fees payable to UM, respectively, and $

10,000
and $

15,000
, respectively, for patent related reimbursements based on the estimated progress to date.

The Company also entered into an additional Exclusive License Agreement with UM, signed and effective as of July 18, 2024, for technology rights developed by our CSO at UM. This License is a worldwide, exclusive license, with right to sublicense, with respect to any and all know-how, SOPs, data and other all other rights related to UMP-144, entitled “A method to derive GHRHR+ cardiomyogenic cells from pluripotent stem cells (PSCs) for therapeutic and pharmacologic applications” and having inventors Joshua Hare and Konstantinos Chatzistergos. UM retained a non-exclusive, royalty-free, perpetual, irrevocable, worldwide right to practice, make, and use the Patent Rights or Technology for any non-profit purposes, including educational, and research purposes. Pursuant to the terms of the license agreement, Longeveron must pay to UM: (a) $

5,000
within 30 days of the Effective Date; and (b) reimbursement of $

21,307
within 90 days of the Effective Date for previously incurred patent expenses; and (c) an annual $

10,000
fee which is both creditable against other royalty payments for the applicable license year and is waived so long as Company is current on annual fee payments in accordance with the Exclusive License Agreement entered into November 20, 2014 between Company and UM. In addition to certain those certain other royalty payments that would be due should the Company’s sublicense of the technology result in revenue, Longeveron also agreed to the following additional milestones and payments: (c) $

150,000
upon completion of the first Phase 3 Clinical Trial; and (d) $

250,000
upon issuance of a biologics license application or new drug application based on the licensed technology. The Company has the right to terminate the new UM License for convenience upon 90 days’ prior written notice, and both parties have additional termination rights for material breach of the agreement. To date, the Company has made payments totaling $

5,000
to UM, and as of September 30, 2024, the Company had not yet accrued any milestone fees payable to UM.

CD271

On December 22, 2016, the Company entered into an exclusive license agreement with an affiliated entity of Dr. Joshua Hare, JMH MD Holdings, LLC (“JMHMD”), for the use of CD271 cellular therapy technology. The Company recorded the value of the cash consideration and membership units issued to obtain this license agreement as an intangible asset. The Company is required to pay as a royalty

1
% of the annual net sales of the licensed product(s) used, leased, or sold by or for the licensee or its sub-licensees. If the Company sublicenses the technology, it is also required to pay an amount equal to

10
% of the net sales of the sub-licensees. In addition, on December 23, 2016, as required by the license agreement, the Company paid an initial fee of $

250,000
to JMHMD, and issued to it

10,000
Series C Units, valued at $

250,000
. The $

0.5
million of value provided to JMHMD for the license agreement, along with professional fees of approximately $

27,000
, were recorded as an intangible asset that is amortized over the life of the license agreement which was defined as 20 years. Further, expenses related to the furtherance of the CD271+ technology are being capitalized and amortized as incurred over 20 years. There were

no

license fees due for September 30, 2024 and December 31, 2023 pertaining to this agreement.

Other Royalty

Under the grant award agreement with the Alzheimer's Association, the Company may be required to make revenue sharing or distribution of revenue payments for products or inventions generated or resulting from this clinical trial program. The potential payments, although not currently defined, could result in a maximum payment of five times (5x) the award amount of $

3.0
million.

Contingencies – Legal

From time to time, the Company could become involved in disputes and various litigation matters that arise in the normal course of business. These may include disputes and lawsuits related to intellectual property, licensing, contract law and employee relations matters. As of September 30, 2024, the Company is not aware of any legal proceedings or material developments requiring disclosure.

10. Employee Benefits Plan

The Company sponsors a defined contribution employee benefit plan (the "Plan") under the provisions of Section 401(k) of the Internal Revenue Code. The Plan covers substantially all full-time employees of the Company who are eligible upon date of hire. Contributions to the Plan by the Company are at the discretion of the Board of Directors.

The Company contributed approximately $

0.1

million to the Plan during both of the nine months ended September 30, 2024 and 2023, and less than $

0.1

million to the Plan during the three months ended September 30, 2024 and 2023, respectively.

11. Loss Per Share

Basic and diluted net loss per share have been computed using the weighted-average number of shares of common stock outstanding during the period. We have outstanding stock-based awards that are not used in the calculation of diluted net loss per share because to do so would be anti-dilutive.

The following instruments (in thousands) were excluded from the calculation of diluted net loss per share because their effects would be antidilutive:

	Nine months ended September 30,	
	2024	2023
RSUs	753	123
PSUs	–	125
Stock options	121	381
Warrants	6,806	1,271
Total	7,680	1,900

12. Subsequent Events

In October 2024, the Company entered into additional inducement letter agreements with the remaining holders of its existing Purchaser Warrants issued as part of the Company's 2021 private placement offering to amend and reduce the exercise price of the Purchaser Warrants to $

1.00

per share in consideration for the holders' cash exercise of all Purchaser Warrants held by such holder. In connection with the October 2024 inducement transaction, Purchaser Warrants were exercised for

2,858

shares of Class A common stock. As of the date of this Quarterly Report on Form 10-Q, the Purchaser Warrants have been exercised in full.

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

In this document, the terms "Longeveron," "Company," "Registrant," "we," "us," and "our" refer to Longeveron Inc. We have no subsidiaries.

This Quarterly Report on Form 10-Q (this "10-Q") contains forward-looking statements, within the meaning of the Private Securities Litigation Reform Act of 1995, that reflect our current expectations about our future results, performance, prospects and opportunities. This 10-Q contains forward-looking statements that can involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this 10-Q, including statements regarding our future results of operations and financial position, business strategy, prospective products, product approvals, research and development costs, future revenue, timing and likelihood of success, plans and objectives of management for future operations, future results of anticipated products and prospects, plans and objectives of management are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," or "would" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. Factors that could cause actual results to differ materially from those expressed or implied in any forward-looking statements contained in this report include, but are not limited to, statements about:

- our cash position and need to raise additional capital, the difficulties we may face in obtaining access to capital, and the dilutive impact it may have on our investors;
- our financial performance, and ability to continue as a going concern;
- the period over which we estimate our existing cash and cash equivalents will be sufficient to fund our future operating expenses and capital expenditure requirements;
- the ability of our clinical trials to demonstrate safety and efficacy of our product candidates, and other positive results;
- the timing and focus of our ongoing and future preclinical studies and clinical trials, and the reporting of data from those studies and trials;
- the size of the market opportunity for our product candidates, including our estimates of the number of patients who suffer from the diseases we are targeting;
- the success of competing therapies that are or may become available;
- the beneficial characteristics, safety, efficacy and therapeutic effects of our product candidates;
- our ability to obtain and maintain regulatory approval of our product candidates in the U.S., and other jurisdictions;
- our plans relating to the further development of our product candidates, including additional disease states or indications we may pursue;
- our plans and ability to obtain or protect intellectual property rights, including extensions of existing patent terms where available and our ability to avoid infringing the intellectual property rights of others;
- the need to hire additional personnel and our ability to attract and retain such personnel; and
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing.

The forward-looking statements contained in this 10-Q are made on the basis of the views and assumptions of management regarding future events and business performance as of the date this 10-Q is filed with the Securities and Exchange Commission (the "SEC"). We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements are subject to a number of risks, uncertainties and assumptions described in the section titled "Risk Factors" and elsewhere in this 10-Q. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified, you should not rely on these forward-looking statements as predictions of future events. The events and circumstances reflected in our forward-looking statements may not be achieved or occur and actual results could differ materially from those projected in the forward-looking statements. We operate in a highly competitive and rapidly changing environment; therefore, new risk factors can arise, and it is not possible for management to predict all such risk factors, nor to assess the impact of all such risk

factors on our business or the extent to which any individual risk factor, or combination of risk factors, may cause results to differ materially from those contained in any forward-looking statement. In addition, statements that “we believe” and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this 10-Q, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely upon these statements. We do not undertake any obligation to update these statements to reflect events or circumstances occurring after the date this 10-Q is filed. In addition, this discussion and analysis should be read in conjunction with our unaudited condensed financial statements and notes thereto included in this 10-Q and the audited condensed financial statements and notes thereto included in our Annual Report on Form 10-K for the year ended December 31, 2023, filed with the SEC on February 27, 2024, as amended on Form 10-K/A filed with the SEC on March 11, 2024 (the “2023 10-K”). Operating results are not necessarily indicative of results that may occur in future periods.

Introduction and Overview

We are a clinical stage biotechnology company developing regenerative medicines to address unmet medical needs. The Company’s lead investigational product is Lomecel-B™, an allogeneic Medicinal Signaling Cell (“MSC”) formulation sourced from the bone marrow of young, healthy adult donors. Lomecel-B™ has multiple potential mechanisms of action that promote tissue repair and healing with broad potential applications across a spectrum of disease areas. The underlying mechanism(s) of action that may lead to the tissue repair programs include the stimulation of new blood vessel formation, modulation of the immune system, reduction in tissue fibrosis, and the stimulation of endogenous cells to divide and increase the numbers of certain specialized cells in the body.

We currently have three pipeline indications: Hypoplastic Left Heart Syndrome (“HLHS”), Alzheimer’s disease (“AD”), and Aging-related Frailty. Our mission is to advance Lomecel-B™ and other cell-based product candidates into pivotal or Phase 3 trials, with the goal of achieving regulatory approvals, subsequent commercialization, and broad use by the healthcare community.

In November of 2023, Longeveron received notice from the World Health Organization (“WHO”) that “laromestrocel” has been selected as the proposed International Nonproprietary Name for Longeveron’s Lomecel-B™ product. Upon final approval of the name by the WHO, Longeveron will adopt that name.

Financial Overview. Since inception, the Company has primarily been engaged in organizational activities, including raising capital, and research and development activities. The Company does not yet have a product that has been approved by the FDA, and has only generated revenues from grants, the Bahamas Registry Trials and contract manufacturing. The Company has not yet achieved profitable operations or generated positive cash flows from operations. The Company has incurred recurring losses from operations since its inception, and as of September 30, 2024 the Company had an accumulated deficit of $105.5 million. The Company expects to continue to generate operating losses for the foreseeable future.

With the completion of the offering and financing transactions in April and June 2024, subsequent warrant exercises, and offering and inducement transactions undertaken in July and September 2024, we believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements through the fourth quarter of 2025 based on our current operating budget and cash flow forecast. However, as a result of its successful Type C meeting with the U.S. FDA in August 2024 with respect to the HLHS regulatory pathway, we have started to ramp up Biologics License Application (BLA) enabling activities as we currently anticipate a potential filing with the FDA in 2026 if the current ELPIS II trial is successful. To the extent that our operating expenses and capital expenditure requirements accelerate in calendar 2025 as a result of these activities, including CMC (Chemistry, Manufacturing, and Controls) and manufacturing readiness, there will be a need to increase our current proposed spend and further increase our capital investments. We intend to seek additional financing/capital raises/non-dilutive funding options to support these activities, and current cash projections may be impacted by these ramped up activities and any financing transactions entered into. We have based these estimates on assumptions that may prove to be imprecise, and we could utilize our available capital resources sooner than we expect. We currently have no credit facility or committed sources of capital. To continue as a going concern we will need to obtain additional capital, which we will likely obtain through a variety of means, including through public or private equity, debt financings or other sources, including up-front payments and milestone payments from strategic collaborations. To the extent that we raise additional capital through the sale of convertible debt or equity securities, current stockholder ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect stockholder rights. Such financing will likely result in dilution to stockholders, and may result in imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business. If we raise additional funds through up-front payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Hypoplastic Left Heart Syndrome (HLHS)

Our HLHS program is focused on the potential clinical benefits of Lomecel-B™ as an adjunct therapeutic to standard-of-care HLHS surgery. HLHS is a rare and devastating congenital heart defect in which the left ventricle is severely underdeveloped. As such, babies born with this condition die shortly after birth without undergoing a complex series of reconstructive heart surgeries. Despite the availability of life-saving surgical interventions, clinical studies show that only 50 to 60 percent of affected individuals survive to adolescence. Early clinical study data shows the potential survival benefit of Lomecel-B™ for HLHS patients and supports Longeveron's belief that this data shows the potential to alter the treatment landscape for patients with HLHS. We have completed a Phase 1 open-label study ("ELPIS I")[1] that supported the safety and tolerability of Lomecel-B™ for HLHS, when directly injected into the functional right ventricle ("RV") during the second-stage standard-of-care surgery (adding minimal additional time to the surgical procedure). Preliminary data revealed that several indices of right ventricular function show suggestions of either improvement or prevention of deterioration over one year following surgery. Heart transplant-free survival for patients who received Lomecel-B™ intracardiac injection is favorable as compared to historical controls for survival. The improvement in HLHS survival following the Phase 1 ELPIS I clinical trial resulted in acceptance by the American Heart Association ("AHA") for a poster presentation at an AHA meeting in November 2023. The ELPIS I trial showed 100 percent transplant-free survival in children up to 5 years of age after receiving Lomecel-B™, compared to a 20 percent mortality rate observed from historical control data.

Based on these findings, the U.S. Food and Drug Administration (the "FDA") granted Lomecel-B™ Rare Pediatric Disease (RPD") Designation, Orphan Drug Designation ("ODD"), and Fast Track Designation for treatment of infants with HLHS. On September 3, 2024, Longeveron announced a positive Type C meeting with the FDA supporting the advancement of Lonecel-B™. Longeveron is currently conducting a controlled Phase 2b trial ("ELPIS II") to compare the effects of Lomecel-B™ as an adjunct therapeutic versus standard-of-care (HLHS surgery alone). We hope that a positive outcome could add to the clinical data suggesting the functional and clinical benefit of Lomecel-B™ as part of standard-of-care treatment in HLHS patients. As a result of the Type C meeting, we reached foundational alignment with the FDA on the primary endpoint and secondary endpoints for ELPIS II. The FDA confirmed that, with several conditional requirements (including submission of a prespecified Statistical Analysis Plan and a Chemistry, Manufacturing and Controls readiness plan to the FDA for prior review), ELPIS II is pivotal, and, if positive, acceptable for Biological License Application (BLA) submission for full traditional approval.

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1. Sunjay Kaushal, MD, PhD, Joshua M Hare, MD, Jessica R Hoffman, PhD, Riley M Boyd, BA, Kevin N Ramdas, MD, MPH, Nicholas Pietris, MD, Shelby Kutty, MD, PhD, MS, James S Tweddell, MD, S Adil Husain, MD, Shaji C Menon, MBBS, MD, MS, Linda M Lambert, MSN-cFNP, David A Danford, MD, Seth J Kligerman, MD, Narutoshi Hibino, MD, PhD, Laxminarayana Korutla, PhD, Prashanth Vallabhajosyula, MD, MS, Michael J Campbell, MD, Aisha Khan, PhD, Eric Naioti, MSPH, Keyvan Yousefi, PharmD, PhD, Danial Mehranfard, PharmD, MBA, Lisa McClain-Moss, Anthony A Oliva, PhD, Michael E Davis, PhD, Intramyocardial cell-based therapy with Lomecel-B™ during bidirectional cavopulmonary anastomosis for hypoplastic left heart syndrome: The ELPIS phase I trial, *European Heart Journal Open*, 2023.

Alzheimer's disease (AD)

In September 2023, we completed our Phase 2a AD clinical trial, known as the CLEAR MIND trial. This trial enrolled patients with mild AD and was designed as a randomized, double-blind, placebo-controlled study across ten U.S. centers. Our primary objective was to assess safety, and we tested three distinct Lomecel-B™ multiple dosing regimens against placebo.

The study demonstrated positive results. The established safety profile of Lomecel-B™ for single and multiple dosing regimens was demonstrated in study data that showed no incidence of hypersensitivity or infusion-related reactions, there were no cases of amyloid-related imaging abnormalities (ARIA), and all Lomecel-B™ treatment groups met the safety primary endpoint and showed slowing/prevention of disease worsening relative to placebo. There were statistically significant improvements in the secondary efficacy endpoint, composite AD score ("CADS") for both the low-dose Lomecel-B™ group and the pooled treatment groups compared to placebo. Other doses also indicated promising results in slowing/prevention of disease worsening. Additionally, a statistically significant improvement versus placebo was observed in the Montreal cognitive assessment ("MoCA") and in the activity of daily living observed by a caregiver and measured by Alzheimer's disease Cooperative Study Activities of Daily Living ("ADCS-ADL"). The study indicated potential preservation of brain volumes in some but not all AD related areas of brain. Brain magnetic resonance imaging ("MRI") results demonstrated a 49% reduction in brain volume loss and improvement in cerebral blood flow.

The results of the CLEAR MIND trial were accepted for oral presentation in the Featured Research Session at the 2024 Alzheimer's Association International Conference ("AAIC") in July 2024. The MRI results from this trial also were accepted for poster presentation at AAIC. These findings support both the safety and potential therapeutic benefit of Lomecel-B™ in managing mild AD, and we believe lays the groundwork for subsequent trials in this indication. Based on these results, the FDA granted Regenerative Medicine Advanced Therapeutics (RMAT) Designation on July 9, 2024, and Fast Track designation on July 17, 2024, to Lomecel-B™ for the treatment of mild AD.

Aging-related Frailty

Improvement of the quality of life for the aging population is one of the strategic directions of the Company. Life expectancy has substantially increased over the past century due to medical and public health advancements. However, this longevity increase has not been paralleled by health span – the period of time one can expect to live in relatively good health and independence. For many developed and developing countries, health span lags life-expectancy by over a decade. This has placed tremendous strain on healthcare systems in the management of aging-related ailments and presents additional socioeconomic consequences due to a patient's decreased independence and quality-of-life. Since these strains continue to increase with demographic shifts towards an increasingly older population, improving health span has become a priority for health agencies, such as the National Institute on Aging ("NIA") of the National Institutes of Health ("NIH"), the Japanese Pharmaceuticals and Medical Devices Agency ("PMDA"), and the European Medicines Agency ("EMA"). As we age, we experience a decline in our own stem cells, a decrease in immune system function (known as "immunosenescence"), diminished blood vessel functioning, chronic inflammation (known as "inflammaging"), and other aging-related alterations that affect biological functioning. Our preliminary clinical data suggest that Lomecel-B™ may potentially address these problems through multiple potential mechanisms of action ("MOAs") that simultaneously target key aging-related processes. We are using Lomecel-B™ in registry trials in The Bahamas as part of the real-world data generation for the aging population.

Summary of Clinical Development Strategy

Our core strategy is to become a world-leading regenerative medicine company through the development, approval, and commercialization of novel cell therapy products for unmet medical needs, with a focus on HLHS. Key elements of our current business strategy are as follows.

- Execution of ELPIS II, a Phase 2b randomized controlled trial set forth in greater detail below, to measure the efficacy of Lomecel-B™ in HLHS. This trial is ongoing and is being conducted in collaboration with the National Heart, Lung, and Blood Institute ("NHLBI") through grants from the NIH.

- Continue to pursue the therapeutic potential of Lomecel-B™ in mild AD. We completed a Phase 2a trial, the ("CLEAR MIND Trial"), which demonstrated the potential benefits of Lomecel-B™ over placebo to maintain cognitive function and slow deterioration of brain structure atrophy, with no safety issues observed. Specifically, the safety primary endpoint was met, and the trial demonstrated a statistical significance in the secondary CADS endpoint. Overall, in Lomecel-B™ groups, brain MRI demonstrated whole brain volume loss slowed accompanied by significant preservation of left hippocampal volume relative to placebo. We plan to continue to analyze the data in order to further develop our clinical development strategy. Our objective is to forge strategic collaborations, consider potential partnerships, or pursue other available pathways or opportunities for the advancement of Lomecel-B™ in addressing AD.

- Limited focus on our international program. In line with the Company's strategic direction for 2024 and moving forward to focus on HLHS and AD as set forth previously, the Company has discontinued its clinical trial in Japan to evaluate Lomecel-B™ for Aging-related Frailty. The Company will continue to enroll patients on the Frailty and Cognitive Impairment registry trials in The Bahamas and plans to also launch an Osteoarthritis registry trial.

- Expand our manufacturing capabilities to commercial-scale production. We operate a current good manufacturing practice ("cGMP")-compliant manufacturing facility and produce our own product candidates for testing. We continue to improve and expand our capabilities with the goal of achieving cost-effective manufacturing that may potentially satisfy future commercial demand for certain potential Lomecel-B™ commercialization opportunities.

- Collaborative arrangements and out-licensing opportunities. We will be opportunistic and consider entering into co-development, out-licensing, or other collaboration agreements for the purpose of eventually commercializing Lomecel-B™ and other products domestically and internationally if appropriate approvals are obtained.

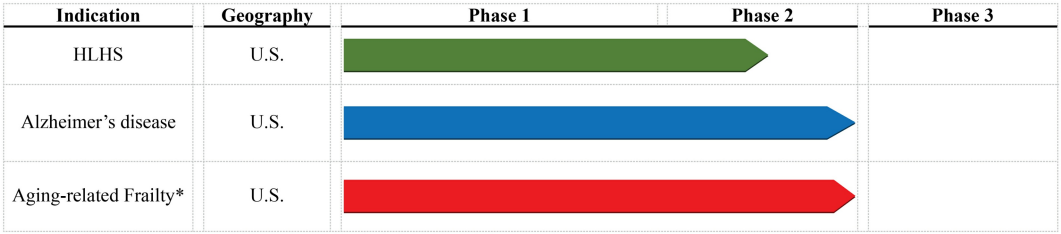
- Product candidate development pipeline through internal research and development, and in-licensing. Through our research and development program, and through strategic in-licensing agreements, or other business development arrangements, we intend to actively explore promising potential additions to our pipeline.

- Continue to expand our intellectual property portfolio. Our intellectual property is vitally important to our business strategy, and we have taken and continue to take significant steps to develop this property and protect its value. Results from our ongoing research and development efforts are intended to add to our existing intellectual property portfolio.

Clinical Development Pipeline in 2024

We are currently in clinical development of a single product, Lomecel-B™ for three potential indications:

Figure 1: Lomecel-B™ clinical development pipeline



* Not currently active for 2024

Hypoplastic Left Heart Syndrome (HLHS). The FDA granted Lomecel-B™ for the treatment of HLHS a Rare Pediatric Disease ("RPD") Designation (on November 8, 2021), Orphan Drug Designation ("ODD") (on December 2, 2021), and Fast Track Designation (on August 24, 2022). HLHS is a rare congenital heart condition affecting approximately 1,000 newborns in the US annually. HLHS is a birth defect that affects normal blood flow through the heart. As the baby develops during pregnancy, the left side of the heart does not form correctly so that babies are born with a single ventricle. It is one type of congenital heart defect present at birth. Because a baby with this defect needs surgery or other procedures soon after birth, HLHS is considered a critical congenital heart defect. To prevent certain death shortly after birth, these babies undergo a series of three heart surgeries (staged surgical palliation) that reconfigures the single RV) to support systemic circulation. Despite these life-saving surgeries, HLHS patients nevertheless still have high early mortality and morbidity rates due primarily to heart failure.

We are currently conducting a Phase 2b clinical trial (ELPIS II) under FDA IND 017677. ELPIS II is a multi-center, randomized, double-blind, controlled clinical trial designed to evaluate Lomecel-B™ as an adjunct therapy to the standard-of-care second-stage HLHS heart reconstructive surgery which is typically performed at 4-6 months after birth. The primary objective is to evaluate change in right ventricular ejection fraction after Lomecel-B™ treatment versus standard-of-care surgery alone (38 subjects total: 19 per arm) at 12 months. This trial is more than 80% enrolled and is funded in part by the NHLBI/NIH. Enrollment completion is currently targeted for the end of 2024. However, given the relatively small patient population, clinical trial enrollment timing for rare diseases like HLHS is difficult to predict and full enrollment may occur in the first quarter of 2025.

ELPIS II is a next-step trial to our completed 10-patient open-label Phase 1 trial (ELPIS I) under the same IND. This Phase 1 trial was designed to evaluate the safety and tolerability of Lomecel-B™ as an adjunct to the second-stage HLHS surgery, and to obtain preliminary evidence of Lomecel-B's effect to support a next-phase trial. The primary safety endpoint was met: no major adverse cardiac events ("MACE") or treatment-related infections during the first month post-treatment, and no triggering of stopping rules. Furthermore, fluid-based and imaging biomarker data supported multiple potentially relevant mechanisms-of-action of Lomecel-B™, and the potential to improve post-surgical heart function. In addition to the 12-month follow-up evaluation on ELPIS, we continue to follow these patients on an annual basis for the survival status As of September 2024, all 10 patients have survived (100%), seven of the patients have reached the age of five and have successfully undergone the third-stage surgery, and two of them have reached the age of six years old, all without the need for a heart transplantation. Based on historical data, the incidence of interstage attrition between the Glenn operation (Stage 2) and Fontan (Stage 3) ranges from 6% to 12% with the most common cause of death being RV dysfunction. Longer-term follow-up studies showed that the transplant-free survival to age 15 is only approximately 50 % in these patients.

We have filed patent applications relating to the administration of mesenchymal stem cells for treating HLHS in Australia, the Bahamas, Canada, China, the European Patent Office, Japan, South Korea, Taiwan, and the United States.

Alzheimer's disease. AD, a devastating neurologic disease leading to cognitive decline, currently has limited therapeutic options. An estimated 6.7 million Americans aged 65 and older have AD, and this number is projected to more than double by 2060. Lomecel-B™ treated patients showed an overall slowing/prevention of disease worsening compared to placebo in the completed Phase 2a study (CLEAR MIND Trial) as previously detailed in this report and met its primary endpoint of safety. These results are consistent with those of our earlier Phase I study[2]. Based on these results, the FDA granted RMAT Designation and Fast Track designation to

Lomecel-B™ for the treatment of mild AD. As previously indicated, we intend to forge strategic collaborations, consider potential partnerships, or pursue other available pathways or opportunities for the advancement of Lomecel-B™ in addressing AD.

2. Mark Brody, Marc Agronin, Brad J. Herskowitz, Susan Y. Bookheimer, Gary W. Small, Benjamin Hitchinson, Kevin Ramdas, Tyler Wishard, Katalina Fernández McInerney, Bruno Vellas, Felipe Sierra, Zhijie Jiang, Lisa McClain-Moss, Carmen Perez, Ana Fuquay, Savannah Rodriguez, Joshua M. Hare, Anthony A. Oliva Jr., Bernard Baumel. "Results and insights from a phase I clinical trial of Lomecel-B™ for Alzheimer's disease" (2023) Alzheimer's & Dementia: The Journal of the *Alzheimer's Association 19:261-273.*

We have filed patent applications relating to the treatment of AD using mesenchymal stem cells in Australia, the Bahamas, Canada, China, the European Patent Office, Hong Kong, Israel, Japan, New Zealand, South Korea, Singapore, South Africa, and the United States.

Aging-related Frailty. Aging-related Frailty is a life-threatening geriatric condition that disproportionately increases risks for poor clinical outcomes from disease and injury. While the definition of Aging-related Frailty lacks consensus, would be a new indication from a regulatory standpoint, and has no approved pharmaceutical or biologic treatments, there are a number of companies now working to develop potential therapeutics for this unmet medical need.

We have previously completed two U.S. clinical trials under FDA IND 016644. One is a multicenter, randomized, placebo-controlled Phase 2b trial which showed that a single infusion of Lomecel-B™ significantly improved 6-Minute Walk Test ("6MWT") distance 9 months after infusion (although results were inconclusive at six months after infusion), and also showed a dose-dependent increase in 6MWT distance 6 months after infusion. The second is a multicenter, randomized, placebo-controlled Phase 1/2 trial ("HERA Trial") intended primarily to evaluate safety, and explore the effect Lomecel-B™ may have on specific biomarkers of immune system function in older, frail individuals receiving the high dose influenza vaccine, as well as to evaluate the potential effects of Lomecel-B™ on signs and symptoms of Aging-related Frailty. Results from this study showed that Lomecel-B™ was generally safe and well tolerated in patients with Aging-related Frailty. Additionally, hemagglutinin inhibition ("HAI") assay results in the Lomecel-B™ and placebo groups to influenza were not statistically different, indicating Lomecel-B™ does not suppress the immune system.

We have filed patent applications relating to the administration of MSC for Aging-related Frailty in Australia, Canada, China, the European Patent Office, Hong Kong, Israel, Japan, Singapore, South Korea, New Zealand, South Africa, Taiwan, the Bahamas and United States.

Components of Our Results of Operations

Revenue

We have generated revenue from three sources:

- Grant awards. Extramural grant award funding, which is non-dilutive, has been a core strategy for supporting our ongoing clinical research. Since 2016 our clinical programs have received over $16.0 million in competitive extramural grant awards ($11.5 million which has been directly awarded to us and which are recognized as revenue when the performance obligations are met) from the National Institutes of Health, Alzheimer's Association, and Maryland Stem Cell Research Fund.

- The Bahamas Registry Trials. Participants in The Bahamas Registry Trials pay us a fee to receive Lomecel-B™, imported into The Bahamas, and administered at one of two private medical clinics in Nassau. While Lomecel-B™ is considered an investigational product in The Bahamas, under the approval terms received from the National Stem Cell Ethics Committee, we are permitted to charge a fee for participation in the Registry Trial. The fee is recognized as revenue and is used to pay for the costs associated with manufacturing and testing of Lomecel-B™, administration, shipping and importation fees, data collection and management, biological sample collection and sample processing for biomarkers and other data, and overall management of the Registry, including personnel costs. Lomecel-B™ is considered an investigational treatment in The Bahamas and is not licensed for commercial sale.

- Contract development and manufacturing services. From time to time, we enter into fee-for-service agreements with third parties for our product development and manufacturing capabilities. In February 2024, we entered into our first manufacturing services contract with Secretome Therapeutics.

Cost of Revenues

We record cost of revenues based on expenses directly related to revenue. For grants we record allocated expenses for research and development costs to a grant as a cost of revenues. For the clinical trial revenue, directly related expenses for that program are allocated and accrued as incurred. These expenses are similar to those described under “Research and Development Expenses” below. For the contract manufacturing, the Company records costs incurred under the contract as cost of revenues.

Research and Development Expenses

Research and development costs are charged to expense when incurred in accordance with Financial Accounting Standards Board (“FASB”) Accounting Standards Codification (“ASC”) 730 Research and Development. ASC 730 addresses the proper accounting and reporting for research and development costs. It identifies:

1. Those activities that should be identified as research and development;
2. The elements of costs that should be identified with research and development activities, and the accounting for these costs; and
3. The financial statement disclosures related to them.

Research and development include costs such as clinical trial expenses, contracted research and license agreement fees with no alternative future use, supplies and materials, salaries, share-based compensation, employee benefits, property and equipment depreciation and allocation of various corporate costs. We accrue for costs incurred by external service providers, including contract research organizations (“CROs”) and clinical investigators, based on estimates of service performed and costs incurred. These estimates include the level of services performed by the third parties, subject enrollment in clinical trials, administrative costs incurred by the third parties, and other indicators of the services completed. Based on the timing of amounts invoiced by service providers, we may also record payments made to those providers as prepaid expenses that will be recognized as expense in future periods as the related services are rendered.

We currently do not carry any inventory for our product candidates, as we have yet to launch a product for commercial distribution. Historically our operations have focused on conducting clinical trials, product research and development efforts, and improving and refining our manufacturing processes, and accordingly, manufactured clinical doses of product candidates were expensed as incurred, consistent with the accounting for all other research and development costs. Once we begin commercial distribution, all newly manufactured approved products will be allocated either for use in commercial distribution, which will be carried as inventory and not expensed, or for research and development efforts, which will continue to be expensed as incurred.

We expect that our research and development expenses will continue to be significant in the future as we increase our headcount to support increased research and development activities relating to our clinical programs, as well as incur additional expenses related to our clinical trials.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation, for personnel in our executive, finance, business development and administrative functions. General and administrative expenses also include public company related expenses; Board of Director fees; legal fees relating to corporate matters; insurance costs; professional fees for accounting, auditing, tax and consulting services; travel expenses; and facility-related expenses, which include direct depreciation costs and allocated expenses for rent and maintenance of facilities and other operating costs. General and administrative costs also include royalty and license fees associated with our agreements with the University of Miami as well as attending and sponsoring industry, investment, organization and medical conferences and events.

Other Income

Interest income consists of interest earned on cash equivalents and marketable securities. We expect our interest income to vary in conjunction with changes in our monthly cash and marketable securities balances. Other income consists of funds earned that are not part of our normal operations. In past years they have been primarily a result of tax refunds received for social security taxes as part of a research and development tax credit program.

Income Taxes

No provision for income taxes has been recorded for the years ended December 31, 2024 and 2023. We may incur income taxes in the future if we have earnings. At this time the Company has not evaluated the impact of any future profits.

RESULTS OF OPERATIONS

COMPARISON OF THE THREE MONTHS ENDED SEPTEMBER 30, 2024 AND 2023

The following table summarizes our results of operations for the three months ended September 30, 2024 and 2023, together with the changes in those items in dollars (in thousands):

	Three Months Ended September 30,		Increase (Decrease)
	2024	2023	
Revenues	$ 773	$ 150	$ 623
Cost of revenues	91	96	(5)
Gross profit	682	54	628
Expenses			
General and administrative	3,125	3,372	(247)
Research and development	2,206	1,843	363
Total operating expenses	5,331	5,215	116
Loss from operations	(4,649)	(5,161)	512
Other income	230	55	175
Net loss	$ (4,419)	$ (5,106)	$ 687

Revenues, Cost of Revenues and Gross Profit: Revenues for the three months ended September 30, 2024 and 2023 were $0.8 million and $0.2 million, respectively. This represents an increase of $0.6 million, or 415%, in 2024 compared to 2023, driven primarily by an increased participant demand for our Bahamas Registry Trial and the addition of our manufacturing services contract.

Clinical trial revenue from the Bahamas Registry Trial, for the three months ended September 30, 2024 and 2023 was $0.2 million and $0.1 million, respectively, reflecting an increase of $0.1 million, or 40%, due to increased participant demand. Contract manufacturing revenue for the three months ended September 30, 2024 was $0.6 million, generated from our manufacturing services contract.

Related cost of revenues was $0.1 million for the three months ended September 30, 2024 and 2023. This resulted in a gross profit of approximately $0.7 million for the three months ended September 30, 2024, an increase of $0.6 million, or greater than 100%, compared to a gross profit of less than $0.1 million in 2023.

General and Administrative Expense: General and administrative expenses for the three months ended September 30, 2024 decreased to approximately $3.1 million, compared to $3.3 million for the same period in 2023. This decrease of approximately $0.2 million, or 7%, was primarily due to lower legal and other administrative expenses, partially offset by higher stock compensation costs in 2024.

Research and Development Expenses: Research and development expenses for the three months ended September 30, 2024 increased to approximately $2.2 million from approximately $1.8 million for the same period in 2023. The increase of $0.4 million, or 20%, was primarily due to $0.5 million of higher compensation and benefit costs and $0.3 million in additional equity-based compensation expenses allocated to research and development expenses. These increases were partially offset by a $0.6 million

decrease in expenses related to the now-completed CLEAR MIND Alzheimer's disease clinical trial, as well as reduced costs for the Aging-related frailty clinical trial following our decision to discontinue trial activities in Japan.

Research and development expenses consisted primarily of the following items (less those expenses allocated to the cost of revenues for the grants) (in thousands):

	Three Months Ended September 30,	
	2024	2023
Employee compensation and benefits	$ 853	$ 384
Clinical trial expenses-statistics, monitoring, labs, sites, etc.	441	1,019
Depreciation	178	176
Supplies and costs to manufacture Lomecel-B™	110	64
Equity-based compensation	464	141
Amortization	56	56
Travel	25	3
Other activities	79	-
	$ 2,206	$ 1,843

Other Income (Expense): Other income for the three months ended September 30, 2024 was $0.2 million, primarily consisting of interest earned on money market funds. Other income for the three months ended September 30, 2023 was less than $0.1 million.

Net Loss: Net loss decreased to approximately $4.4 million for the three months ended September 30, 2024 from $5.1 million for the same period in 2023. This decrease of $0.7 million, or 13%, was due to the factors outlined above.

COMPARISON OF THE NINE MONTHS ENDED SEPTEMBER 30, 2024 AND 2023

The following table summarizes our results of operations for the nine months ended September 30, 2024 and 2023, together with the changes in those items in dollars (in thousands):

	Nine Months Ended September 30,		Increase
	2024	2023	(Decrease)
Revenues	$ 1,789	$ 646	$ 1,143
Cost of revenues	435	423	12
Gross profit	1,354	223	1,131
Expenses			
General and administrative	7,447	8,902	(1,455)
Research and development	6,148	6,910	(762)
Total operating expenses	13,595	15,812	(2,217)
Loss from operations	(12,241)	(15,589)	3,348
Other income	349	204	145
Net loss	$ (11,892)	$ (15,385)	$ 3,493

Revenues, Cost of Revenues and Gross Profit: Revenues for the nine months ended September 30, 2024 and 2023 were $1.8 million and $0.6 million, respectively. This represents an increase of $1.1 million, or 177%, in 2024 compared to 2023, primarily driven by increased participant demand for our Bahamas Registry Trial and our manufacturing services contract.

Clinical trial revenue, derived from the Bahamas Registry Trial, for the nine months ended September 30, 2024 and 2023 was $1.0 million and $0.6 million, respectively. This increase of $0.4 million, or 67%, for the nine months ended September 30, 2024 was due to higher participant demand. Contract manufacturing revenue for the nine months ended September 30, 2024 was $0.8 million, generated from our manufacturing services contract.

Related cost of revenues was $0.4 million for the nine months ended September 30, 2024 and 2023. This resulted in a gross profit of approximately $1.3 million for the nine months ended September 30, 2024, an increase of $1.1 million, or 506%, compared to a gross profit of $0.2 million in 2023.

General and Administrative Expense: General and administrative expenses for the nine months ended September 30, 2024 decreased to approximately $7.4 million, compared to $8.9 million for the same period in 2023. This decrease of approximately $1.5 million, or 16%, was primarily due to lower personnel expenses as a result of reduced severance, legal and other administrative expenses, partially offset by higher stock compensation costs in 2024.

Research and Development Expenses: Research and development expenses for the nine months ended September 30, 2024 decreased to approximately $6.1 million, from approximately $6.9 million for the same period in 2023. This decrease of $0.8 million, or 11%, was primarily driven by a reduction of $1.8 million in expenses related to the completed CLEAR MIND Alzheimer's disease clinical trial, reduced costs for the Aging-related frailty clinical trial following our decision to discontinue trial activities in Japan, and a $0.4 million decrease in supply costs. These reductions were partially offset by $1.1 million in higher compensation and benefit costs and a $0.2 million increase in equity-based compensation expenses allocated to research and development . Research and development expenses consisted primarily of the following items (less those expenses allocated to the cost of revenues for the grants) (in thousands):

	Nine Months Ended September 30,	
	2024	2023
Employee compensation and benefits	$ 2,531	$ 1,421
Clinical trial expenses-statistics, monitoring, labs, sites, etc.	1,671	3,499
Depreciation	548	542
Equity-based compensation	677	418
Supplies and costs to manufacture Lomecel-B™	254	619
Amortization	168	168
Travel	97	11
Other activities	202	232
	$ 6,148	$ 6,910

Other Income (Expense): Other income for the nine months ended September 30, 2024 was $0.3 million, primarily consisting of interest earned on money market funds and marketable securities. Other income for the same period in 2023 was $0.2 million, primarily due to gains from marketable securities.

Net Loss: Net loss decreased to approximately $11.9 million for the nine months ended September 30, 2024, from $15.3 million for the same period in 2023. This decrease of $3.5 million, or 23%, was due to the factors outlined above.

Cash Flows

The following table summarizes our sources and uses of cash for the period presented (in thousands):

	Nine months ended September 30,	
	2024	2023
Net cash used in operating activities	$ (10,495)	$ (15,005)
Net cash (used in) provided by investing activities	(517)	6,622
Net cash provided by (used in) financing activities	28,841	(153)
Change in cash and cash equivalents	$ 17,829	$ (8,536)

Operating Activities. We have incurred losses since inception. Net cash used in operating activities for the nine months ended September 30, 2024 was $10.5 million, consisting primarily of our net loss of $11.9 million and payments of $0.2 million in prepaid expenses and other assets, and $0.7 million for accrued expenses. This was partially offset by non-cash expenses of $1.9 million for equity-based compensation and $0.7 million for depreciation and amortization. Net cash used in operating activities for the nine months ended September 30, 2023 was $15.0 million, consisting primarily of our net loss of $15.4 million, payments of $0.6 million in prepaid and other assets and non-operating lawsuit of $1.4 million. This was partially offset by non-cash expenses of $1.6 million in equity-based compensation expenses, $0.7 million in depreciation and amortization, and an increase in accrued expenses of $0.8 million.

Investing Activities. Net cash used in investing activities for the nine months ended September 30, 2024 was $0.5 million consisting primarily of the purchases of property and equipment and intangible assets, which was partially offset by the redemption of

marketable securities. Net cash provided by investing activities for the nine months ended September 30, 2023 was $6.6 million, consisting primarily of proceeds from the sale of marketable securities.

Financing Activities. Net cash provided by financing activities for the nine months ended September 30, 2024 was approximately $28.8 million for proceeds from the issuance of common stock of $12.9 million and warrants exercised of $16.2 million, which was partially offset by the payment of taxes upon vesting of RSUs. Net cash used in financing activities for the nine months ended September 30, 2023 was $0.2 million for the payment of taxes upon vesting of RSUs.

LIQUIDITY AND CAPITAL RESOURCES

Since our inception, we have incurred significant operating losses. We expect to incur significant expenses and operating losses as we advance the preclinical and clinical development of our programs. We expect that our sales, research and development and general and administrative costs will increase in connection with conducting additional preclinical studies and clinical trials for our current and future programs and product candidates, contracting with CROs to support preclinical studies and clinical trials, expanding our intellectual property portfolio, and providing general and administrative support for our operations. As a result, we will need additional capital to fund our operations, which we may obtain from additional equity or debt financings, collaborations, licensing arrangements, or other sources.

To date, we have financed our operations primarily through our IPO, public and privately placed equity financings, grant awards, and fees generated from the Bahamas Registry Trial and contract manufacturing services. Since we were formed, we have raised approximately $132.2 million in gross proceeds from the issuance of equity. At September 30, 2024, the Company had cash and cash equivalents of $22.8 million and working capital of approximately $20.7 million.

Following the capital raises from a registered direct offering and warrant exercises in July 2024 as well as an inducement transaction in September 2024, as detailed below in the section entitled “Capital Raising Efforts”, which resulted in gross proceeds of $15.4 million and net proceeds of $14.0 million after deducting placement agent fees and other deductions for offering expenses as discussed below, we believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements through the fourth quarter of 2025 based on our current operating budget and cash flow forecast. However, as a result of our successful Type C meeting with the U.S. FDA in August 2024 with respect to the HLHS regulatory pathway, we have started to ramp up Biologics License Application (BLA) enabling activities as we currently anticipate a potential filing with the FDA in 2026 if the current ELPIS II trial is successful. To the extent that our operating expenses and capital expenditure requirements accelerate in calendar 2025 as a result of these activities, including CMC (Chemistry, Manufacturing, and Controls) and manufacturing readiness, there will be a need to increase our current proposed spend and further increase our capital investments. We intend to seek additional financing/capital raises/non-dilutive funding options to support these activities, and current cash projections may be impacted by these ramped up activities and any financing transactions entered into. We have based these estimates on assumptions that may prove to be imprecise, and we could utilize our available capital resources sooner than we expect. We are actively seeking financing opportunities to extend our cash runaway while taking measures to reduce our cash expenditures as we focus our resources on our primary strategic program in HLHS. These cost saving measures include the discontinuation of our Aging-related Frailty clinical trial in Japan, related staff reductions, and continued prudent management of discretionary spend.

Capital Raising Efforts

On July 10, 2024, certain holders of the June Inducement Warrants exercised the same to purchase an aggregate of 150,000 shares of Class A common stock for cash (the “July 10 warrant exercise”). Accordingly, on July 17, 2024, we issued to the placement agent additional warrants to purchase up to 10,500 shares of Class A common stock, equal to 7.0% of the aggregate number of shares of Class A common stock issued in the July 10 warrant exercise (the “first tranche July ordinary course placement agent warrants”). The first tranche July ordinary course placement agent warrants have substantially the same terms as the private placement agent warrants issued in June, except that the first tranche July ordinary course placement agent warrants have an exercise price of $3.125 per share and expire July 17, 2026. Separately, on July 10, 2024, a holder of Series C Warrants issued in an April 24 inducement letter agreement transaction exercised the same for 50,000 shares of common stock for cash (the "July Series C warrant exercise").

On July 17, 2024, holders of the June Inducement Warrants exercised June Inducement Warrants to purchase an aggregate of 2,319,186 shares of Class A common stock for cash (the “July 17 warrant exercise” and together with the July Series C warrant exercise and the July 10 warrant exercise, collectively, the “July warrant exercises”). Accordingly, on July 24, 2024, we issued to the placement agent additional warrants to purchase up to 162,344 shares of Class A common stock, equal to 7.0% of the aggregate number of shares of Class A common stock issued in the July 17 warrant exercise (the “second tranche July ordinary course placement agent warrants”, and together with the first tranche July ordinary course placement agent warrants, the “July ordinary course placement agent warrants”, and collectively with the July transaction placement agent warrants, the “July placement agent warrants”).

The second tranche July ordinary course placement agent warrants have substantially the same terms as the first tranche July ordinary course placement agent warrants, except that the second tranche July ordinary course placement agent warrants expire July 24, 2026.

The gross proceeds to the Company from the July warrant exercises, inclusive of the payment consideration for such warrants, were approximately $6.3 million, before deducting placement agent fees payable by the Company.

On July 18, 2024, we entered into a securities purchase agreement with institutional and accredited investors relating to the registered direct offering and sale of an aggregate of 2,236,026 shares of our Class A common stock at a purchase price of $4.025 per share of Class A common stock and associated warrant (the "July registered direct offering"). The securities issued in the July registered direct offering were offered pursuant to a prospectus supplement, dated July 18, 2024, and accompanying prospectus, in connection with a takedown from our shelf registration statement on Form S-3 (File No. 333-264142), which was declared effective by the SEC on April 14, 2022.

In a concurrent private placement (the "July private placement" and together with the July registered direct offering, the "July offering"), we also sold unregistered Class A common stock warrants to purchase up to an aggregate of 2,236,026 shares of our Class A common stock (the "July private placement warrants"). The unregistered July private placement warrants have an exercise price of $3.90 per share, became exercisable on July 19, 2024, and expire on July 20, 2026. Additionally the Company agreed to issue to the placement agent, or its designees, warrants to purchase up to an aggregate of 156,522 shares of Class A common stock (the "July offering placement agent warrants"), equal to 7.0% of the aggregate number of shares of Class A common stock sold in the offering, which have substantially the same terms as the unregistered July private placement warrants, except that the July offering placement agent warrants have an exercise price of $5.0313 per share.

The gross proceeds to the Company from the July offering were approximately $9.0 million, before deducting placement agent fees and other offering expenses payable by the Company.

In September 2024, the Company entered into additional inducement letter agreements with certain holders of its existing Purchaser Warrants issued as part of the Company's 2021 private placement offering to amend and reduce the exercise price of the Purchaser Warrants to $1.00 per share in consideration for the holders' cash exercise of all Purchaser Warrants held by such holder on or before September 27, 2024. In connection with the September 2024 inducement transaction, Purchaser Warrants were exercised for 114,077 shares of Class A common stock, resulting in gross proceeds to the Company of $114,077.

Grant Awards

From inception through December 31, 2023, we have been awarded approximately $11.9 million in governmental and non-profit association grants, which have been used to fund our clinical trials, research and development, production and overhead. Grant awards are recognized as revenue, and depending on the funding mechanism, are deposited directly in our accounts as lump sums, which are staggered over a predetermined period or drawn down from a federal payment management system account for reimbursement of expenses incurred. Revenue recognition occurs when the grant related expenses are incurred or supplies and materials are received. As of September 30, 2024, and December 31, 2023, the amount of unused grant funds that were available for us to draw was approximately $0.1 million.

Terms and Conditions of Grant Awards

Grant projects are typically divided into periods (e.g., a three-year grant may have three one-year periods), and the total amount awarded is divided according to the number of periods. At pre-specified time points, which are detailed in the grant award notifications, we are required to submit interim financial and scientific reports to the granting agency totaling funds spent, and in some cases, detailing use of proceeds and progress made during the reporting period. After funding the initial period, receipt of additional grant funds is contingent upon satisfactory submission of our interim reports to the granting agency.

Grant awards arise from submitting detailed research proposals to granting agencies, and winning a highly competitive and rigorous application review and process that is judged on the merits of the proposal. There are typically multiple applicants applying and competing for a finite amount of funds. As such we cannot be sure that we will be awarded grant funds in the future despite our past success in receiving such awards.

Funding Requirements

Our operating costs will continue to be substantial for the foreseeable future in connection with our ongoing activities. In past years we have been able to fund a large portion of our clinical programs and our administrative overhead with the use of grant funding.

Specifically, our expenses will increase as we:

- advance the clinical development of Lomecel-B™ for the treatment of several disease states and indications;
- pursue the preclinical and clinical development of other current and future research programs and product candidates;
- in-license or acquire the rights to other products, product candidates or technologies;
- maintain, expand and protect our intellectual property portfolio;
- hire additional personnel in research, manufacturing and regulatory and clinical development as well as management personnel;
- seek regulatory approval for any product candidates that successfully complete clinical development; and
- expand our operational, financial and management systems and increase personnel, including personnel to support our operations as a public company.

We believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements through the fourth quarter of 2025 based on our current operating budget and cash flow forecast. However, as a result of our successful Type C meeting with the U.S. FDA in August 2024 with respect to the HLHS regulatory pathway, we have started to ramp up Biologics License Application (BLA) enabling activities as we currently anticipate a potential filing with the FDA in 2026 if the current ELPIS II trial is successful. To the extent that our operating expenses and capital expenditure requirements accelerate in calendar 2025 as a result of these activities, including CMC (Chemistry, Manufacturing, and Controls) and manufacturing readiness, there will be a need to increase our current proposed spend and further increase our capital investments. We intend to seek additional financing/capital raises/non-dilutive funding options to support these activities, and current cash projections may be impacted by these ramped up activities and any financing transactions entered into. We have based these estimates on assumptions that may prove to be imprecise, and we could utilize our available capital resources sooner than we expect. We are actively seeking financing opportunities to extend our cash runaway while taking measures to reduce our cash expenditures as we focus our resources on our primary strategic program in HLHS. These cost saving measures include the discontinuation of our Aging-related Frailty clinical trial in Japan, related staff reductions, and continued prudent management of discretionary spend.

Because of the numerous risks and uncertainties associated with research, development and commercialization of our product candidates, it is difficult to estimate with certainty the amount of our working capital requirements. Our future funding requirements will depend on many factors, including:

- the progress, costs and results of our clinical trials for our programs for our cell-based therapies, and additional research and preclinical studies in other research programs we initiate in the future;
- the costs and timing of process development and manufacturing scale-up activities associated with our product candidates and other programs we advance through preclinical and clinical development;
- our ability to establish and maintain strategic collaborations, licensing or other agreements and the financial terms of such agreements;
- the extent to which we in-license or acquire rights to other products, product candidates or technologies; and
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and protecting our intellectual property rights and defending against any intellectual property-related claims.

Further, our operating results may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such operating plans. Until such time, if ever, that we can generate product revenue sufficient to achieve profitability, we expect to finance our cash needs through a combination of equity offerings, debt financings, grant awards, collaboration agreements, other third-party funding, strategic alliances, licensing arrangements and marketing and distribution arrangements.

We currently have no credit facility or committed sources of capital. 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 capital expenditures or declaring dividends. If we raise additional funds through other third-party funding, collaboration agreements, strategic alliances, licensing arrangements or marketing and distribution arrangements, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable to us. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our biologic drug development or future commercialization efforts or grant rights to develop and market products or product candidates that we would otherwise prefer to develop and market ourselves.

In order to meet our operational goals, we will need to obtain additional capital, which we will likely obtain through a variety of means, including through public or private equity, debt financings or other sources, including up-front payments and milestone payments from strategic collaborations. To the extent that we raise additional capital through the sale of convertible debt or equity securities, current stockholder ownership interest will be diluted, and the terms may include liquidation or other preferences that adversely affect your rights as a stockholder. Such financing may result in dilution to stockholders, and may result in imposition of debt covenants, increased fixed payment obligations or other restrictions that may affect our business. If we raise additional funds through up-front payments or milestone payments pursuant to strategic collaborations with third parties, we may have to relinquish valuable rights to our product candidates, or grant licenses on terms that are not favorable to us. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

Contractual Obligations and Commitments

As of September 30, 2024, we have $1.6 million in operating lease obligations and $0 in contract research organization obligations due to the termination of our active master services agreements with third parties that were previously engaged to conduct its clinical trials and manage clinical research programs and clinical development services. This termination was due to the Company's decision to discontinue trial activities in Japan. We enter into contracts in the normal course of business with third-party contract organizations for clinical trials, preclinical studies, manufacturing and other services and products for operating purposes. These contracts generally provide for termination following a certain period after notice and therefore we believe that our non-cancelable obligations under these agreements are not material.

We have not included milestone or royalty payments or other contractual payment obligations if the timing and amount of such obligations are unknown or uncertain.

Critical Accounting Estimates

For a discussion of our critical accounting estimates, refer to "Management's Discussion and Analysis of Results of Operations and Financial Condition" in Part II, Item 7 and the notes to our financial statements in Part II, Item 8 of our 2023 Form 10-K. See also Note 1 to the condensed financial statements. There have been no material changes to our critical accounting estimates since the filing of our 2023 Form 10-K.

Emerging Growth Company Status

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act, or JOBS Act, which is a law intended to encourage funding of small businesses in the U.S. by easing many of the country's securities regulations, and we may take advantage of reduced reporting requirements that are otherwise applicable to public companies. Section 107 of the JOBS Act exempts emerging growth companies from being required to comply with new or revised financial accounting standards until private companies are required to comply with those standards. We have elected to take advantage of the extended transition period for complying with new or revised accounting standards; and as a result of this election, our condensed financial statements may not be comparable to companies that comply with public company effective dates. The JOBS Act also exempts us from having to provide an auditor attestation of internal control over financial reporting under Sarbanes-Oxley Act Section 404(b).

We will remain an "emerging growth company" until the earliest of (1) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more, (2) the last day of the fiscal year following the fifth anniversary of the completion of our IPO, (3) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three years or (4) the date on which we are deemed to be a large accelerated filer under the rules of the SEC, which generally is when a company has more than $700 million in market value of its reported class of stock held by non-affiliates and has been a public company for at least 12 months and have filed at least one Annual Report on Form 10-K.

Recent Accounting Pronouncements

A description of recent accounting pronouncements that may potentially impact our financial position, results of operations or cash flows is disclosed in Note 2 to our unaudited condensed financial statements included in Item 1 of this 10-Q.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

There have been no material changes in our exposure to market risks from those disclosed in Management's Discussion and Analysis of Financial Condition and Results of Operations in our 2023 10-K.

Item 4. Controls and Procedures.

Disclosure controls and procedures

Our management, under the supervision of and with the participation of our Chief Executive Officer and our Chief Financial Officer, has evaluated the effectiveness of our disclosure controls and procedures, as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as of the end of the period covered by this Quarterly Report on Form 10-Q. Based upon this evaluation, our Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this Quarterly Report on Form 10-Q, our disclosure controls and procedures were effective.

Changes in internal control over financial reporting

There were no changes in our internal control over financial reporting that occurred during the fiscal quarter ended September 30, 2024, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, the Company could become involved in disputes and various litigation matters that arise in the normal course of business. These may include disputes and lawsuits related to intellectual property, licensing, contract law and employee relations matters. As of September 30, 2024, the Company is not aware of any legal proceedings or material developments requiring disclosure.

Item 1A. Risk Factors.

There have been no material changes to the risk factors affecting the Company from those disclosed in the 2023 10-K.

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

ISSUER PURCHASES OF EQUITY SECURITIES

Period	Total Number of Shares Purchased (a)	Average Price Paid per Share (or Unit) (b)	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs (c)	Dollar Value of Shares that May Yet Be Purchased Under the Plans or Programs (d)
July 1-31, 2024	949	$ 1.57	-	-
August 1-31, 2024	109,312	2.46	-	-
September 1-30, 2024	-	-	-	-
Total	110,261	$ 2.45	-	-

(a) Includes shares withheld from employees to satisfy minimum tax withholding obligations associated with the vesting of restricted stock and performance stock units during the period.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Trading Arrangements

On July 10, 2024 , Rock Soffer , a member of the Company's Board of Directors , terminated his previously adopted "Rule 10b5-1 trading arrangement." The trading arrangement, adopted January 11, 2024 , and effective January 12, 2024, was intended to satisfy the affirmative defense of Rule 10b5-1(c). The trading arrangement, was set to expire on the earlier of (a) April 17, 2025; (b) completion of the sale of

275,000

shares of Longeveron Class A common stock; (c) notice or awareness of the closing of a tender or exchange offer or a merger, acquisition, reorganization, recapitalization, or comparable transaction for Longeveron in which its capital stock is exchanged or converted; (d) the death, incapacity, bankruptcy, or insolvency of Mr. Soffer; or (e) such other termination in accordance with its terms. During its term, no shares of Longeveron Class A common stock were sold pursuant to the arrangement.

Other than Mr. Soffer, none of the Company's directors or "officers," as defined in Rule 16a-1(f) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), adopted , modified , or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408 of Regulation S-K, during the Company's fiscal quarter ended September 30, 2024.

Item 6. Exhibits.

Exhibit No.	Description
4.1	Form of Common Stock Warrant, incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed July 19, 2024
4.2	Form of Placement Agent Warrant, incorporated by reference to Exhibit 4.2 to the Registrant's Current Report on Form 8-K filed July 19, 2024
10.1*	Form of Securities Purchase Agreement, incorporated by reference to Exhibit to the Registrant's Current Report on Form 8-K filed July 19, 2024
10.2	Second Amended and Restated Longeveron Inc. 2021 Incentive Award Plan, incorporated by reference to Appendix A to the Registrant's Definitive Proxy Statement filed with the SEC on May 20, 2024
31.1	Certification of principal executive officer, pursuant to SEC Rules 13a-14(a) and 15d-14(a) adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2	Certification of principal financial officer, pursuant to SEC Rules 13a-14(a) and 15d-14(a) adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1	Certification of principal executive officer, and principal financial officer, pursuant to 18 U.S.C. Section 1350, adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101.INS	Inline XBRL Instance Document - the instance document does not appear in the Interactive Data File as its XBRL tags are embedded within the Inline XBRL Document
101.SCH	Inline XBRL Taxonomy Extension Schema With Embedded Linkbase Documents
104	Inline Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101)

* Schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The Company hereby undertakes to furnish copies of any of the omitted schedules upon request by the SEC.

SIGNATURES

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 thereunto duly authorized.

LONGEVERON INC.

Date: November 12, 2024

/s/ Wa'el Hashad

Mohamed Wa'el Ahmed Hashad
Chief Executive Officer
(principal executive officer)

Date: November 12, 2024

/s/ Lisa A. Locklear

Lisa A. Locklear
Executive Vice President and Chief Financial Officer
(principal financial and accounting officer)

Exhibit 31.1

Rule 13a-14(a)/15(d)-14(a) Certifications

I, Mohamed Wa'el Ahmed Hashad, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Longeveron Inc.;

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

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

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

(a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant 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.

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.

/s/ Wa'el Hashad
Mohamed Wa'el Ahmed Hashad
Chief Executive Officer

Date: November 12, 2024

Exhibit 31.2

Rule 13a-14(a)/15(d)-14(a) Certifications

I, Lisa A. Locklear, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Longeveron Inc.;

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

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

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

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

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

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

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

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

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

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

/s/ Lisa A. Locklear
Lisa A. Locklear
Executive Vice President and Chief Financial Officer

Date: November 12, 2024

Exhibit 32.1

SECTION 1350 CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) or Rule 15d-14(b) of the Securities Exchange Act of 1934, as amended, and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. § 1350), as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Mohamed Wa'el Ahmed Hashad, Chief Executive Officer (principal executive officer) of Longeveron Inc. (the "Company"), and Lisa A. Locklear, the Chief Financial Officer (principal financial officer) of the Company, each hereby certifies that, to his knowledge on the date hereof:

(a) The Quarterly Report on Form 10-Q of the Company for the period ended September 30, 2024 filed on the date hereof with the Securities and Exchange Commission (the "Quarterly Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

(b) The information contained in the Quarterly Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the period covered by the Quarterly Report.

This certification shall not be deemed to be filed with the Securities and Exchange Commission and shall not be incorporated by reference into any filing of the Company under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Quarterly Report), irrespective of any general incorporation language contained in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained and furnished to the Securities and Exchange Commission or its staff upon request.

/s/ Wa'el Hashad
Mohamed Wa'el Ahmed Hashad
Chief Executive Officer
(Principal Executive Officer)
November 12, 2024

/s/ Lisa A. Locklear
Lisa A. Locklear
Executive Vice President and Chief Financial Officer
(Principal Financial Officer)
November 12, 2024