

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

FORM 10-Q

(Mark One)

☒

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 2024.

or

☐

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d)
OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from to

Commission File Number: 001-41934

FibroBiologics, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of
incorporation or organization)

86-3329066

(I.R.S. Employer
Identification No.)

**455 E. Medical Center Blvd, Suite 300
Houston, TX 77598**

(Address of principal executive offices)

77598

(Zip Code)

(281) 651-5150

(Registrant's telephone number, including area code)

N/A

(Former name, former address and former fiscal year, if changed since last report)

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

Title of each class:	Trading symbol(s)	Name of each exchange on which registered:
Common Stock, \$0.00001 par value	FBLG	The Nasdaq Global 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 ☐

Non-accelerated filer ☒

Smaller reporting company ☒

Emerging growth company ☒

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

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

At November 11, 2024, 34,659,125 shares of FibroBiologics, Inc.'s Common Stock, \$0.00001 par value per share, were outstanding.

FibroBiologics, Inc.

Quarterly Report on Form 10-Q
For the Quarter Ended September 30, 2024

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This quarterly report on Form 10-Q, or Quarterly Report, and the documents incorporated by reference herein, if any, contain forward-looking statements that can involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this Quarterly Report, 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. Forward-looking statements contained in this quarterly report include, but are not limited to, statements about:

- the timing, progress and results of preclinical studies and clinical trials for our current and future product candidates, including statements regarding the timing of initiation and completion of studies or trials and related preparatory work, the period during which the results of the trials will become available and our research and development programs;
- the timing, scope or likelihood of regulatory submissions, filings, and approvals, including final regulatory approval of our product candidates;
- our ability to develop and advance product candidates into, and successfully complete, clinical trials;
- our expectations regarding the size of the patient populations for our product candidates, if approved for commercial use;
- the implementation of our business model and our strategic plans for our business, product candidates and technology;
- our commercialization, marketing and manufacturing capabilities and strategy;
- the pricing and reimbursement of our product candidates, if approved;
- the rate and degree of market acceptance and clinical utility of our product candidates, in particular, and cell therapy, in general;
- our ability to establish or maintain collaborations or strategic relationships or obtain additional funding;

- our competitive position;
- the scope of protection we and/or our licensors are able to establish and maintain for intellectual property rights covering our product candidates;
- developments and projections relating to our competitors and our industry;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing;
- 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; and
- the impact of laws and regulations.

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 speak only as of the date of this Quarterly Report and are subject to a number of risks, uncertainties and assumptions described in the section titled “*Risk Factors*” and elsewhere in this Quarterly Report. 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. Except as required by applicable law, we do not plan to publicly update or revise any forward-looking statements contained herein until after we distribute this Quarterly Report, whether as a result of any new information, future events or otherwise.

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 Quarterly Report, 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.

PART I — FINANCIAL INFORMATION

Item 1. Financial Statements (Unaudited)

FibroBiologics, Inc.
Condensed Balance Sheets
(in thousands, except shares and per share data)

	September 30, 2024	December 31, 2023
	(Unaudited)	
Assets		
Current assets		
Cash and cash equivalents	\$ 7,827	\$ 9,163
Prepaid expenses	353	36
Other current assets	18	16
Total current assets	8,198	9,215
Property and equipment, net	772	797
Operating lease right-of-use asset, net	1,499	1,809
Total assets	\$ 10,469	\$ 11,821
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable and accrued expenses	\$ 1,179	\$ 1,444
Parent company payable	—	141
Operating lease liability, short-term	392	362
GEM commitment fee payable	1,863	—
Forward contract liability	241	—
Liability instrument	—	7,236
Warrant liability	2,887	—
Short-term note payable	115	—
Total current liabilities	6,677	9,183
Operating lease liability, long-term	1,055	1,385
Total liabilities	7,732	10,568
Stockholders' equity		
Preferred Stock, \$0.00001 par value; 10,000,000 shares and 20,000,000 shares authorized as of September 30, 2024 and December 31, 2023, respectively	—	—
Preferred Stock, \$0.00001 par value; 0 shares and 8,750,000 Series A Preferred shares authorized as of September 30, 2024 and December 31, 2023, respectively; 0 shares and 8,750,000 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	—	—
Preferred Stock, \$0.00001 par value; 0 shares and 5,000,000 Series B Preferred shares authorized as of September 30, 2024 and December 31, 2023, respectively; 0 shares and 4,171,445 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	—	—
Preferred Stock, \$0.00001 par value; 0 shares and 5,000,000 Series B-1 Preferred shares authorized as of September 30, 2024 and December 31, 2023, respectively; 0 shares and 89,781 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	—	—
Preferred Stock, \$0.00001 par value; 2,500 Series C Preferred shares authorized; 2,500 shares and 0 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	—	—
Non-voting Common Stock, \$0.00001 par value; 0 shares and 30,000,000 shares authorized as of September 30, 2024 and December 31, 2023, respectively; 0 shares and 28,230,842 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	—	1
Voting Common Stock, \$0.00001 par value; 100,000,000 shares authorized; 33,917,961 shares and 0 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	—	—
Additional paid-in capital	35,156	25,609
Accumulated deficit	(32,419)	(24,357)
Total stockholders' equity	2,737	1,253
Total liabilities and stockholders' equity	\$ 10,469	\$ 11,821

The accompanying notes are an integral part of these Unaudited Condensed Financial Statements.

FibroBiologics, Inc.
Condensed Statements of Operations
(unaudited, in thousands, except shares and per share data)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	\$ 1,213	\$ 571	\$ 3,148	\$ 1,595
General, administrative and other	2,139	1,481	6,877	4,814
Total operating expenses	3,352	2,052	10,025	6,409
Loss from operations	(3,352)	(2,052)	(10,025)	(6,409)
Other income/(expense):				
Change in fair value of warrant liability	1,927	—	4,349	—
Change in fair value of forward contract liability	849	—	(650)	—
Commitment fee expense	—	—	(1,941)	—
Other income/(loss)	2	(141)	31	(213)
Interest income	79	—	188	—
Interest expense	(5)	—	(14)	(146)
Total other income/(expense)	2,852	(141)	1,963	(359)
Net loss	(500)	(2,193)	(8,062)	(6,768)
Deemed dividend	—	—	—	(2,573)
Net loss attributable to common stockholders	\$ (500)	\$ (2,193)	\$ (8,062)	\$ (9,341)
Net loss per common share, basic and diluted	\$ (0.01)	\$ (0.08)	\$ (0.25)	\$ (0.33)
Weighted-average common shares outstanding, basic and diluted	33,516,656	28,230,842	32,457,473	28,230,842

The accompanying notes are an integral part of these Unaudited Condensed Financial Statements.

FibroBiologics, Inc.
Condensed Statements of Changes in Stockholders' Equity/(Deficit)
(unaudited, in thousands, except shares)

For the three and nine months ended September 30, 2024

		Series A		Series B		Series B-1		Series C		Non-voting		Voting		Additional	Accumulated	Total
	Net Parent	Preferred Stock		Preferred Stock		Preferred Stock		Preferred Stock		Common Stock		Common Stock		Paid-in	Deficit	Stockholders'
	Investment	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Equity/
																(Deficit)
Balance – December 31, 2023	\$ —	8,750,000	\$ —	4,171,445	\$ —	89,781	\$ —	—	\$ —	28,230,842	\$ 1	—	\$ —	\$ 25,609	\$ (24,357)	\$ 1,253
Issuance of Series C Preferred Stock	—	—	—	—	—	—	—	2,500	—	—	—	—	—	45	—	45
Conversion to Voting Common Stock	—	—	—	(4,171,445)	—	(89,781)	—	—	—	(28,230,842)	(1)	32,492,068	—	1	—	—
Cancellation of Series A Preferred Stock upon Direct Listing	—	(8,750,000)	—	—	—	—	—	—	—	—	—	—	—	—	—	—
Sale of Common Stock	—	—	—	—	—	—	—	—	—	—	—	227,057	—	2,819	—	2,819
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	480	—	480
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(8,460)	(8,460)
Balance (Unaudited) – March 31, 2024	—	—	—	—	—	—	—	2,500	—	—	—	32,719,125	—	28,954	(32,817)	(3,863)
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	578	—	578
Net income	—	—	—	—	—	—	—	—	—	—	—	—	—	—	898	898
Balance (Unaudited) – June 30, 2024	\$ —	—	\$ —	—	\$ —	—	\$ —	2,500	\$ —	—	\$ —	32,719,125	\$ —	\$ 29,532	\$ (31,919)	\$ (2,387)
Sale of Common Stock	—	—	—	—	—	—	—	—	—	—	—	1,198,836	—	5,052	—	5,052
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	572	—	572
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(500)	(500)
Balance (Unaudited) – September 30, 2024	<u>\$ —</u>	<u>—</u>	<u>\$ —</u>	<u>—</u>	<u>\$ —</u>	<u>—</u>	<u>\$ —</u>	<u>2,500</u>	<u>\$ —</u>	<u>—</u>	<u>\$ —</u>	<u>33,917,961</u>	<u>\$ —</u>	<u>\$ 35,156</u>	<u>\$ (32,419)</u>	<u>\$ 2,737</u>

For the three and nine months ended September 30, 2023

		Series A		Series B		Series B-1		Series C		Non-voting		Voting		Additional	Accumulated	Total
	Net Parent	Preferred Stock		Preferred Stock		Preferred Stock		Preferred Stock		Common Stock		Common Stock		Paid-in	Deficit	Stockholders'
	Investment	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Equity/
																(Deficit)
Balance – December 31, 2022	\$ 1,461	8,750,000	\$ —	381,658	\$ —	—	\$ —	—	\$ —	28,230,842	\$ 1	—	\$ —	\$ 2,414	\$ (7,872)	\$ (3,996)
Sale of Series B Preferred Stock, net of direct costs	—	—	—	911,379	—	—	—	—	—	—	—	—	—	4,889	—	4,889
Issuance of Series B Preferred Stock for conversion of Notes and accrued interest	—	—	—	799,603	—	—	—	—	—	—	—	—	—	4,286	—	4,286
Deemed dividend related to ROFN Agreement derivative liability	(1,461)	—	—	—	—	—	—	—	—	—	—	—	—	(1,112)	—	(2,573)
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	—	448	—	448
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	—	(2,415)	(2,415)
Balance (Unaudited) – March 31, 2023	—	8,750,000	—	2,092,640	—	—	—	—	—	28,230,842	1	—	—	10,925	(10,287)	639

The accompanying notes are an integral part of these Unaudited Condensed Financial Statements.

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

	For the Nine Months Ended September 30,	
	2024	2023
Cash flows from operating activities		
Net loss	\$ (8,062)	\$ (6,768)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of liability instrument and warrant liability	(4,349)	—
Change in fair value of forward contract liability	650	—
Stock-based compensation expense	1,675	1,333
Other loss on derivative liability	—	72
Amortization of convertible notes debt discount	—	81
Amortization of operating lease right-of-use asset	310	291
Depreciation expense	110	16
Changes in operating assets and liabilities:		
Change in prepaid expenses	(317)	2
Change in other current assets	(2)	(91)
Change in accounts payable and accrued expenses	(265)	396
Change in commitment fee payable	1,863	—
Change in payable to Parent	(141)	141
Change in operating lease liability	(300)	(273)
Net cash used in operating activities	(8,828)	(4,800)
Cash flows from investing activities		
Purchases of property and equipment	(85)	(493)
Net cash used in investing activities	(85)	(493)
Cash flows from financing activities		
ROFN Agreement payments to Parent	—	(2,645)
Repayment and proceeds of note receivable from Parent	—	300
Proceeds from short-term borrowing	574	—
Repayments of short-term borrowing	(459)	—
Proceeds from issuance of Series B Preferred Stock, net of direct costs	—	14,945
Proceeds from issuance of Series B-1 Preferred Stock, net of direct costs	—	1,193
Proceeds from issuance of common stock, net of direct costs	7,462	—
Net cash provided by financing activities	7,577	13,793
Net increase/(decrease) in cash and cash equivalents	(1,336)	8,500
Cash and cash equivalents, beginning of period	9,163	2,266
Cash and cash equivalents, end of period	\$ 7,827	\$ 10,766
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	\$ —	\$ —
Cash paid for interest	\$ 14	\$ 1
Supplemental disclosure of non-cash investing and financing activities:		
Issuance of Series B Preferred Stock for conversion of Notes and accrued interest	\$ —	\$ 5,866
Reclassification of derivative liability for conversion of Notes to Series B Preferred Stock	\$ —	\$ 538
Settlement of forward contract liability for sale of shares to GEM pursuant to Draw Down and Closing Notices	\$ 409	\$ —

The accompanying notes are an integral part of these Unaudited Condensed Financial Statements.

1. Organization, Description of Business, and Liquidity

Organization and Business

FibroBiologics, Inc. (the “Company” or “FibroBiologics”) was originally formed as a limited liability company (“LLC”) under the laws of the State of Texas on April 8, 2021 (“Inception”) and then converted to a Delaware corporation on December 14, 2021. FibroBiologics is a clinical stage biotechnology company headquartered in Houston, Texas, developing innovative treatments for chronic diseases using fibroblast cells. The Company’s primary focus is the initiation and progression of preclinical studies and clinical-stage U.S. Food and Drug Administration trials related to fibroblast treatments for Wound Healing, Multiple Sclerosis, Degenerative Disc Disease, Psoriasis, Cancer, and other diseases. Prior to Inception, preclinical research and development related to these disease pathways took place under the parent company, SpinalCyte, LLC (the “Parent” or “FibroGenesis”).

Direct Listing

On January 31, 2024, the Company completed a direct listing of its common stock on Nasdaq (the “Direct Listing”). Upon completion of the Direct Listing, all outstanding shares of the Company’s Non-voting Common Stock, Series B Preferred Stock, and Series B-1 Preferred Stock automatically converted into shares of Voting Common Stock on a one-for-one basis, and all outstanding shares of the Company’s Series A Preferred Stock were canceled for no consideration.

Going Concern and Management’s Plan

The Company has incurred operating losses since Inception and expects such losses to continue in the future as it builds infrastructure, develops intellectual property, and conducts research and development activities. The Company has primarily relied on a combination of angel investors and private equity and debt placements to fund its operations. As of September 30, 2024, the Company had an accumulated deficit of \$32,419 thousand and cash and cash equivalents of \$7,827 thousand. A transition to profitability will depend on the successful development, approval, and commercialization of product candidates and on the achievement of sufficient revenues to support the Company’s cost structure. The Company currently does not generate revenues and may never achieve profitability. Unless and until such time that revenue and net income are generated, the Company will need to continue to raise additional capital. These factors raise substantial doubt about the Company’s ability to continue as a going concern for one year from the issuance of the financial statements. The ability of the Company to continue as a going concern is dependent on the Company’s ability to raise additional capital. The financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern. As further described in Note 7, management has entered into a Share Purchase Agreement as of November 12, 2021. With the completion of the Company’s Direct Listing, this agreement provides the Company with access to additional liquidity. In February and March 2024, the Company utilized this facility to raise a total of \$2,819 thousand, net of costs. In July through September 2024, the Company raised an additional \$4,643 thousand, and may utilize this facility to raise additional capital if needed.

Segments

Operating segments are identified as components of an enterprise about which separate discrete financial information is available for evaluation by the chief operating decision maker in making decisions regarding resource allocation and assessing performance. The chief executive officer, who is the chief operating decision maker, reviews financial information on an aggregate basis for purposes of allocating resources and evaluating financial performance. The Company operates and manages its business as a single operating segment and therefore has one reportable segment.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying Unaudited Condensed Financial Statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") for interim financial information and in accordance with the instructions to Form 10-Q and Article 8 of Regulation S-X of the rules and regulations of the U.S. Securities and Exchange Commission ("SEC"). The accompanying Unaudited Condensed Balance Sheet as of September 30, 2024, Unaudited Condensed Statements of Operations for the three and nine months ended September 30, 2024 and 2023, Unaudited Condensed Statements of Stockholders' Equity/(Deficit) for the three and nine months ended September 30, 2024 and 2023, and Unaudited Condensed Statements of Cash Flows for the nine months ended September 30, 2024 and 2023, are unaudited. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. The accompanying unaudited condensed financial statements should be read in conjunction with the Company's Annual Report on Form 10-K for the year ended December 31, 2023 as filed with the SEC on February 29, 2024, which contains the audited financial statements and notes thereto. The Unaudited Condensed Financial Statements have been prepared on the same basis as the annual consolidated financial statements and, in the opinion of management, reflect all adjustments (consisting of normal recurring adjustments) necessary to state fairly the Company's financial position as of September 30, 2024, the results of operations for the three and nine months ended September 30, 2024 and 2023, the unaudited condensed statements of stockholders' equity/(deficit) for the three and nine months ended September 30, 2024 and 2023 and the unaudited condensed statements of cash flows for the nine months ended September 30, 2024 and 2023. The December 31, 2023, Unaudited Condensed Balance Sheet included herein was derived from the audited financial statements, but it does not include all disclosures or notes required by GAAP for complete financial statements.

The financial data and other information disclosed in these notes to the unaudited condensed financial statements related to the three and nine months ended September 30, 2024 and 2023, are unaudited. Interim results are not necessarily indicative of results for an entire year or for any future period.

During the period from January 1, 2021, to its formation on April 8, 2021, the Company operated as a line of business of FibroGenesis rather than as a separate stand-alone entity. Consequently, prior to the Company's formation on April 8, 2021, the financial statements were derived from the historical accounting records of the Parent. All general and administrative expenses and research and development expenses directly associated with the business activity of the Company that were originally incurred by the Parent from January 1, 2021, through the Company's formation on April 8, 2021, were allocated and included in the Company's financial statements. The resulting net Parent investment was presented within stockholders' equity/(deficit) and represented the Parent's interest in the recorded net assets of the Company and has been eliminated through the ROFN Agreement as further described in Notes 6 and 10.

In October 2023, the Company amended and restated its certificate of incorporation with the State of Delaware to immediately effect a 1-for-4 shares reverse stock split. All share and per share amounts have been adjusted on a retroactive basis to reflect the effect of the reverse stock split.

Use of Estimates

The preparation of the Unaudited Condensed Financial Statements in conformity with 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 Unaudited Condensed Financial Statements and the reported amounts of expenses during the reporting periods. These estimates are based on information available as of the date of the Unaudited Condensed Financial Statements; therefore, actual results could differ from those estimates and assumptions.

Concentration of Credit Risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents. The Company has significant cash balances at financial institutions, which, throughout the year, regularly exceed the federally insured limit of \$250,000. Any loss incurred or a lack of access to such funds could have a significant adverse impact on the Company's financial condition, results of operations and cash flows.

Risks and Uncertainties

The Company is subject to certain risks and uncertainties, including, but not limited to, changes in any of the following areas that the Company believes could have a material adverse effect on the future financial position or results of operations: the timing of, and the Company's ability to advance its current and future product candidates into and through clinical development; costs and timelines associated with the manufacture of clinical supplies of the Company's product candidates; regulatory approval and market acceptance of its product candidates; performance of third-party contract research organizations ("CROs") and contract development and manufacturing organizations ("CDMOs"); competition from pharmaceutical companies with greater financial resources or expertise; protection of the intellectual property, litigation or claims against the Company based on intellectual property, or other factors; the need to obtain additional funding; and its ability to attract and retain employees necessary to support its growth. Disruption from the operations of CROs, CDMOs or suppliers would likely have a negative impact on the Company's business, financial position and results of operations.

Cash and Cash Equivalents

Cash and cash equivalents consist of unrestricted cash balances and short-term, liquid investments with an original maturity date of three months or less at the time of purchase. The Company had \$6,488 thousand and no cash equivalents as of September 30, 2024 and December 31, 2023, respectively.

Property and Equipment

Property and equipment are stated at cost, net of accumulated depreciation. Depreciation of property and equipment is computed using the straight-line method over the estimated useful lives of the respective assets, generally three to five years, and includes laboratory equipment that is recorded at cost and depreciated using the straight-line method over the estimated useful lives of five years. Depreciation expense is classified in either research and development expense or in general and administrative expense, depending upon the nature of the asset, in the accompanying Unaudited Condensed Statements of Operations. When property and equipment assets are retired or otherwise disposed of, the cost and related accumulated depreciation are removed from the balance sheets and the resulting gain or loss is recorded in other income (loss) in the period realized. Maintenance and repairs are expensed as incurred.

Property and equipment are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets might not be recoverable. Conditions that would necessitate an impairment assessment include a significant decline in the observable market value of an asset, a significant change in the extent or manner in which an asset is used, or a significant adverse change that would indicate that the carrying amount of an asset or group of assets is not recoverable. For long-lived assets to be held and used, the Company will recognize an impairment loss only if the carrying amount is not recoverable through its undiscounted cash flows and measure any impairment loss based on the difference between the carrying amount and estimated fair value. The Company incurred no such losses for the three and nine months ended September 30, 2024 and 2023.

Leases

The Company determines if an arrangement is a lease at inception. An arrangement is or contains a lease if it conveys the right to control the use of an identified asset for a period of time in exchange for consideration. If a lease is identified, classification is determined at lease commencement. Operating lease liabilities are recognized at the present value of the future lease payments at the lease commencement date. The Company's leases do not provide an implicit interest rate and therefore the Company estimates its incremental borrowing rate to discount lease payments. The incremental borrowing rate reflects the interest rate that the Company would have to pay to borrow on a collateralized basis an amount equal to the lease payments in a similar economic environment over a similar term. Operating lease right-of-use ("ROU") assets are based on the corresponding lease liability adjusted for any lease payments made at or before commencement, initial direct costs, and lease incentives. Renewals or early terminations are not accounted for unless the Company is reasonably certain to exercise these options. Operating lease expense is recognized and the ROU asset is amortized on a straight-line basis over the lease term.

Operating leases are included in operating lease right-of-use asset, operating lease liability, short-term, and operating lease liability, long-term on the Company's Unaudited Condensed Balance Sheets.

The Company has elected in accordance with Accounting Standards Codification ("ASC") 842-20-25-2 an accounting policy to not record short-term leases, defined as those with terms of 12 months or less, on the Unaudited Condensed Balance Sheets. Rent expense recorded under leases, for financial statement purposes, is recognized on a straight-line basis over the lease term based on the most recent contractual terms available.

Fair Value Measurements

ASC 820, *Fair Value Measurement*, establishes a fair value hierarchy for instruments measured at fair value that distinguishes between assumptions based on market data (observable inputs) and the Company's own assumptions (unobservable inputs). Observable inputs are inputs that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs are inputs that reflect the Company's assumptions about the inputs that market participants would use in pricing the assets or liability and are developed based on the best information available in the circumstances. ASC 820 identifies fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. As a basis for considering market participant assumptions in fair value measurements, ASC 820 establishes a three-tiered value hierarchy that distinguishes between the following:

Level 1 - Quoted market prices in active markets for identical assets or liabilities.

Level 2 - Inputs other than Level 1 inputs that are either directly or indirectly observable, such as quoted market prices, interest rates and yield curves.

Level 3 - Unobservable inputs for the asset or liability (i.e., supported by little or no market activity). Level 3 inputs include management's own assumptions about the assumptions that market participants would use in pricing the asset or liability (including assumptions about risk).

Categorization within the valuation hierarchy is based upon the lowest level of input that is significant to the fair value measurement.

Derivatives

Derivative financial instruments, including the liability instrument, are recorded at fair value on the Unaudited Condensed Balance Sheets. Liability classified derivatives are remeasured at their fair value at each reporting date, with decreases or increases in the fair value recognized as other gain or loss, respectively, within the Unaudited Condensed Statements of Operations. Equity classified derivatives are not remeasured at each reporting date. If a liability classified derivative becomes eligible for reclassification to an equity classified derivative, any gains or losses recognized up to the point of reclassification are not reversed.

Research and Development

Research and development costs are charged to expense as incurred. Research and development costs consist of costs incurred in performing research and development activities, including salaries and bonuses, scientist recruiting costs, employee benefits, facilities costs, laboratory supplies, manufacturing expenses, preclinical expenses, research materials, and consulting and other contracted services. Costs for certain research and development activities are recognized based on the terms of the individual arrangements, which may differ from the pattern of costs incurred, and are reflected in the Unaudited Condensed Financial Statements as prepaid or accrued research and development.

Patent Costs

As the Company continues to incur costs to obtain market approval of patented technology, patent costs are expensed as incurred in general, administrative and other expense in the Unaudited Condensed Statements of Operations. Costs include fees to renew or extend the term of recognized intangible assets, patent defense costs, and patent application costs. Management will continue to expense such costs until market approval is obtained through regulatory approval by the appropriate governing body.

Income Taxes

The Company is a C corporation, and accounts for income taxes under the asset and liability method. Under this method, deferred tax assets and liabilities are determined based on the difference between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. Valuation allowances are established when necessary to reduce deferred tax assets to an amount that is more likely than not to be realized.

Under the provisions of ASC 740-10, *Income Taxes*, the Company evaluates uncertain tax positions by reviewing against applicable tax law all positions taken by the Company with respect to tax years for which the statute of limitations is still open. ASC 740-10 provides that a tax benefit from an uncertain tax position may be recognized when it is more likely than not that the position will be sustained upon examination, including resolutions of any related appeals or litigation processes, based on the technical merits. The Company recognizes interest and penalties related to the liability for unrecognized tax benefits, if any, as a component of the income tax expense line in the accompanying Unaudited Condensed Statements of Operations.

Stock-Based Compensation

The Company recognizes compensation costs related to stock options granted to employees and nonemployees based on the estimated fair value of the awards on the date of grant and recognizes expense on a straight-line basis over the requisite service period, which is generally the vesting period of the award. Forfeitures are recognized as they occur. The fair value of stock options is estimated on the date of grant using a Black-Scholes option pricing model which requires management to apply judgment and make estimates, including:

- *Fair Value of Common Stock*—For grants made prior to the Direct Listing on January 31, 2024, the estimated fair value of common stock underlying the Company's stock-based awards has been determined by the board of directors as of each option grant date with input from management, considering the Company's most recently available third-party valuations of common stock and the board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation (the Practice Aid). For grants made after the Direct Listing, the fair value of common stock underlying stock-based awards is based on the closing price as reported on The Nasdaq Global Market on the date of grant.
- *Expected Term*—The expected term represents the period that a stock-based award is expected to be outstanding. The Company uses the simplified method to determine the expected term, which is based on the average of the time-to-vesting and the contractual life of the option.
- *Expected Volatility*—Due to the Company's limited operating history and lack of company-specific historical and implied volatility data, the expected volatility is estimated based on the average historical volatilities of common stock of comparable publicly traded entities over a period of time commensurate with the expected term of the stock option grants. The comparable companies are chosen based on their size, stage in the product development cycle, or area of specialty. The Company will continue to apply this process until sufficient historical information regarding the volatility of its own stock price becomes available.
- *Risk-Free Interest Rate*—The risk-free interest rate is based on the U.S. Treasury yield in effect at the time of grant for zero-coupon U.S. Treasury notes with maturities approximately equal to the expected term of the awards.
- *Expected Dividend*—The Company has never paid dividends on its common stock and has no plans to pay dividends on its common stock. Therefore, the Company used an expected dividend yield of zero.

Emerging Growth Company

With the completion of the Direct Listing, the Company is an emerging growth company ("EGC"), as defined in the Jumpstart Our Business Startups Act of 2012 ("JOBS Act"). Under the JOBS Act, an EGC can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies; however, the Company may adopt new or revised accounting standards early if the standard allows for early adoption.

In addition, the Company will utilize other exemptions and reduced reporting requirements provided to EGCs by the JOBS Act. Subject to certain conditions set forth in the JOBS Act, an EGC is not required to, among other things, (i) provide an auditor's attestation report on the Company's system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, (ii) provide all of the compensation disclosure that may be required of non-EGC public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act, (iii) comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis), or (iv) disclose certain executive compensation-related items, such as the correlation between executive compensation and performance and comparisons of the chief executive officer's compensation to median employee compensation.

Recently Issued Accounting Pronouncements

In November 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures* ("ASU 2023-07"), which is 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. The guidance is effective for fiscal years beginning after December 15, 2023, and interim periods within fiscal years beginning after December 15, 2024. Early adoption is permitted. ASU 2023-07 is to be applied retrospectively to all prior periods presented in the Unaudited Condensed Financial Statements. The Company is currently evaluating the potential impact that the adoption of this new guidance may have on the Company's Unaudited Condensed Financial Statements.

In December 2023, the FASB issued ASU No. 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures* ("ASU 2023-09"). The guidance in ASU 2023-09 improves the transparency of income tax disclosures by greater disaggregation of information in the rate reconciliation and income taxes paid disaggregated by jurisdiction. The standard is effective for public companies for fiscal years beginning after December 15, 2024, with early adoption permitted. The Company is currently evaluating the impact that the adoption of ASU 2023-09 may have on its Unaudited Condensed Financial Statements.

3. Net Income/(Loss) Per Share Attributable to Common Stockholders

The following table summarizes the computation of basic and diluted net loss per share attributable to common stockholders of the Company:

(in thousands, except share and per share amounts)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Numerator:				
Net loss	\$ (500)	\$ (2,193)	\$ (8,062)	\$ (6,768)
Adjustment to numerator for earnings per share:				
Deemed dividend	—	—	—	(2,573)
Net loss attributable to common stockholders	\$ (500)	\$ (2,193)	\$ (8,062)	\$ (9,341)
Denominator:				
Weighted-average number of common shares outstanding, basic and diluted	33,516,656	28,230,842	32,457,473	28,230,842
Net loss per common share attributable to common stockholders, basic and diluted	\$ (0.01)	\$ (0.08)	\$ (0.25)	\$ (0.33)

As further described in Note 6, the Company issued 28,230,842 shares of non-voting common stock on August 18, 2022. Because the issuance of nonvoting common stock shares was treated as a stock split for accounting purposes, these shares are treated as having been issued on January 1, 2022. The weighted average number of shares outstanding for the three and nine months ended September 30, 2023, is based upon the non-voting common stock shares issued on August 18, 2022. The weighted average number of shares outstanding for the three and nine months ended September 30, 2024 is based upon the non-voting common stock shares issued on August 18, 2022, the conversion of all outstanding shares of non-voting common stock, Series B Preferred Stock and Series B-1 Preferred Stock into voting common stock upon completion of the Direct Listing on January 31, 2024, the issuance of 227,057 shares of common stock issued to GEM Global Yield LLC SCS, or GEM, in February through March 2024, and the issuance of 1,198,836 shares of common stock to GEM in July through September 2024.

As further described in Note 7, the Company issued 741,164 shares of common stock to GEM in September 2024 to facilitate a Draw Down Notice. For accounting purposes, these shares are not considered issued as of September 30, 2024, because no proceeds were received for these shares at issuance and the shares will either be purchased by GEM through a subsequent Closing Notice and payment or returned to the Company, so these shares are contingently returnable.

As further described in Note 10, the Company agreed to pay to FibroGenesis 15% of the gross proceeds from any equity investments in FibroBiologics prior to an IPO, Direct Listing or Sale of the Company to eliminate upon the occurrence of such event the Series A Preferred Stock and its \$35 million liquidation preference. This redemption of preferred stock created a derivative liability that exceeded the net Parent Investment of \$1,461 thousand by \$1,112 thousand, and is reflected as a reduction of the amount available to common stockholders in the calculation of earnings per share.

The Company had \$5,600 thousand of convertible notes outstanding as of December 31, 2022, which could have been converted into common stock in the event that the Company sold and issued shares of capital stock in excess of \$10,000 thousand. During the three and nine months ended September 30, 2023, \$0 and \$5,600 thousand, respectively, of the outstanding convertible notes were converted into shares of Series B Preferred Stock. For the three and nine months ended September 30, 2023, the Company reported net losses and, accordingly, potential common shares were not included since such inclusion would have been anti-dilutive. No convertible notes were outstanding during the three and nine months ended September 30, 2024. The Company's basic and diluted net losses per share are the same because it generated a net loss in all periods presented.

4. Property and Equipment

Property and equipment, net consist of the following:

(in thousands)	September 30, 2024	December 31, 2023
Laboratory equipment	\$ 882	\$ 816
Computer equipment, software, and other	47	28
Total property and equipment at cost	929	844
Less: Accumulated depreciation	(157)	(47)
Property and equipment, net	<u>\$ 772</u>	<u>\$ 797</u>

The useful life of laboratory equipment is five years, and the useful life of computer equipment, software, and other is three years for depreciation. Depreciation expense was \$38 thousand and \$13 thousand for the three months ended September 30, 2024 and 2023, respectively, and was \$110 thousand and \$16 thousand for the nine months ended September 30, 2024 and 2023, respectively.

5. Fair Value of Financial Instruments

As of December 31, 2022, the Company measured its derivative liability related to the conversion option feature in the 2022 Notes at fair value. As of September 30, 2023, \$5,600 thousand of the 2022 Notes had been converted, which eliminated \$538 thousand of the derivative liability.

As of December 31, 2023, the Company measured its liability instrument to investors under the Share Purchase Agreement, as further described in Note 7, at \$7,236 thousand. This liability instrument was comprised of a warrant liability and a forward contract liability, both of which were contingent upon an IPO event, and is classified within Level 3 of the value hierarchy because the liability was based upon a valuation model that used inputs and assumptions including potential outcomes, interest rates, probabilities, and timing. The Company completed its Direct Listing on January 31, 2024, which qualified as an IPO event, and bifurcated the liability instrument into its separate Warrant liability and Forward contract liability components. The fair value of the Warrant liability to be issued upon completion of the Direct Listing on January 31, 2024 was \$20,963 thousand, and this fair value decreased to \$2,887 thousand at September 30, 2024. The fair value of the Forward contract liability was de minimis at January 31, 2024 and September 30, 2024.

The following tables summarize the Company's financial assets and liabilities measured at fair value on a recurring basis based on the three-tier fair value hierarchy:

(in thousands)	Fair Value Measurement as of September 30, 2024			
	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	\$ 6,488	\$ —	\$ —	\$ 6,488
Total assets fair value	<u>\$ 6,488</u>	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 6,488</u>
Liabilities:				
Forward contract liability	\$ —	\$ —	\$ 241	\$ 241
Warrant liability	—	—	2,887	2,887
Total liabilities fair value	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 3,128</u>	<u>\$ 3,128</u>
(in thousands)	Fair Value Measurement as of December 31, 2023			
	Level 1	Level 2	Level 3	Total
Liabilities:				
Liability instrument	\$ —	\$ —	\$ 7,236	\$ 7,236
Total fair value	<u>\$ —</u>	<u>\$ —</u>	<u>\$ 7,236</u>	<u>\$ 7,236</u>

The following table summarizes the activity related to Level 3 financial liabilities for the nine months ended September 30, 2024:

(in thousands)	Liability Instrument	Forward Contract Liability	Warrant Liability
Fair value at December 31, 2023	\$ 7,236	\$ —	\$ —
Bifurcation of the liability instrument upon Direct Listing	(7,236)		7,236
Increase in Warrant liability at issuance January 31, 2024	—	—	13,727
Forward contract liability as of June 30, 2024	—	1,500	—
Change in fair value of Forward contract liability	—	(1,259)	—
Change in fair value of Warrant liability	—	—	(18,076)
Fair value at September 30, 2024	<u>\$ —</u>	<u>\$ 241</u>	<u>\$ 2,887</u>

As of December 31, 2023, the liability instrument included the contingent warrant liability and the contingent put option (forward contract) liability as a single unit of account. The liability instrument value was determined using a Black-Scholes valuation model and management's assumption of a 50% likelihood as of December 31, 2023, of becoming a public company prior to the expiration of the Stock Purchase Agreement. Inputs used in the Black-Scholes valuation model included an estimated number of warrants, an assumed common stock share price of \$15.00 per share, the five-year time to maturity, a 0% dividend yield, an annual risk-free interest rate of 3.84% for the five-year time to maturity, and an assumed annualized volatility of 96% based on comparable companies with a five-year history of stock prices.

Upon completion of the Direct Listing on January 31, 2024, the warrant liability and the forward contract liability were no longer contingent and were bifurcated out of the liability instrument and treated as separate units of account. As of January 31, 2024, the warrant liability value for the warrant issued to GEM Yield Bahamas Limited ("GYBL") was determined using a Black-Scholes valuation model. Inputs used in the Black-Scholes valuation model included the 1,299,783 warrants issued to GYBL, the closing bid price of \$21.54 per share on January 31, 2024, the five-year time to maturity, a 0% dividend yield, an annual risk-free interest rate of 3.91% for the five-year time to maturity, and an assumed annualized volatility of 97% based on comparable companies with a five-year history of stock prices. As of September 30, 2024, the warrant liability value for the warrant issued to GYBL was determined using a Black-Scholes valuation model. Inputs used in the Black-Scholes valuation model included the 1,299,783 warrants issued to GYBL, the closing bid price of \$3.09 per share on September 30, 2024, the four-year time to maturity, a 0% dividend yield, an annual risk-free interest rate of 3.58% for the five-year time to maturity, and an assumed annualized volatility of 100% based on comparable companies with a five-year history of stock prices.

As further described in Note 7, the Company issued a Draw Down Notice on September 12, 2024, for 1,000,000 shares. On September 26, 2024, an initial Closing Notice was provided by GEM to purchase 258,836 shares and the remainder of the Draw Down Notice remained open. The fair value of the remaining forward contract liability was remeasured at September 30, 2024, based upon the remaining 741,164 shares, a price per share of \$3.25, based on the floor price of \$3.25 per share because the closing price was lower than the floor price on September 30, 2024, and the 10% discount to be provided to the investor purchasing the shares from the Company.

The carrying amounts of cash and cash equivalents, prepaid expenses, other current assets, accounts payable, accrued expenses, and Parent company payable and receivable approximate their fair values due to their short-term maturities.

There were no transfers in or out of Level 1, Level 2 or Level 3 assets and liabilities for the nine months ended September 30, 2024 and for the year ended December 31, 2023.

6. Stockholders' Equity/(Deficit) / Net Parent Investment

Authorized Capital – As of September 30, 2024 and December 31, 2023, the Company authorized 10,000,000 and 20,000,000, respectively, preferred stock shares. As of December 31, 2023, the Company had issued 8,750,000 Series A Preferred Stock shares to FibroGenesis, which were tendered pursuant to the formation of the Company in exchange for the contribution of certain in-process research and development and patent assets through Patent Assignment and Intellectual Property Cross-License Agreements. The Series A Preferred Stock shares had the right to vote and ranked prior to non-voting common stock and common stock with respect to payment of dividends and distributions and upon liquidation, dissolution, winding-up or otherwise. In addition, the Series “A” Preferred Stock had a liquidation preference equal to \$35,000 thousand to be allocated among the holders of the Series “A” Preferred Stock shares in the event of a liquidation, dissolution, or winding-up of the Company, which was subsequently eliminated as part of the ROFN Agreement as further described below, and each share of Series “A” Preferred Stock could be converted into one share of common stock at any time at the election of the holder of such shares of Series “A” Preferred Stock. Unless otherwise elected by the holder(s), a merger or consolidation in which the Company is not the majority surviving entity or the sale of all or substantially all of the assets of the corporation would be a deemed liquidation event. The Company has also authorized 62,500,000 shares of non-voting common stock, and has issued during the year ended December 31, 2022, a total of 28,230,842 shares. In August 2022, the Company issued 28,179,592 shares of non-voting common stock to its Parent, which in turn distributed the shares to its members. This issuance of non-voting common stock was accounted for as stock split and no proceeds were received by the Company. The Company also issued to its board of directors, a consultant, and an employee an additional 51,250 total shares in 2022 and recorded \$168 thousand of expense for the issuance of these shares, which was based upon a third-party valuation of the shares at the time of issuance.

In December 2022, the Company amended its Certificate of Incorporation to authorize 2,500,000 shares of Series “B” Preferred Stock. The Series “B” Preferred Stock had a liquidation preference after Series “A” Preferred Stock and prior to Common Stock and Non-Voting Common Stock. The Series “B” Preferred Stock had voting rights and would automatically convert into Common Stock upon closing of an IPO transaction, as defined in the Company’s Amended and Restated Certificate of Incorporation.

In January 2023, to reflect the ROFN Agreement with its Parent, as further discussed in Note 10, the Company amended its Certificate of Incorporation to a) make the Series “B” Preferred Stock liquidation preference equal to Series “A” Preferred Stock, and b) to provide that upon IPO, Direct Listing, or Sale of the Company, the Series “A” Preferred Stock would be canceled for no consideration.

In March 2023, the Company accepted a stock subscription to purchase shares of Series B Preferred Stock for \$10,000 thousand and recorded a stock subscription payable for the full amount of the \$10,000 thousand of proceeds received in March 2023. The stock subscription payable as of March 31, 2023, was subsequently eliminated in April 2023 when the Company issued the shares of Series B Preferred Stock to the shareholder.

In April 2023, the Company amended its Certificate of Incorporation to authorize 10,000,000 shares of Common Stock, increase the number of authorized Series “B” Preferred Stock shares up to 5,000,000 shares, and to authorize 5,000,000 shares of Series “B-1” Preferred Stock with liquidation preference equal to the Series “A” and “B” Preferred Stock. The Series “B-1” Preferred Stock had voting rights and would automatically convert into Common Stock upon closing of an IPO transaction, as defined in the Company’s Amended and Restated Certificate of Incorporation.

In October 2023, the Company amended and restated its certificate of incorporation with the State of Delaware to increase to 100,000,000 shares its authorized shares of voting common stock, par value \$0.00001 per share, reduce to 30,000,000 shares its authorized shares of non-voting common stock, par value \$0.00001 per share, and authorize 2,500 shares of Series C Preferred Stock, par value \$0.00001 per share. The Series C Preferred Stock ranked senior to common stock and non-voting common stock and junior to the Series A Preferred Stock, Series B Preferred Stock and Series B-1 Preferred Stock upon liquidation, dissolution, winding-up or otherwise. The Series C Preferred Stock had no voting rights prior to an IPO, and 13,000 votes per share upon closing of an IPO. The Series C Preferred Stock is not entitled to dividends, has a liquidation preference of \$18.00 per share, subject to adjustment, may be converted 1:1 at any time at the option of the holder into common stock, and upon closing of an IPO, would, if transferred, automatically convert 1:1 into common stock.

In January 2024, the Company issued 2,500 shares of Series C Preferred Stock to its CEO, who in turn granted a proxy to the Board of Directors to vote these shares as outlined in the amended and restated certification of incorporation.

On January 31, 2024, the Company completed its Direct Listing, which qualified as an IPO transaction. As a result of the IPO, the outstanding Series A Preferred Stock shares were canceled for no consideration and the outstanding Series B Preferred Stock, Series B-1 Preferred Stock, and non-voting common stock shares were all converted 1:1 into shares of voting common stock. In addition, the Series C Preferred Stock voting rights increased from none to 13,000 votes per share and, if transferred, these shares will automatically convert 1:1 into common stock.

In August 2024, the Company amended and restated its certificate of incorporation with the State of Delaware to eliminate its non-voting common stock, Series A Preferred Stock, Series B Preferred Stock, and Series B-1 Preferred Stock, and to reduce to 10,000,000 shares its authorized preferred stock, par value \$0.00001 per share, of which 2,500 shares are designated as Series C Preferred Stock.

7. Share Subscription Agreement

On November 12, 2021, the Company entered into a Share Purchase Agreement with certain investors for the sale of up to \$100,000 thousand of common stock (the "Aggregate Limit"). This agreement was contingent upon the Company achieving a public listing of its common stock. Major terms of the agreement include a commitment fee of 2% of the Aggregate Limit, which is due no later than one year after public listing even if no drawdowns are taken, and five-year warrants issued to the investors at the time of public listing to purchase common stock equal to 4% of the total equity interests of the Company at the lesser of a) the price per share at the time of the public listing or b) the quotient of \$700,000 thousand divided by the total number of equity interests (fully diluted common shares). The Company may request a drawdown, or sale of common stock shares to the investors, over the five-year term of this agreement following the public listing unless terminated earlier. The amount of the drawdowns requested is limited by the trading volumes of the Company's common stock over the 30-day period preceding the drawdown, and the price per share is equal to 90% of the average price per share over that same period. A 1% fee was due to the investors if the Company were sold in a private sale transaction rather than completing a public listing of its shares.

After completion of its public listing on January 31, 2024, and during the three months ended March 31, 2024, the Company sold a total of 227,057 shares of common stock for \$2,819 thousand of net proceeds through the Share Purchase Agreement.

Upon completion of its public listing the Company recorded a payable of \$2,000 thousand for the commitment fee obligation due under the Share Purchase Agreement within one year, and expensed the \$1,941 thousand remaining amount of the commitment fee at March 31, 2024.

On June 27, 2024, the Company issued 3,000,000 shares of Common Stock to facilitate a Draw Down Notice under the Share Purchase Agreement. The Company recorded upon issuance a \$1,410 thousand fair value of the forward contract liability for its requirement to sell up to 3,000,000 shares to the investor at 90% of the average closing price per share during the Draw Down Period based upon the number of shares, the closing price per share of \$4.66 on June 27, 2024, and the 10% discount to be provided to the investor purchasing the shares from the Company. The fair value of the forward contract liability was remeasured to \$638 thousand at July 11, 2024, upon receipt of the Closing Notice from GEM, based upon the 840,000 shares accepted, the \$4.85 closing price per share, and a net purchase price per share of \$4.09 after the 10% discount provided to the investor, and the forward contract liability was eliminated. GEM returned 560,000 shares to the Company, which canceled those shares, and the remaining 1,600,000 shares were retained by GEM to facilitate a subsequent Draw Down Notice.

On July 12, 2024, the Company issued a Draw Down Notice for 1,600,000 shares. The Company recorded upon issuance a \$758 thousand fair value of the forward contract liability for its requirement to sell up to 1,600,000 shares to the investor at 90% of the average closing price per share during the Draw Down Period based upon the number of shares, the closing price per share of \$4.74 on July 12, 2024, and the 10% discount to be provided to the investor purchasing the shares from the Company. The fair value of the forward contract liability was remeasured to a \$286 thousand asset at August 26, 2024, upon receipt of the Closing Notice from GEM, based upon the 100,000 shares accepted, the \$1.65 closing price per share, and a net price per share of \$4.51 after the 10% discount provided to the investor, and the forward contract liability was eliminated. GEM returned 500,000 shares to the Company, which canceled those shares, and the remaining 1,000,000 shares were retained by GEM to facilitate a subsequent Draw Down Notice.

On September 12, 2024, the Company issued a Draw Down Notice for 1,000,000 shares. The Company recorded upon issuance a \$325 thousand fair value of the forward contract liability for its requirement to sell up to 1,000,000 shares to the investor at 90% of the average closing price per share during the Draw Down Period based upon the number of shares, a price per share of \$3.25, based on the floor price of \$3.25 per share because the closing price was lower than the floor price on September 12, 2024, and the 10% discount to be provided to the investor purchasing the shares from the Company. Upon receipt of an initial Closing Notice from GEM on September 26, 2024, the fair value of the portion of the forward contract liability covered by the Closing Notice was remeasured to \$57 thousand at, based upon the 258,836 shares accepted, the \$3.14 price per share, and a net price per share of \$2.93 after the 10% discount provided to the investor, and that portion of the forward contract liability was eliminated. The September 12, 2024, Draw Down Notice remained open for 741,164 shares, which will either be sold to GEM pursuant to a future Closing Notice or returned to the Company. The fair value of the of the remaining portion of the forward contract liability was remeasured at September 30, 2024, based on the remaining 741,164 shares, a price per share of \$3.25, based on the floor price of \$3.25 per share because the closing price was lower than the floor price on September 30, 2024, and the 10% discount to be provided to the investor purchasing the shares from the Company.

8. Income Taxes

The Company did not record any tax provision or benefit for the three and nine months ended September 30, 2024 or 2023. Management has evaluated the positive and negative evidence bearing upon the realizability of the Company's net deferred tax assets and has determined that it is more likely than not that the Company will not recognize the benefits of the net deferred tax assets. As a result, the Company has recorded a full valuation allowance at September 30, 2024, and December 31, 2023.

9. Leases, Commitments and Contingencies

In October 2022, the Company entered into a lease agreement for office space with a term of 62 months, which expires on November 30, 2027. This lease is accounted for as an operating lease under the ASC 842 guidance for lease accounting. A right-of-use lease asset and lease liability of \$2,293 thousand each were recorded at inception of the lease term using a discount rate of 7.5%.

In June 2023, the Company entered into a new lease for temporary lab and office space for its research operations. This lease has a term of 12 months and monthly rent of \$6 thousand and is accounted for as a short-term lease. This lease commenced in August 2023. In September 2023, the Company entered into an amendment of this lease for additional space, and the monthly rent increased to \$7 thousand. In March 2024, the Company entered into a second amendment of this lease for additional space, and effective April 1, 2024, the monthly rent increased to \$8 thousand. In July 2024, the Company signed an amendment of this lease, effective August 1, 2024, to extend the term for an additional 12 months, and the monthly rent decreased to \$7 thousand.

Rent expense for the nine months ended September 30, 2024 and 2023, was \$466 thousand and \$504 thousand, respectively. As of September 30, 2024, noncancelable lease payments under operating leases were \$1,629 thousand and noncancelable lease payments under short-term leases were \$74 thousand.

As of September 30, 2024, future minimum payments during the remaining period and the next five years are as follows (in thousands):

2024	\$	88
2025		488
2026		544
2027		509
2028		—
Thereafter		—
Total lease payments		1,629
Less: Imputed interest		(182)
Total lease liabilities		1,447
Less: Current lease liabilities		(392)
Total non-current lease liabilities	\$	1,055

10. Related Party Transactions

As described in Note 6, the Company acquired from FibroGenesis certain in-process research and development and patent assets through Patent Assignment and Intellectual Property Cross-License Agreements. The Patent Assignment Agreement transferred the right, title and interest in and to certain patents from FibroGenesis to the Company for further development. The Intellectual Property Cross-License Agreement grants to the Company exclusive rights to patents owned by FibroGenesis in a limited field of use, which includes the diagnosis, treatment, prevention and palliation of a) spinal diseases, disorders, or conditions, b) cancer, c) orthopedics diseases, disorders or conditions, and d) multiple sclerosis.

In January 2023, the Company entered into an Agreement Regarding Right of First Negotiation (“ROFN Agreement”) with its Parent, FibroGenesis. In exchange for FibroGenesis’ consent to amend the Certificate of Incorporation to a) eliminate upon IPO, Direct Listing, or Sale of the Company the Series A Preferred Stock \$35,000 thousand liquidation preference, b) make the Series B Preferred Stock liquidation preference equal to Series “A” Preferred Stock, and c) to provide that upon IPO, Direct Listing, or Sale of the Company Series A Preferred Stock will be cancelled for no consideration, FibroBiologics agreed to pay to FibroGenesis 15% of the gross proceeds from any equity investments in FibroBiologics prior to an IPO, Direct Listing or Sale of the Company. In addition, FibroBiologics received a five-year right of first negotiation if FibroGenesis decides to license externally any of its technology. During the nine months ended September 30, 2023, the Company amended its Certificate of Incorporation to reflect these changes, recorded a derivative liability of \$2,573 thousand for the expected future payments to FibroGenesis, and paid \$2,645 thousand to FibroGenesis for 15% of the gross proceeds from equity issued by the Company through the nine months ended September 30, 2023, and recorded a loss on derivative liability of \$15 thousand. Based on its relationship to Series A Preferred Stock as described above, the derivative liability was recorded first against the net Parent Investment and then to Additional paid-in capital after the net Parent Investment was eliminated. Amounts paid in excess of the derivative liability are recorded as other losses in the Unaudited Condensed Statements of Operations. During the nine months ended September 30, 2024, the Company completed its Direct Listing, which resulted in the cancellation of all outstanding shares of Series A Preferred Stock for no consideration, and paid \$141 thousand to FibroGenesis. There was no derivative liability as of September 30, 2024 and December 31, 2023. There was a payable to FibroGenesis of \$0 and \$141 thousand, respectively, as of September 30, 2024 and December 31, 2023.

11. Share-Based Compensation

The Company adopted on August 10, 2022, and the stockholders approved on August 18, 2022, the 2022 Stock Plan (the “Plan”). The Plan provides for the grant of incentive stock options, nonstatutory stock options, stock appreciation rights, restricted stock awards, restricted stock unit awards, and other stock awards. The Plan, through the grant of stock awards, is intended to help the Company secure and retain the services of eligible award recipients, provide incentives for such persons to exert maximum efforts for the success of the Company and provide a means by which the eligible recipients may benefit from increases in value of the common stock. In September 2022, the Company issued a total of 101,250 options with a strike price of \$3.28 per share to employees, directors, and scientific advisory board members under this Plan. In February 2023, the Company issued a total of 3,689,750 options with a strike price of \$2.28 per share to employees and directors under this Plan. In August 2023, a total of 2,500 options with a strike price of \$3.28 per share were forfeited. In March 2024, the Company issued 216,875 options with a strike price of \$13.00 per share to employees under this Plan. In June 2024, the Company issued 6,875 options with a strike price of \$6.73 per share to employees under this Plan. In August 2024, the Company issued 25,000 options with a strike price of \$1.73 per share to directors under this Plan. Generally, awards granted by the Company vest over four years and have an exercise price equal to the estimated fair value of the common stock as determined by the board of directors with consideration given to contemporaneous valuations of the Company’s common stock prepared by an independent third-party valuation firm for options granted prior to public listing or the closing bid price on the date of grant for options granted after public listing.

As of September 30, 2024, and December 31, 2023, there were 8,467,889 and 8,711,500 shares, respectively, available for future issuance under the Plan.

Stock-based compensation expense is recognized in the Unaudited Condensed Statements of Operations as follows:

(in thousands of dollars)	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	2023	2024	2023
Research and development	\$ 82	\$ 66	\$ 248	\$ 196
General, administrative and other	490	374	1,383	1,137
Total stock-based compensation expense	<u>\$ 572</u>	<u>\$ 440</u>	<u>\$ 1,631</u>	<u>\$ 1,333</u>

In addition to the \$1,631 thousand stock-based compensation expense for stock options, a \$45 thousand stock-based compensation expense was recognized for the grant of 2,500 shares of Series C Preferred Stock to the CEO during the nine months ended September 30, 2024.

Unrecognized stock-based compensation costs related to unvested awards and the weighted-average period over which the costs are expected to be recognized as of September 30, 2024, are as follows:

	Stock Options
Unrecognized stock-based compensation expense (in thousands)	\$ 5,766
Expected weighted-average period compensation costs to be recognized (years)	2.6

A summary of the Company’s stock option activity is as follows:

	Stock Options	Weighted-Average Exercise Price per Share	Weighted-Average Remaining Contractual Life (years)	Aggregate Intrinsic Value (in thousands)
Outstanding as of December 31, 2023	3,788,500	\$ 2.31	8.4	\$ 2,989
Granted	248,750	\$ 11.69	9.5	\$ 34
Exercised	—	\$ —	—	\$ —
Forfeited/Cancelled	(5,139)	\$ 12.74	9.4	\$ —
Outstanding as of September 30, 2024	<u>4,032,111</u>	<u>\$ 2.88</u>	<u>8.4</u>	<u>\$ 3,023</u>
Exercisable as of September 30, 2024	<u>1,696,210</u>	<u>\$ 2.33</u>	<u>8.4</u>	<u>\$ 1,307</u>

The fair value of stock options granted to employees, directors, and consultants was estimated on the date of grant using the Black-Scholes option pricing model using the following assumptions:

Assumptions:	Nine Months Ended September 30, 2024	Nine Months Ended September 30, 2023
Risk-free interest rate	3.7 to 4.3%	3.9%
Expected volatility	97 to 101%	90%
Expected term (years)	5.5 to 7.0	7.0
Expected dividend	0%	0%

During the nine months ended September 30, 2024, the weighted-average grant date fair value of the options granted was \$9.70 per share.

12. Subsequent Events

The Company has evaluated subsequent events through November 12, 2024, the date these unaudited condensed financial statements were issued, and determined that there have been no events that have occurred that would require adjustments to the disclosures in these unaudited condensed Financial Statements, other than the following.

On October 18, 2024, the Company received a Closing Notice from GEM to purchase 15,683 shares at a price of \$2.91 per share for proceeds of \$46 thousand.

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

The following discussion and analysis should be read in conjunction with the unaudited financial statements and notes thereto included in Part 1, Item 1 of this Quarterly Report and with the audited Consolidated Financial Statements and related notes thereto included as part of our Annual Report on Form 10-K for the year ended December 31, 2023.

Overview

We are a clinical-stage biotechnology company focused on developing and commercializing fibroblast-based therapies for patients suffering from chronic diseases with significant unmet medical needs, including wound healing, multiple sclerosis (MS), degenerative disc disease, psoriasis and certain cancers, and potential human longevity applications including thymic involution reversal. At present, our novel manufacturing process entails collecting excess tissue from surgical procedures and using the allogeneic fibroblasts to grow a cell bank for use in our procedures. Our most advanced product candidates are CYWC628, CYMS101 and CybroCell™.

We are in the late pre-clinical stages of developing CYWC628 as an allogeneic fibroblast cell-based therapy for wound healing. Our studies are presently focused on utilizing fibroblasts and fibroblast-derived cells to treat wounds in diabetic mice. The results of our studies to date have shown statistically significant acceleration in the rate of wound closure in comparison with both a marketed wound care product and control, and improved quality of healed wounds. Based upon our results achieved to date and the expected timing of our remaining preclinical studies, we are planning to initiate a twelve-week Phase 1/2 clinical trial in Australia for treatment of diabetic foot ulcers in the second quarter of 2025 as funding allows.

We are developing CYMS101 as an allogeneic fibroblast cell-based therapy to treat MS. After completing animal studies using CYMS101, we received approval to conduct clinical investigations in Mexico using the fibroblast cell composition for patients with MS and have completed a Phase 1 study. The study was conducted in five participants. The primary objective of the study was to assess safety, and the secondary objective was to assess efficacy. The primary objective was achieved as we saw no adverse events related to the treatment. We are currently conducting further research to determine the mode of action of fibroblasts in oligodendrocyte expansion and expect to file an IND application for a Phase 1/2 clinical trial in MS as funding allows. We will likely seek a strategic partner to collaborate with us on the development of CYMS101 either before initiating the Phase 1/2 clinical trial, or after its completion, if successful, and prior to commencing with a Phase 3 clinical trial.

CybroCell™ is an allogeneic fibroblast cell-based therapy for degenerative disc disease and is being designed as an alternative method for repairing the cartilage of the intervertebral disc (or any other articular cartilage). We have completed two animal studies. The results from the studies were positive and resulted in “first in human” trial approval. We have received IND clearance from the FDA, conditional upon approval of our master cell bank, to run a Phase 1 study for patients suffering from degenerative disc disease and will be conducting this study within the United States. A timeline will be determined through discussions with the FDA and as funding allows.

CYPS317 is our allogeneic intravenously administered fibroblast cell-based therapeutic for the treatment of psoriasis. We are moving this early phase project to our product candidate pipeline. Our early pre-clinical animal model studies have demonstrated significant efficacy in the treatment of mild and severe psoriasis. Our studies have also demonstrated improved efficacy as compared to anti IL-23 monoclonal antibody, with no adverse effects noted with the respiratory, circulatory, hepatic and renal organ systems. We are currently in the process of continuing our IND-enabling animal model studies, with a projected completion timeline of the fourth quarter of 2025.

We also have human longevity, cancer, and artificial pancreatic organoid programs in the early stages of development, and we plan to accelerate such programs as funding allows.

We currently utilize a CDMO to manufacture our cell therapy product candidates. If our product candidates receive marketing approval, we will evaluate the longer-term feasibility of building our own cGMP manufacturing facility or continuing to outsource production to a CDMO for clinical testing and commercial sales.

Since our spinoff from FibroGenesis in April 2021, our operations have included business planning, hiring personnel, raising capital, building our intellectual property portfolio, and performing research and development on our product candidates and our fibroblast technology, leveraging the clinical benefits of fibroblasts as the basis of our cell therapy platform.

We have incurred net losses since Inception and expect to incur losses in the future as we continue our research and development activities. To date, we have funded our operations primarily through investment from FibroGenesis, the issuance of \$5.6 million of our convertible promissory notes from December 2021 through April 2022, the issuance of \$18.6 million of preferred stock, and the issuance of \$8.0 million of common stock.

As of September 30, 2024, we had cash and cash equivalents of approximately \$7.8 million. Since our Inception, we have incurred significant operating losses. We incurred net losses of approximately \$8.1 million and \$6.8 million for the nine months ended September 30, 2024 and 2023, respectively. As of September 30, 2024, we had an accumulated deficit of approximately \$32.4 million. We expect to continue to incur significant expenses and operating losses for the next several years. See “—Funding Requirements” below.

We expect to continue to incur significant losses for the foreseeable future, and we expect these losses to increase substantially if and as we:

- advance the development of our lead product candidates through clinical development, and, if approved by the FDA, commercialization;
- advance our preclinical development programs into clinical development;
- incur manufacturing costs for cell production to supply our product candidates;
- seek regulatory approvals for any of our product candidates that successfully complete clinical trials;
- increase our research and development activities to identify and develop new product candidates;
- hire additional personnel;
- expand our operational, financial and management systems;
- meet the requirements and demands of being a public company;
- invest in further development to protect and expand our intellectual property;
- establish a sales, marketing, medical affairs, and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval and intend to commercialize; and
- expand our manufacturing and develop our commercialization efforts.

Due to the numerous risks and uncertainties associated with biopharmaceutical product development and the economic and developmental uncertainty, we may be unable to accurately predict the timing or magnitude of all expenses. Our ability to ultimately generate revenue to achieve profitability will depend heavily on the development, approval, and subsequent commercialization of our product candidates. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

As a result, we will need substantial additional funding to support our long-term continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources, which may include collaborations with other companies or other strategic transactions. We may not be able to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we will have to significantly delay, reduce or eliminate the development and commercialization of one or more of our product candidates or delay our pursuit of potential in-licenses or acquisitions.

General Trends and Outlook

Recent Developments

CYWC628

We completed pre-clinical studies investigating (i) multiple administrations of CYWC628 on a chemically induced chronic wound NONcNZO10/LtJ mouse model, (ii) dose titration to provide information on the effective dose range of CYWC628, and (iii) acute and chronic toxicity. We expect to complete our remaining pre-clinical studies by the end of 2024.

As part of the preparation for a Phase I/II clinical trial of CYWC628 for the potential treatment of diabetic foot ulcers (DFUs), we entered into a master service agreement with a CDMO that will govern the production of our master cell bank, working cell bank, and our CYWC628 drug product candidate. We also entered into a master service agreement with a CRO that will carry out the Phase I/II clinical trial of CYWC628 for the potential treatment of diabetic foot ulcers in Australia in 2025.

Psoriasis

We have completed an early phase project utilizing a psoriasis mouse model to assess the potential use of intravenous administration of fibroblast spheroids for the treatment of psoriasis. Results to date include that a single administration of fibroblast spheroids resulted in significant improvement in mice with moderate psoriasis, and that multiple administrations of fibroblast spheroids resulted in significant improvement in mice with severe psoriasis. We also compared fibroblast spheroid with single and multiple administration of an anti-IL-23 monoclonal antibody in treatment of mice with mild to moderate psoriasis. We noted that a single treatment of fibroblast spheroids was significantly better than single and multiple administration of an anti-IL-23 monoclonal antibody. We are in the process of carrying out a dosage titration animal model study to determine optimal efficacious dose range, in addition to determining the durability of treatment for mild to moderate, and moderate to severe psoriasis. Three anti-IL-23 monoclonal antibody treatments are approved by the FDA for the treatment of psoriasis, including Tremfya®, Illumya®, and Skyrizi®. As a result of these studies, we have moved this project to our product candidate pipeline with the name of CYP317.

Intellectual Property

We have filed two new patent applications with the United States Patent Office. The first patent application covers the use of fibroblast cell-based technology in an adhesive bandage for wound healing. The second patent application covers the use of fibroblast cell-based technology in generating three-dimensional hemopoietic organoids that can give rise to functional immune cells.

Components of Results of Operations

Revenue

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products in the foreseeable future. If our development efforts for any of our product candidates are successful and result in regulatory approval, we may generate revenue in the future from product sales. We cannot predict if, when or to what extent we will generate revenue from the commercialization and sale of any of our product candidates. We may never succeed in obtaining regulatory approval for any of our product candidates.

Research and Development Expenses

Our research and development expenses consist of expenses incurred in connection with the development of our product candidates and include:

- employee-related expenses, which include salaries, benefits, travel and stock-based compensation for our research and development personnel;
- laboratory equipment and supplies;
- direct third-party costs such as expenses incurred under agreements with CROs and CDMOs;
- consultants that conduct research and development activities on our behalf;
- costs associated with conducting preclinical studies and clinical trials;
- costs associated with technology; and
- facilities and other allocated expenses, which include expenses for rent and other facility related costs and other supplies.

We expense research and development costs as incurred. Nonrefundable advance payments that we make for goods or services to be received in the future for use in research and development activities are recorded as prepaid expenses. The prepaid amounts are expensed as the related goods are delivered or the services are performed.

We expect our research and development expenses to increase substantially for the foreseeable future as we continue to invest in research and development activities related to developing our product candidates as they advance into later stages of clinical development and our other product candidates in preclinical development as they advance into clinical development. The process of conducting the necessary clinical research to obtain regulatory approval is costly and time-consuming, and the successful development of our product candidates is highly uncertain. As a result, we are unable to determine the duration and completion costs of our research and development projects or when and to what extent we will generate revenue from the commercialization and sale of any of our product candidates. This is due to the numerous risks and uncertainties associated with developing product candidates, including uncertainty related to:

- the duration, costs and timing of clinical trials for our current development programs and any further clinical trials related to new product candidates;
- the sufficiency of our financial and other resources to complete the necessary preclinical studies and clinical trials;
- the acceptance of IND applications for future clinical trials;
- the successful and timely enrollment and completion of clinical trials;
- the successful completion of preclinical studies and clinical trials;
- successful data from our clinical program that supports an acceptable risk-benefit profile of our product candidates in the intended populations;
- the receipt and maintenance of regulatory and marketing approvals from applicable regulatory authorities;
- establishing agreements with third-party manufacturers for clinical supply for our clinical trials and commercial manufacturing, if any of our product candidates are approved;
- the entry into collaborations to further the development of our product candidates;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity for our product candidates; and
- successfully launching our product candidates and achieving commercial sales, if and when approved.

A change in the outcome of any of these variables with respect to the development of any of our programs or any product candidate we develop would significantly change the costs, timing and viability associated with the development and/or regulatory approval of such programs or product candidates.

General, Administrative and Other Expenses

Our general, administrative, and other expenses consist primarily of personnel costs, allocated facilities costs, and other expenses for outside professional services, including legal, marketing, investor relations, human resources services, and accounting services. Personnel costs consist of salaries, benefits, and stock-based compensation for our general and administrative personnel. We will continue to incur additional expenses as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the SEC, Nasdaq, additional insurance expenses, investor relations activities and other administrative and professional services. We also expect to increase the size of our administrative function to support the growth of our business.

Interest Expense

Our interest expense consists primarily of accrued interest expense and amortization of discount on our convertible notes.

Statements of Operations

Results of Operations

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

The following tables set forth our results of operations for the three and nine months ended September 30, 2024 and 2023.

	Three Months Ended September 30,		Change Amount
	2024	2023	
	(unaudited, in thousands)		
Operating expenses:			
Research and development	\$ 1,213	\$ 571	\$ 642
General, administrative and other	2,139	1,481	659
Total operating expenses	3,352	2,052	1,300
Loss from operations	(3,352)	(2,052)	(1,300)
Change in fair value of liability instrument and warrant liability	1,927	—	1,927
Change in fair value of forward contract liability	849	—	1,090
Other income/(loss)	2	(141)	143
Interest income	79	—	79
Interest expense	(5)	—	(5)
Net loss	\$ (500)	\$ (2,193)	\$ 1,934

	Nine Months Ended September 30,		Change Amount
	2024	2023	
	(unaudited, in thousands)		
Operating expenses:			
Research and development	\$ 3,148	\$ 1,595	\$ 1,553
General, administrative and other	6,877	4,814	2,063
Total operating expenses	10,025	6,409	3,616
Loss from operations	(10,025)	(6,409)	(3,616)
Change in fair value of liability instrument and warrant liability	4,349	—	4,349
Change in fair value of future contract liability	(651)	—	(410)
Commitment fee expense	(1,941)	—	(1,941)
Other income/(loss)	32	(213)	245
Interest income	188	—	188
Interest expense	(14)	(146)	132
Net loss	\$ (8,062)	\$ (6,768)	\$ (1,053)

Research and Development Expenses

Research and development expenses were \$1.2 million and \$0.6 million for the three months ended September 30, 2024 and 2023, respectively. The increase of \$0.6 million was primarily due to:

- increased tissue acquisition and CDMO costs of \$0.3 million for cell manufacturing activities;
- increased personnel related expenses of \$0.2 million due to hiring additional research scientists after September 30, 2023; and
- increased research materials and supplies expenses of \$0.1 million due to increased laboratory personnel and preclinical studies.

Research and development expenses were \$3.1 million and \$1.6 million for the nine months ended September 30, 2024 and 2023, respectively. The increase of \$1.5 million was primarily due to:

- increased personnel related expenses of \$0.6 million due to hiring additional research scientists after September 30, 2023;
- increased tissue acquisition and CDMO costs of \$0.5 million for cell manufacturing activities; and
- increased research materials and supplies, conferences, and depreciation expenses of \$0.4 million due to increased laboratory personnel and preclinical studies.

Research and development expenses are not tracked by product candidate.

General, Administrative and Other Expenses

General, administrative and other expenses were \$2.1 million and \$1.5 million for the three months ended September 30, 2024 and 2023, respectively. The increase of \$0.6 million was primarily due to:

- increased expense of \$0.2 million for public company D&O insurance;
- increased expenses of \$0.2 million for patent filing and maintenance costs;
- increased expenses of \$0.2 million for added personnel in 2024;
- increased expenses of \$0.1 million for investor relations and marketing costs, and.
- decreased expenses of \$0.1 million for legal fees.

General, administrative and other expenses were \$6.9 million and \$4.8 million for the nine months ended September 30, 2024 and 2023, respectively. The increase of \$2.1 million was primarily due to:

- increased expenses of \$0.7 million for regulatory, listing, accounting, investor relations and marketing expenses related to our Direct Listing completed in January 2024 and subsequent financing efforts;
- increased expenses of \$0.7 million for added personnel in 2024;
- increased expenses of \$0.5 million for patent filing and maintenance costs;
- increased expense of \$0.5 million for public company D&O insurance;
- decreased expenses of \$0.3 million due to timing of an executive bonus in January 2023.

Change in fair value of warrant liability

Change in fair value of warrant liability was a gain of \$1.9 million and none for the three months ended September 30, 2024 and 2023, respectively. The liability instrument to investors under the Share Purchase Agreement among us, GEM Global Yield LLC SCS, or GEM, and GEM Yield Bahamas Limited, or GYBL, dated November 12, 2021, or the GEM SPA, was comprised of the contingent warrant liability and contingent put option. The \$1.9 million gain during the three months ended September 30, 2024 resulted from the mark to market of the warrant liability, which will occur at the end of each reporting period as long as the warrants are outstanding and classified as a liability.

Change in fair value of warrant liability was a gain of \$4.3 million and none for the nine months ended September 30, 2024 and 2023, respectively. This change in fair value resulted primarily from the decrease in our stock price.

Change in fair value of forward contract liability

Change in fair value of forward contract liability was a net gain of \$0.8 million and \$0.0 million for the three months ended September 30, 2024 and 2023, respectively. A forward contract liability to sell shares to the investor at 90% of the average daily closing price per share over the Draw Down Pricing Period is recorded each time we issue a Draw Down Notice to GEM under the Share Purchase Agreement. The forward contract liability is remeasured at the end of each quarter, if open, and again upon receipt of the Closing Notice from the investor. The forward contract liability is eliminated upon receipt of the Closing Notice and funds from the investor.

Change in fair value of forward contract liability was a net loss of \$0.7 million and \$0.0 million for the nine months ended September 30, 2024 and 2023, respectively.

Commitment fee expense

Commitment fee expense was \$1.9 million and none for the nine months ended September 30, 2024 and 2023, respectively. A \$2 million commitment fee pursuant to the GEM SPA became payable to GEM upon completion of the Direct Listing in January 2024. The commitment fee is payable to GEM as drawdown notices are issued, with any remaining balance payable one year after public listing. We sold \$3.0 million of common stock to GEM under the GEM SPA during the three months ended March 31, 2024, which made approximately \$0.1 million of the commitment fee payable immediately. This \$0.1 million portion of the commitment fee was netted against the proceeds received in additional paid-in capital. The remaining \$1.9 million was expensed immediately because we were planning to raise funds through other sources and had no plans to issue further Draw Down Notices to GEM prior to the one-year anniversary of our public listing when this remaining amount will be due.

Other loss

For the three and nine months ended September 30, 2023, the \$0.1 million and \$0.2 million, respectively, of other loss is comprised of the payments to FibroGenesis in excess of the derivative liability established at inception of the Agreement Regarding Right of First Negotiation entered into by us and FibroGenesis in January 2023, or the ROFN Agreement.

Interest income

Interest income is comprised of interest income and unrealized gain/losses on cash equivalents.

Interest Expense

Interest expense was \$0.0 million and \$0.1 million for the nine months ended September 30, 2024 and 2023, respectively. The decrease of \$0.1 million was due to the maturities and conversions of the notes during the year ended December 31, 2023. Interest expense was recorded in 2023 for the nominal interest rate of 6.0% plus the amortization of the discount on the 2022 convertible notes.

Income Taxes

The effective income tax rate was 0.0% for all periods. Currently, we have recorded a full valuation allowance against our net deferred tax assets.

Liquidity and Capital Resources

Overview

To date, we have financed our operations primarily with investment from FibroGenesis, proceeds from borrowings under our convertible loan agreements, and proceeds from the issuance of preferred stock and common stock. From Inception through September 30, 2024, we have received gross proceeds of approximately \$5.6 million from sales of our convertible notes, \$18.6 million from the issuance of preferred stock, and \$8.0 million from the issuance of common stock. As of September 30, 2024, we had cash and cash equivalents of approximately \$7.8 million and an accumulated deficit of approximately \$32.3 million. As of September 30, 2024, we had no outstanding debt.

Cash Flows

The following table sets forth a summary of our cash flows for the nine months ended September 30, 2024 and 2023.

	Nine Months Ended	
	September 30,	
	2024	2023
	(in thousands)	
Net cash used in operating activities	\$ (8,828)	\$ (4,800)
Net cash used in investing activities	(85)	(493)
Net cash provided by financing activities	7,577	13,793
Net increase/(decrease) in cash and cash equivalents	\$ (1,336)	\$ 8,500

Cash Flows from Operating Activities

Net cash used in operating activities was \$8.8 million and \$4.8 million for the nine months ended September 30, 2024 and 2023, respectively, and consisted primarily of net losses of \$8.1 million and \$6.8 million, respectively. Noncash losses on stock-based compensation expense of \$1.7 million and change in fair value of forward contract liability of \$0.7 million, and amortization of operating lease right-of-use asset of \$0.3 million, and change in commitment fee payable of \$1.9 million partially offset the net loss, while noncash gain on change in fair value of liability instrument of \$4.3 million, an increase in prepaid expenses of \$0.3 million, a decrease in accounts payable and accrued expenses of \$0.3 million, a decrease in payable to Parent of \$0.1 million, and a decrease in operating lease liability of \$0.3 million added to the cash used in operations in the nine months ended September 30, 2024. Noncash expenses of stock-based compensation of \$1.3 million, other loss on derivative liability of \$0.1 million, amortization of convertible notes debt discount of \$0.1 million, and amortization of operating lease right-of-use asset of \$0.3 million, and an increase in accounts payable and accrued expenses of \$0.4 million and an increase in payable to Parent of \$0.1 million partially offset the net loss, while a decrease in operating lease liability of \$0.3 million added to the cash used in operations in the nine months ended September 30, 2023.

Cash Flows from Investing Activities

Net cash used in investing activities was approximately \$0.1 million and \$0.5 million for the nine months ended September 30, 2024 and 2023, respectively, and consist primarily of laboratory equipment purchases.

Cash Flows from Financing Activities

Net cash provided by financing activities was approximately \$7.6 million and \$13.8 million for the nine months ended September 30, 2024 and 2023, respectively. During the nine months ended September 30, 2024, we entered into a \$0.6 million short-term borrowing agreement to finance the D&O insurance policy premiums and repaid \$0.5 million of the principal borrowed, and we raised \$7.5 million of net proceeds from the sale of common stock under the GEM SPA. During the nine months ended September 30, 2023, we paid to FibroGenesis \$2.6 million under the ROFN Agreement, we received \$0.3 million from FibroGenesis' repayment of its note payable to us, and we received \$15.2 million in total net proceeds from the issuance of Series B Preferred Stock and Series B-1 Preferred Stock.

Funding Requirements

We do not have any products approved for sale, and we have never generated any revenue from contracts with customers. We do not expect to generate any meaningful revenue unless and until we obtain regulatory approval of and commercialize any of our current or future product candidates and we do not know when, or if, that will occur. We expect to continue to incur significant losses for the foreseeable future, and we expect the losses to increase as we continue the development of, and seek regulatory approvals for, our current and future product candidates, and begin to commercialize any approved products. We are subject to all the risks typically related to the development of new product candidates, and we may encounter unforeseen expenses, difficulties, complications, delays, and other unknown factors that may adversely affect our business. Moreover, we will continue to incur additional costs associated with operating as a public company.

The financial statements have been prepared as though we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. We have incurred operating losses and negative cash flows from operations since Inception. As of September 30, 2024, we had an accumulated deficit of approximately \$32.4 million. Management expects to continue to incur operating losses and negative cash flows.

These factors raise substantial doubt about our ability to continue as a going concern for one year from the issuance of the financial statements. Our ability to continue as a going concern is dependent on the Company's ability to raise additional capital. We will need to raise additional capital to continue to fund our operations. We believe we will be able to obtain additional capital through equity financings or other arrangements to fund operations; however, there can be no assurance that such additional financing, if available, can be obtained on acceptable terms. If we are unable to obtain such additional financing, future operations would need to be scaled back or discontinued.

Our future funding requirements will depend on many factors, including, but not limited to:

- the initiation, progress, timeline, cost and results of our clinical trials for our product candidates;
- the initiation, progress, timeline, cost and results of additional research and preclinical studies related to pipeline development and other research programs we initiate in the future;
- the cost and timing of manufacturing activities, including our planned manufacturing scale-up activities associated with our product candidates and other programs as we advance them through preclinical and clinical development through commercialization;
- the potential expansion of our current development programs to seek new indications;
- the outcome, timing and cost of meeting regulatory requirements established by the FDA and other comparable foreign regulatory authorities;
- the cost of filing, prosecuting, defending, and enforcing patent claims and other intellectual property rights, in-licensed or otherwise;

- the effect of competing technological and market developments;
- the payment of licensing fees, potential royalty payments and potential milestone payments;
- the cost of general operating expenses;
- the cost of establishing sales, marketing, and distribution capabilities for any product candidates for which we may receive regulatory approval in regions where we choose to commercialize our products on our own; and
- the costs of operating as a public company.

Further, our operating plan may change, and we may need additional funds to meet operational needs and capital requirements for clinical trials and other research and development expenditures.

If we need to raise additional capital to fund our operations, funding may not be available to us on acceptable terms, or at all. If we are unable to obtain adequate financing when needed, we may have to delay, reduce the scope of or suspend one or more of our preclinical studies, clinical trials, research and development programs or commercialization efforts. We may seek to raise any necessary additional capital through a combination of public or private equity offerings, debt financings, collaborations, and other licensing arrangements. If we raise additional capital through debt financing, we may be subject to 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 capital through marketing and distribution arrangements or other collaborations, strategic alliances, or licensing arrangements with third parties, we may have to relinquish certain valuable rights to our product candidates, technologies, future revenue streams or research programs or grant licenses on terms that may not be favorable to us.

Contractual Obligations and Commitments

Material contractual obligations arising in the normal course of business primarily consist of operating leases. Future minimum lease payments under non-cancellable leases as of September 30, 2024, were approximately \$1.6 million, of which \$0.5 million is due within one year. We generally expect to satisfy these commitments with cash on hand and cash provided by financing activities.

Critical Accounting Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities as of the dates of the balance sheets and the reported amounts of expenses during the reporting periods. In accordance with GAAP, we evaluate our estimates and judgments on an ongoing basis. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

We define our critical accounting estimates as those under GAAP that require us to make subjective estimates and judgments about matters that are uncertain and are likely to have a material impact on our financial condition and results of operations, as well as the specific manner in which we apply those principles. For a description of our critical accounting policies and estimates, please see the disclosures in Part II, Item 7 of our Annual Report on Form 10-K for the year ended December 31, 2023. During the nine months ended September 30, 2024, we recorded a Forward contract liability with each Draw Down Notice issued to GEM and have remeasured this Forward contract liability at each quarter end and upon receipt of each Closing Notice from GEM. Other than the Forward contract liability critical accounting estimates and changes in the fair value of the Warrant liability, as described in this Quarterly Report, there have not been any material changes to our critical accounting policies and estimates since December 31, 2023.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

We are a smaller reporting company as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and are not required to provide the information specified under this item.

Item 4. Controls and Procedures

We maintain disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e) and 15d-15(e)) that are designed to ensure that information required to be disclosed in our reports under the Exchange Act, and the rules and regulations thereunder, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

Evaluation of Disclosure Controls and Procedures

We have carried out an evaluation, under the supervision, and with the participation, of management, including our chief executive officer and chief financial officer, of our disclosure controls and procedures (as defined in Rule 13a-15(e) of the Exchange Act) as of the end of the period covered by this Quarterly Report on Form 10-Q. During the preparation of our financial statements for the fiscal year ended December 31, 2023, our management identified a material weakness in our internal control over financial reporting due to a lack of segregation of duties. A material weakness is defined as a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

Specifically, our management identified a material weakness in our internal controls within the financial reporting function that resulted from an ineffective design and implementation of controls over proper segregation of duties for the period of time covered by our financial statements due to a limited number of individuals. Based upon such evaluation, and due to the material weakness identified, our principal executive officer and principal financial and accounting officer have concluded that our disclosure controls and procedures were not effective.

Remediation Plan for Material Weakness

We will continue to add staff, evaluate segregation of duties, and implement initiatives to improve our internal controls over financial reporting as we grow.

Changes in Internal Control over Financial Reporting

There has been no change in the Company's internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) that occurred during the three months ended September 30, 2024, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls

A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues, if any, within an organization have been detected. Accordingly, our disclosure controls and procedures and our internal control over financial reporting are designed to provide reasonable, not absolute, assurance that the objectives of the control system are met. We continue to implement, improve, and refine our disclosure controls and procedures and our internal control over financial reporting.

PART II — OTHER INFORMATION

Item 1. Legal Proceedings

From time to time, we may be involved in legal proceedings relating to intellectual property, commercial, employment and other matters arising in the ordinary course of business. Such matters are subject to uncertainty and there can be no assurance that such legal proceedings will not have a material adverse effect on our business, results of operations, financial position, or cash flows. We are not party to any legal proceedings at this time.

Item 1A. Risk Factors

Our business is subject to risks, uncertainties, and events that, if they occur, could adversely affect our financial condition and results of operations and the trading price of our securities. Except as set forth below, there have been no material changes from the risk factors previously described in “Part I, Item 1A. Risk Factors” of our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, filed with the SEC on February 29, 2024.

Risks Related to Our Financial Condition and Capital Requirements

There is substantial doubt about our ability to continue as a going concern.

In connection with the preparation of this Quarterly Report, our management concluded that there is substantial doubt as to whether we can continue as a going concern for the twelve months following the issuance of this Quarterly Report. Our ability to continue as a going concern is dependent upon raising capital to maintain current operations and continue research and development efforts. We plan to raise additional capital to fund our operations through public or private equity offerings, debt financings, and/or potential collaborations and license arrangements or other sources. There is no assurance, however, that any additional financing or any revenue-generating collaboration will be available when needed or that we will be able to obtain financing or enter into a collaboration on terms acceptable to us.

These factors raise substantial doubt about our ability to continue as a going concern. Substantial doubt about our ability to continue as a going concern may materially and adversely affect the price per share of our common stock, and it may be more difficult for us to obtain financing. If existing or potential collaborators decline to do business with us or potential investors decline to participate in any future financings due to such concerns, our ability to increase our cash position may be limited. The perception that we may not be able to continue as a going concern may cause others to choose not to deal with us due to concerns about our ability to meet our contractual obligations. We have prepared our unaudited condensed consolidated financial statements on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities and commitments in the normal course of business. Our unaudited condensed consolidated financial statements included in this Quarterly Report do not include any adjustments that might be necessary if we are unable to continue as a going concern. If we are unable to continue as a going concern, we will be forced to delay, reduce or discontinue our research and development programs or consider other various strategic alternatives and you could lose all or part of your investment in us.

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

The following sets forth information regarding all unregistered securities we sold during the three months ended September 30, 2024. Unless stated otherwise, the sales of the securities listed below were deemed to be exempt from registration pursuant to Section 4(a)(2) of the Securities Act, including Regulation D and Rule 506 promulgated thereunder, as transactions by an issuer not involving a public offering.

On June 27, 2024, the Company issued 3,000,000 shares of Common Stock to facilitate a Draw Down Notice under the Share Purchase Agreement. The investor subsequently accepted the Draw Down Notice for 840,000 shares and sent a Closing Notice dated July 11, 2024, for the 840,000 shares issued at a net price of \$4.09 per share after applying the 10% discount and remitted \$3,436 thousand gross proceeds to the Company. Of the remaining 2,160,000 shares, 560,000 shares were returned and canceled, and 1,600,000 shares were utilized in a subsequent Draw Down Notice.

On July 12, 2024, the Company issued a Draw Down Notice for 1,600,000 shares. The investor subsequently accepted the Draw Down Notice for 100,000 shares and sent a Closing Notice dated August 26, 2024, for the 100,000 shares issued at a net price of \$4.51 per share after applying the 10% discount and remitted \$451 thousand gross proceeds to the Company. Of the remaining 1,500,000 shares, 500,000 shares were returned and canceled, and 1,000,000 shares were utilized in a subsequent Draw Down Notice.

On September 12, 2024, the Company issued a Draw Down Notice for 1,000,000 shares. The investor subsequently accepted a portion of the Draw Down Notice for 258,836 shares and sent a Closing Notice dated September 26, 2024, for the 258,836 shares issued at a net price of \$2.93 per share after applying the 10% discount and remitted \$758 thousand gross proceeds to the Company. With the consent of the Company, the investor submitted a second Closing Notice dated October 18, 2024 for an additional 15,683 shares issued at a net price of \$2.91 per share after applying the 10% discount and remitted \$46 thousand gross proceeds to the Company. The remaining 725,481 shares will be returned by the investor and canceled.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Not applicable.

Item 6. Exhibits

Exhibit Number	Exhibit Description	Incorporation By Reference			
		Form	SEC File No.	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation of the Registrant	8-K	001-41934	3.1	August 28, 2024
3.2	Amended and Restated Bylaws of the Registrant	8-K	001-41934	3.1	June 27, 2024
4.1	Form of Warrant of FibroBiologics, Inc. issued pursuant to the GEM SPA	S-1/A	333-277019	4.2	March 15, 2024
10.1	Amendment 1 to the Intellectual Property Cross-License Agreement between SpinalCyte LLC and FibroBiologics, Inc., effective as of May 17, 2021.	10-Q	001-41934	10.1	August 7, 2024
10.2	Amendment 2 to the Patent Assignment Agreement between SpinalCyte LLC and FibroBiologics, Inc., effective as of May 17, 2021.	10-Q	001-41934	10.2	August 7, 2024
10.3+	Master Service Agreement, effective September 19, 2024, between FibroBiologics, Inc. and Charles River Laboratories, Inc.	8-K	001-41934	10.1	September 24, 2024
31.1	Certification of Principal Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.				
31.2	Certification of Principal Financial and Accounting Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated under the Securities Exchange Act of 1934, as amended.				
32.1	Certifications of Chief Executive Officer and Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*				
101.INS	Inline XBRL Instance Document- the instance document does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document.				
101.SCH	Inline XBRL Taxonomy Schema Document.				
101.CAL	Inline XBRL Taxonomy Calculation Linkbase Document.				
101.DEF	Inline XBRL Taxonomy Definition Linkbase Document.				
101.LAB	Inline XBRL Taxonomy Label Linkbase Document.				
101.PRE	Inline XBRL Taxonomy Presentation Linkbase Document.				
104	Cover Page Interactive Data File (formatted as inline XBRL with applicable taxonomy extension information contained in Exhibits 101.INS, 101.SCH, 101.CAL, 101.DEF, 101.LAB, and 101.PRE).				

+ Portions of this exhibit have been redacted in compliance with Regulation S-K Item 601(b)(10)(iv).

* The certifications attached as Exhibit 32.1 accompany this Quarterly Report on Form 10-Q pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, and shall not be deemed “filed” by the Registrant for purposes of Section 18 of the Securities Exchange Act of 1934, as amended.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

FIBROBIOLOGICS, INC.

Date: November 12, 2024

By: /s/ Robert E. Hoffman

Robert E. Hoffman

Interim Chief Financial Officer

(Duly Authorized Officer and Principal Financial Officer)

CERTIFICATION

I, Pete O’Heeron, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended September 30, 2024 of FibroBiologics, Inc. (the “registrant”);
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(s) 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(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: November 12, 2024

/s/ Pete O’Heeron

Pete O’Heeron
Chief Executive Officer
Principal Executive Officer

CERTIFICATION

I, Robert E. Hoffman, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended September 30, 2024 of FibroBiologics, Inc. (the “registrant”);
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(s) 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(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant’s ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant’s internal control over financial reporting.

Date: November 12, 2024

/s/ Robert E. Hoffman

Robert E. Hoffman
Interim Chief Financial Officer
Principal Financial Officer

STATEMENT PURSUANT TO 18 U.S.C. SECTION 1350

With reference to the Quarterly Report of FibroBiologics, Inc. (the “Company”), on Form 10-Q for the period ended September 30, 2024, as filed with the Securities and Exchange Commission on the date hereof (the “Report”), I, Pete O’Heeron, Chief Executive Officer of the Company, and Robert E. Hoffman, Interim Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that to my knowledge:

- 1) The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- 2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

/s/ Pete O’Heeron

Pete O’Heeron
Chief Executive Officer

/s/ Robert E. Hoffman

Robert E. Hoffman
Interim Chief Financial Officer

Date: November 12, 2024
