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 March 31, 2025.

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	**86-3329066**
(State or other jurisdiction of incorporation or organization)	(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) 671-5150
(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 Capital Market**

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

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

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

Large accelerated filer ☐	Accelerated filer ☐
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 ☒

On May 13, 2025, 38,262,586 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 March 31, 2025

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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. We intend such forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in Section 27A of the Securities Act of 1933, as amended, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. 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, planned research programs, preclinical studies and clinical trials, and market opportunities 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 and in our Annual Report on Form 10-K for the year ended December 31, 2024, or the Annual 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. You should read this Quarterly Report, the documents that we reference in this Quarterly Report and the other documents that we file with the Securities and Exchange Commission, or the SEC, with the understanding that our actual future results may be materially different from any future results expressed or implied by these 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)

	March 31, 2025	December 31, 2024
	(unaudited)	
Assets		
Current assets		
Cash and cash equivalents	$ 8,667	$ 13,985
Prepaid expenses	642	225
Other current assets	18	18
Total current assets	9,327	14,228
Property and equipment, net	814	824
Operating lease right-of-use asset, net	1,285	1,393
Total assets	$ 11,426	$ 16,445
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable and accrued expenses	$ 1,417	$ 2,697
Operating lease liability, short-term	412	401
SEPA put option liability	543	460
Short-term convertible note payable	5,839	9,168
Total current liabilities	8,211	12,726
Operating lease liability, long-term	865	984
Total liabilities	9,076	13,710
Stockholders' equity		
Preferred Stock, $0.00001 par value; 10,000,000 shares authorized as of March 31, 2025 and December 31, 2024	—	—
Preferred Stock, $0.00001 par value; 2,500 Series C Preferred shares authorized; 2,500 shares issued and outstanding as of March 31, 2025 and December 31, 2024	—	—
Voting Common Stock, $0.00001 par value; 100,000,000 shares authorized; 37,735,300 shares and 35,085,718 shares issued and outstanding as of March 31, 2025 and December 31, 2024, respectively	—	—
Additional paid-in capital	42,834	38,253
Accumulated deficit	(40,484)	(35,518)
Total stockholders' equity	2,350	2,735
Total liabilities and stockholders' equity	$ 11,426	$ 16,445

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 March 31,	
	2025	**2024**
Operating expenses:		
Research and development	$ 1,780	$ 960
General, administrative and other	2,751	2,490
Total operating expenses	4,531	3,450
Loss from operations	(4,531)	(3,450)
Other income/(expense):		
Change in fair value of warrant liability	—	(3,104)
Change in fair value of SEPA put option liability	(83)	—
Change in fair value of convertible debt	(451)	—
Commitment fee expenses	—	(1,941)
Interest income	99	39
Interest expense	—	(4)
Net loss	(4,966)	(8,460)
Net loss attributable to common stockholders	$ (4,966)	$ (8,460)
Net loss per share, basic and diluted	$ (0.14)	$ (0.27)
Weighted-average shares outstanding, basic and diluted	36,673,126	31,133,762

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

FibroBiologics, Inc.
Condensed Statements of Changes in Stockholders' Equity/(Deficit)
For the Three Months Ended March 31, 2025 and 2024
(unaudited, in thousands, except shares)

	Series A Preferred Stock		Series B Preferred Stock		Series B-1 Preferred Stock		Series C Preferred Stock		Non-voting Common Stock		Voting Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balance – December 31, 2024	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**2,500**	**$ —**	**—**	**$ —**	**35,085,718**	**$ —**	**$ 38,253**	**$ (35,518)**	**$ 2,735**
Issuance of Voting Common Stock for commitment fee payable	—	—	—	—	—	—	—	—	—	—	118,991	—	250	—	250
Conversion of Short-term convertible note payable into Voting Common Stock	—	—	—	—	—	—	—	—	—	—	2,530,591	—	3,780	—	3,780
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	551	—	551
Net loss	—	—	—	—	—	—	—	—	—	—	—	—		(4,966)	(4,966)
Balance (Unaudited) – March 31, 2025	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**2,500**	**$ —**	**—**	**$ —**	**37,735,300**	**$ —**	**$ 42,834**	**$ (40,484)**	**$ 2,350**

	Series A Preferred Stock		Series B Preferred Stock		Series B-1 Preferred Stock		Series C Preferred Stock		Non-voting Common Stock		Voting Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	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 of Series B Preferred Stock, Series B-1 Preferred Stock and Non-voting common stock 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 Voting 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)**

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 Three Months Ended March 31,	
	2025	**2024**
Cash flows from operating activities		
Net loss	$ (4,966)	$ (8,460)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of warrant liability	—	3,104
Change in fair value of SEPA put option liability	83	—
Change in fair value of convertible debt	451	—
Stock-based compensation expense	551	525
Amortization of operating lease right-of-use asset	108	102
Depreciation expense	53	35
Changes in operating assets and liabilities:		
Prepaid expenses	(417)	(710)
Accounts payable and accrued expenses	(1,030)	(630)
Commitment fee payable	—	2,000
Other current assets	—	(2)
Payable to Parent	—	(141)
Operating lease liability	(108)	(98)
Net cash used in operating activities	(5,275)	(4,275)
Cash flows from investing activities		
Purchases of property and equipment	(43)	(8)
Net cash used in investing activities	(43)	(8)
Cash flows from financing activities		
Proceeds from short-term borrowing	—	574
Repayments of short-term borrowing	—	(115)
Proceeds from issuance of common stock, net of direct costs	—	2,819
Net cash provided by financing activities	—	3,278
Net increase/(decrease) in cash and cash equivalents	(5,318)	(1,005)
Cash and cash equivalents, beginning of period	13,985	9,163
Cash and cash equivalents, end of period	$ 8,667	$ 8,158
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	$ —	$ —
Cash paid for interest	$ —	$ 4
Supplemental disclosure of non-cash investing and financing activities:		
Issuance of Voting Common Stock for commitment fee payable	$ 250	$ —
Conversion of Short-term convertible note payable into shares of common stock	$ 3,780	

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 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 an early stage, cell therapy 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 and certain cancers, and potential human longevity applications including thymic involution reversal. Prior to Inception, preclinical research and development related to these disease pathways took place under the parent company, SpinalCyte, LLC (the "Parent").

Direct Listing

On January 31, 2024, the Company completed a direct listing of its common stock, $0.00001 par value per share ("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, private debt placements, convertible debt issuances, and sales of equity to fund its operations. As of March 31, 2025, the Company had an accumulated deficit of $40,484 thousand and cash and cash equivalents of $8,667 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 unaudited condensed financial statements. As further described in Note 7, the Company entered into a Standby Equity Purchase Agreement in December 2024 with a certain investor (the "SEPA") and received net proceeds of $8,675 thousand for the issuance of $10,000 thousand of short-term convertible notes principal. Pursuant to the SEPA, the Company expects to receive the net proceeds from the $5,000 thousand third tranche of short-term convertible notes and may require the investor to purchase up to an additional $10,000 thousand of shares of Common Stock. The ability of the Company to continue as a going concern is dependent on the Company's ability to raise additional capital. The unaudited condensed financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

Segments

The Company adopted Accounting Standards Update ("ASU") 2023-07, *Segment Reporting* (Topic 280) – *Improvements to Reportable Segment Disclosures*, as of January 1, 2024.

Operating segments are defined as components of an entity for which separate discrete financial information is made available and that is regularly evaluated by the chief operating decision maker ("CODM") in making decisions regarding resource allocation and assessing performance. The Company is a clinical-stage cell therapy company with a limited number of employees working on fibroblast-based targets. The Company's operations are organized and reported as a single reportable segment, which includes all activities related to the discovery, development, and commercialization of its products. The Company's CODM, its chief executive officer, reviews operating results on an aggregate basis and manages the operations as a single operating segment.

The accounting policies of the Company's single operating and reportable segment are the same as those described in the summary of significant accounting policies. The measure of segment assets is reported on the condensed balance sheets as total assets. The CODM evaluates performance and allocates resources based on net income (loss) that also is reported on the condensed statements of operations as net loss, and cash used in operations as reported on the condensed statements of cash flows. The significant expenses regularly reviewed by the CODM are consistent with those reported on the Company's condensed statements of operations, and expenses are not regularly provided to or reviewed on a more disaggregated basis for purposes of assessing segment performance and deciding how to allocate resources. Other segment items included in net loss primarily include changes in the fair value of the Company's financial instruments, commitment fees, placement agent costs and a gain on the termination of the Company's share purchase agreement, dated November 12, 2021 (the "GEM SPA"), with GEM Global Yield LLC SCS ("GEM Global") and GEM Yield Bahamas Limited ("GYBL", and together with GEM Global, "GEM").

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 March 31, 2025, unaudited condensed statements of operations for the three months ended March 31, 2025 and 2024, unaudited condensed statements of changes in stockholders' equity/(deficit) for the three months ended March 31, 2025 and 2024, and unaudited condensed statements of cash flows for the three months ended March 31, 2025 and 2024, 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, 2024 as filed with the SEC on March 31, 2025, 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 March 31, 2025, the results of operations for the three months ended March 31, 2025 and 2024, the unaudited condensed statements of changes in stockholders' equity/(deficit) for the three months ended March 31, 2025 and 2024, and the unaudited condensed statements of cash flows for the three months ended March 31, 2025 and 2024. The December 31, 2024, 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 months ended March 31, 2025, are unaudited. Interim results are not necessarily indicative of results for an entire year or for any future period.

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. The most significant estimates include the liability classified instrument, warrant liability, SEPA put option liability, fair value of the short-term convertible note payable, and stock-based compensation.

Fair Value Option of Accounting

The Company has elected the option under ASC 825-10, *Financial Instruments* ("ASC 825"), to measure its short-term convertible notes payable issued pursuant to the SEPA (see Note 7) at fair value. The fair value option may be elected on an instrument-by-instrument basis and is irrevocable unless a new election date occurs. When the fair value option is elected for an instrument, unrealized gains and losses for such instrument are reported in the Statements of Operations at each subsequent reporting date. Upfront costs and fees related to items for which the fair value option is elected shall be recognized in earnings as incurred and not deferred. These amounts are included in Other income/(expense) in the Statements of Operations.

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 thousand. 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 manufacturing organizations ("CMOs"); 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, CMOs 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 $7,850 thousand and $13,501 thousand cash equivalents as of March 31, 2025 and December 31, 2024, 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 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. There were no such losses for the three months ended March 31, 2025 and 2024.

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.

Marketing and Advertising Costs

Marketing and advertising costs to promote the Company and its product candidates are expensed as incurred. Marketing and advertising expenses were $150 thousand and $151 thousand for the three months ended March 31, 2025 and 2024, respectively.

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*—The estimated fair value of our Common Stock underlying our stock-based awards has been determined by our board of directors as of each option grant date with input from management. Prior to completion of the Direct Listing in January 2024, the fair value of our Common Stock was based upon our most recently available third-party valuations of Common Stock and our 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). After completion of the Direct Listing, a public trading market for our Common Stock has been established so the fair value of our Common Stock is based on the closing price as reported on The Nasdaq Stock 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

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 December 2023, the FASB issued ASU No. 2023-09, *Income Taxes* (Topic 740) – *Improvements to Income Tax Disclosures* ("ASU 2023-09"), which is intended to improve 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 financial statements.

In November 2024, the FASB issued ASU No 2024-03 – *Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures* (Subtopic 220-40) – *Disaggregation of Income Statement Expenses* ("ASU 2024-03"), which is intended to require more detailed disclosures about specified categories of expenses (including employee compensation, depreciation, and amortization) included in certain expense captions presented on the face of the income statement. ASU 2024-03 is effective for annual periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. Early adoption is permitted. The amendments may be applied either prospectively to financial statements issued for reporting periods after the effective date of this ASU or retrospectively to all prior periods presented in the financial statements. The Company is in the process of evaluating the impact of this new guidance on its financial statements.

3. Net 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:

	Three Months Ended March 31,	
(in thousands, except share and per share amounts)	**2025**	**2024**
Numerator:		
Net loss	$ (4,966)	$ (8,460)
Net loss attributable to common stockholders:	$ (4,966)	$ (8,460)
Denominator:		
Weighted-average number of common shares outstanding, basic and diluted	36,673,126	31,133,762
Net loss per common share attributable to common stockholders, basic and diluted	$ (0.14)	$ (0.27)

The weighted average number of shares outstanding for the three months ended March 31, 2024 is based upon the shares of our non-voting Common Stock 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, and the issuance of 227,057 shares of Common Stock to GEM Global in February and March 2024.

As further described in Note 7, the Company issued $10,000 thousand of principal in short-term convertible notes during December 2024. During the three months ended March 31,2025, the Company issued 118,991 shares of Common Stock to satisfy the $250 thousand commitment fee payable, and $3,600 thousand of short-term convertible notes were converted into 2,530,591 shares of Common Stock. As of March 31, 2025, the estimated number of shares of Common Stock that would have been issued upon conversion of the remaining $6,400 thousand of principal was 6,867,571 shares of Common Stock. For the three months ended March 31, 2025 and 2024, the Company reported net losses and, accordingly, potential common shares were not included since such inclusion would have been anti-dilutive. As a result, the Company's basic and diluted net loss per share is the same in all periods presented.

4. Property and Equipment

Property and equipment, net consist of the following:

(in thousands)	March 31, 2025	December 31, 2024
Laboratory equipment	$ 998	$ 981
Computer equipment, software, and other	73	47
Total property and equipment at cost	1,071	1,028
Less: Accumulated depreciation	(257)	(204)
Property and equipment, net	$ 814	$ 824

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 $53 and $35 thousand for the three months ended March 31, 2025 and 2024, respectively.

5. Fair Value of Financial Instruments

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:

	Fair Value Measurement as of March 31, 2025			
(in thousands)	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	$ 7,850	$ —	$ —	$ 7,850
Total assets fair value	$ 7,850	$ —	$ —	$ 7,850
Liabilities:				
SEPA put option liability	$ —	$ —	$ 543	$ 543
Short-term convertible note payable	—	—	5,839	5,839
Total liabilities fair value	$ —	$ —	$ 6,382	$ 6,382

	Fair Value Measurement as of December 31, 2024			
(in thousands)	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	$ 13,501	$ —	$ —	$ 13,501
Total assets fair value	$ 13,501	$ —	$ —	$ 13,501
Liabilities:				
SEPA put option liability	$ —	$ —	$ 460	$ 460
Short-term convertible note payable	—	—	9,168	9,168
Total liabilities fair value	$ —	$ —	$ 9,628	$ 9,628

The following table summarizes the activity related to Level 3 financial liabilities for the three months ended March 31, 2025:

(in thousands)	Short-term Convertible Note Payable	SEPA Put Option Liability
Fair value at December 31, 2024	$ 9,168	$ 460
Change in fair value of SEPA put option liability	—	83
Conversions of convertible debt into shares of common stock	(3,780)	—
Change in fair value of convertible debt	451	—
Fair value at March 31, 2025	$ 5,839	$ 543

As further described in Note 7, the Company issued short-term convertible notes payable on December 20, 2024 and December 30, 2024 with a total principal balance of $10,000 thousand and recorded those notes at their initial fair values totaling $9,288 thousand. The total of their fair values at March 31, 2025 and December 31, 2024 was $5,839 thousand and $9,168 thousand, respectively. The fair values of these notes were determined using a Monte Carlo simulation valuation model. Assumptions used in the valuation models at issuance on December 20, 2024 and December 30, 2024 included the closing bid price of $2.25 and $2.24, respectively, a term of one year, an annual risk-free rate of 4.2% and 4.1%, respectively, and a volatility of 60%. Assumptions used in the valuation model at March 31, 2025 for both notes included the closing bid price of $0.90, a term of 0.72 year, an annual risk free rate of 4.1%, and a volatility of 71%, and at December 31, 2024 for both notes included the closing bid price of $2.00, a term of one year, an annual risk free rate of 4.1%, and a volatility of 60%.

As further described in Note 7, the Company entered into the SEPA on December 20, 2024 and recorded a put option liability for the Company's right to require the investor to purchase up to an additional $10,000 thousand of shares of Common Stock by delivering written notice to the investor. As of December 20, 2024, December 31, 2024, and March 31, 2025 the fair value of the SEPA put option liability was $460 thousand, $460 thousand, and $543 thousand, respectively. The fair value of this SEPA put option liability was determined using a Monte Carlo simulation valuation model. For the valuations on December 20, 2024 and December 31, 2024, inputs used in the model included a stock price of $2.25 per share, a 96% purchase price, Company advance notice date of January 1, 2026, expected settlement date of January 4, 2026, expected advance amount of $5,000 thousand, a simulation term of 1.04 years, volatility of 120%, and a 4.23% risk-free rate. For the valuation on March 31, 2025, inputs used in the model included a stock price of $0.90 per share, a 96% purchase price, Company advance notice date of January 1, 2026, expected settlement date of January 4, 2026, expected advance amount of $5,000 thousand, a simulation term of 0.76 years, volatility of 155%, and a 4.08% risk-free rate.

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 three months ended March 31, 2025 and for the year ended December 31, 2024.

6. Stockholders' Equity/(Deficit)

Authorized Capital - As of March 31, 2025 and December 31, 2024, the Company authorized 100,000,000 shares of Common Stock and 10,000,000 shares of preferred stock, of which 2,500 were shares of Series C preferred stock.

In January 2024, the Company issued 2,500 shares of Series C Preferred Stock to its chief executive officer, 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 pursuant to the Company's Amended and Restated Certificate of Incorporation. As a result of the Direct Listing, the outstanding shares of Series A Preferred Stock were canceled for no consideration and the outstanding shares of Series B Preferred Stock, Series B-1 Preferred Stock, and non-voting Common Stock 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. Standby Equity Purchase Agreement

On December 20, 2024, the Company entered into the SEPA. Pursuant to the SEPA, the investor will advance to the Company, subject to the satisfaction of certain conditions, a total principal amount of $15,000 thousand, which will be evidenced by short-term convertible notes, in three tranches. The short-term convertible notes will accrue interest on the outstanding principal balance at an annual rate equal to 0%, which will increase to an annual rate of 18% upon the occurrence of an event of default for so long as such event remains uncured. The short-term convertible notes will mature on December 20, 2025, which may be extended at the option of the Company to January 19, 2026 by paying an extension fee of $100,000, and to February 18, 2026 by paying an additional extension fee of $100,000. The maturity date may also be extended at the option of the investor.

The Company received net proceeds of $4,300 thousand on December 20, 2024 from the first tranche of short-term convertible notes with $5,000 thousand principal (the "First Note"). The Company received net proceeds of $4,375 thousand on December 30, 2024 from the second tranche of short-term convertible notes with $5,000 thousand principal (the "Second Note"). The third tranche has not yet been received. The Company has elected to account for the short-term convertible notes under the fair value option in accordance with ASC 825-10-15-4, and Note 5 includes further discussion of their fair values.

The First Note is convertible at a conversion price equal to the lower of (i) $2.41 per share or (ii) 94% of the lowest daily volume-weighted average price ("VWAP") during the five consecutive trading days immediately preceding the conversion date (but no lower than the "floor price" then in effect, subject to adjustment from time to time).

The Second Note is convertible at a conversion price equal to the lower of (i) $2.84 per share or (ii) 94% of the lowest daily VWAP during the five consecutive trading days immediately preceding the conversion date (but no lower than the "floor price" then in effect, subject to adjustment from time to time). On January 23, 2025, the investor converted $900 thousand in principal amount of the Second Note and the Company issued to the investor 552,113 shares of Common Stock at a $1.6301 conversion price per share. On January 27, 2025, the investor converted $500 thousand in principal amount of the Second Note and the Company issued to the investor 317,238 shares of Common Stock at a $1.5761 conversion price per share. On January 29, 2025, the investor converted $500 thousand in principal amount of the Second Note and the Company issued to the investor 334,336 shares of Common Stock at a $1.4955 conversion price per share. On February 7, 2025, the investor converted $1,100 thousand in principal amount of the Second Note and the Company issued to the investor 732,941 shares of Common Stock at a $1.5008 conversion price per share. On February 21, 2025, the investor converted $250 thousand in principal amount of the Second Note and the Company issued to the investor 232,169 shares of Common Stock at a $1.0768 conversion price per share. On March 4, 2025, the investor converted $350 thousand in principal amount of the Second Note and the Company issued to the investor 361,794 shares of Common Stock at a $0.9674 conversion price per share. The Company recognized a net loss of $180 thousand during the three months ended March 31, 2025 on these conversions into shares of Common Stock.

Pursuant to the SEPA, and subject to certain conditions, the Company will have the right, from time to time, until December 20, 2026, to require the investor to purchase up to an additional $10,000 thousand of shares of Common Stock by delivering written notice to the investor.

The Company paid the investor a structuring fee of $25 thousand, which was expensed immediately, and agreed to pay the investor a commitment fee totaling $250 thousand (the "Commitment Fee"), which was expensed immediately and included in accrued liabilities at December 31, 2024. On January 7, 2025, the Company satisfied the Commitment Fee by issuing 118,991 shares of its Common Stock to the investor at a $2.1010 price per share.

The SEPA was accounted for as a liability under ASC 815 because it includes an embedded put option and an embedded forward option. The put option was recognized at inception and the forward option will be recognized upon the issuance of a notice for the sale of the Company's Common Stock. The fair value of the derivative liability related to the embedded put option was estimated at $460 thousand at inception of the agreement on December 20, 2024, and at December 31, 2024, and at $543 thousand at March 31, 2025. The SEPA put option liability of $543 thousand and $460 thousand is recognized as a current liability on the balance sheet as of March 31, 2025 and December 31, 2024, respectively. The change in estimated issuance date fair value is presented as a single line item within other income (expense) in the accompanying statements of operations under the caption, *Change in fair value of SEPA put option liability*. The embedded forward option was deemed to have no value at March 31, 2025 and December 31, 2024 because there were no notices for the sale of the Company's Common Stock as of March 31, 2025 and December 31, 2024.

8. Income Taxes

The Company did not record any tax provision or benefit for the three months ended March 31, 2025 and 2024. 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 March 31, 2025 and December 31, 2024.

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 will be 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 will be 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.

In March 2025, the Company executed a new lease for 10,693 square feet located in Houston, Texas to be used in its research and development efforts. This lease commenced on April 1, 2025, terminates on May 31, 2031, and specifies initial base and additional rent totaling $32 thousand per month.

Rent expense for the three months ended March 31, 2025 and 2024, was $170 thousand and $155 thousand, respectively. As of March 31, 2025, noncancelable lease payments under operating leases were $1,408 thousand and noncancelable lease payments under short-term leases were $56 thousand.

Maturities of operating lease liability as of March 31, 2025, were as follows:

(in thousands of dollars)		
2025	$	355
2026		544
2027		509
2028		—
Thereafter		—
Total lease payments		1,408
Less: Imputed interest		(131)
Total lease liability		1,277
Less: Current lease liability		(412)
Total non-current lease liability	$	865

10. 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. In November 2024, a total of 255,825 options with a weighted average strike price of $2.50 per share were forfeited. In October 2024, the Company issued 25,000 options with a strike price of $2.83 per share to an employee under this plan. In December 2024, the Company issued 758,739 options with a strike price of $2.36 per share to employees under this plan. In March 2025, the Company issued 831,000 options with a strike price of $1.04 per share to employees 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 March 31, 2025 and December 31, 2024, respectively, there were 7,128,836 and 7,934,836 shares available for future issuance under the Plan.

Stock-based compensation expense is recognized in the condensed statements of operations as follows:

	For the Three Months Ended March 31,	
(in thousands of dollars)	2025	2024
Research and development	$ 84	$ 74
General and administrative	467	406
Total stock-based compensation expense	$ 551	$ 480

In addition to the $480 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 chief executive officer during the three months ended March 31, 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 March 31, 2025, are as follows:

	Stock Options
Unrecognized stock-based compensation expense (in thousands)	$ 5,416
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, 2024	4,565,164	$ 2.82	8.2	$ 7
Granted	831,000	$ 1.04	10.0	$ —
Exercised	—	$ —	—	$ —
Forfeited/canceled	(25,000)	$ 2.83	—	$ —
Outstanding as of March 31, 2025	5,371,164	$ 2.54	7.8	$ —
Exercisable as of March 31, 2025	2,175,771	$ 2.58	7.2	$ —

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 weighted-average assumptions:

Assumptions:	Three Months Ended March 31, 2025	Three Months Ended March 31, 2024
Risk-free interest rate	4.08%	4.2%
Expected volatility	109%	97%
Expected term (years)	5.5	7.0
Expected dividend	0%	0%

The weighted-average grant date fair value of the options granted during the three months ended March 31, 2025 and 2024 was $0.85 per share and $10.79 per share, respectively.

11. Subsequent Events

The Company terminated its lease for temporary lab and office space for its research operations, effective April 30, 2025.

On April 11, 2025, the investor converted $200,000 in principal amount of the Notes and the Company issued to the investor 263,643 shares of Common Stock at a $0.7586 conversion price per share.

On April 15, 2025, the investor converted $200,000 in principal amount of the Notes and the Company issued to the investor 263,643 shares of Common Stock at a $0.7586 conversion price per share.

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

You should read the following discussion and analysis of our financial condition and results of operations together with our unaudited financial statements and related notes and other financial information appearing elsewhere in this Quarterly Report and with our audited financial statements and related notes and other financial information appearing in our Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report, including information with respect to our plans and strategy for our business, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section of this Quarterly Report and in the Annual Report, our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

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, degenerative disc disease, psoriasis and certain cancers, and potential human longevity applications including thymic involution reversal. Our most advanced product candidates are CYWC628, CYMS101 and CybroCell™.

We are in the late pre-clinical stages of developing CYWC628 as a topically administered allogeneic fibroblast cell-based therapy for wound healing. Our pre-clinical studies focused on utilizing single cell fibroblasts, fibroblast spheroids, and fibroblast-derived materials to treat wounds in diabetic mice. We completed pre-clinical studies investigating (i) multiple administrations of CYWC628 spheroids on a chemically induced chronic wound NONcNZO10/LtJ and BKS.Cg-Dock7m +/+ Leprdb/J mouse model, (ii) dose titration to provide information on the proposed dose range of CYWC628, and (iii) acute and chronic toxicity. The results of our studies 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.

We are developing CYMS101 as an intravenously administered allogeneic fibroblast single cell, and fibroblast spheroid cell-based therapy to treat MS. After completing animal studies using CYMS101, we received approval from a U.S.-based IRB to conduct clinical investigations in Mexico using the fibroblast cell composition for patients with MS, and 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 - no adverse events during intravenous injection of the tolerogenic fibroblasts, no short or long-impact in complete blood count tests during the 16-week monitoring period, and no short or long impact in electrocardiogram results during the 16-week monitoring period. In addition, the study assessed clinical activity using a standard set of neurological assessments routinely used to assess MS. We are currently conducting further research to more fully characterize the mode of action of fibroblasts in oligodendrocyte expansion. We plan to file an IND application for a Phase 1/2 clinical trial relating to MS in the United States as funding allows. We expect to seek a strategic partner to collaborate with us on the development of CYMS101 either before initiating the Phase 1/2 study, or after its completion, if successful, and prior to commencing a potential Phase 3 clinical trial.

CybroCell™ is an investigational intradiscal administered allogeneic fibroblast cell-based therapy in development 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 in rabbit models. The results from the studies were positive and supported our IND application to run a "first in human" trial. We received IND clearance from the FDA in 2018, conditional upon approval of our master cell bank, to evaluate this candidate in a planned clinical trial.

CYPS317 is our allogeneic intravenously administered fibroblast spheroid cell-based investigational therapeutic for the treatment of psoriasis. We have completed an early phase pre-clinical project utilizing a psoriasis mouse model to assess the potential use of intravenous administration of fibroblast spheroids for the treatment of psoriasis. We are in the process of continuing our potentially IND-enabling animal model studies, which include 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, with a projected completion timeline of the fourth quarter of 2025.

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

The manufacturing of our master cell bank and working cell bank for CYWC628 is now complete and both are certified as released by our CDMO. This CDMO will also manufacture CYWC628 for use in our twelve-week Phase 1/2 clinical trial for treatment of diabetic foot ulcers that we plan to conduct in Australia. If any of our product candidates receive marketing approval, we expect to evaluate the feasibility of building our own cGMP manufacturing facility or continuing to outsource manufacturing to a CDMO for clinical testing and commercial supply. We expect to rely on third parties for our cell therapy manufacturing process for the foreseeable future.

Since our spinoff from SpinalCyte, LLC, or 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 sale of $5.6 million of our convertible promissory notes, which were all subsequently converted to equity, the sale of $18.6 million of preferred stock, $10.4 million in proceeds from the sale of common stock, $0.00001 par value per shares, or the Common Stock, through the share purchase agreement, dated November 12, 2021, or the GEM SPA, with GEM Global Yield LLC SCS, or GEM Global, and GEM Yield Bahamas Limited, or GYBL, and together with GEM Global, GEM, and $9.4 million in proceeds from the issuance of additional convertible promissory notes.

As of March 31, 2025, we had cash and cash equivalents of approximately $8.7 million. Since our inception, we have incurred significant operating losses. We incurred net losses of approximately $5.0 million and $8.5 million for the three months ended March 31, 2025 and 2024, respectively. As of March 31, 2025, we had an accumulated deficit of approximately $42.8 million.

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 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

Based upon our progress to date, we are planning to initiate our twelve-week Phase 1/2 clinical trial utilizing CYWC628 for treatment of diabetic foot ulcers in Australia in the second half of 2025 and to complete the clinical trial in the first quarter of 2026.

CybroCell™

We expect to carry out experiments to demonstrate the potential of using the CYWC628 master cell bank for use with the manufacturing of the CybroCell™ drug product. If successful, we will accordingly amend the IND clearance with the FDA for the planned Phase I clinical trial. A timeline for the trial will be determined in connection with discussions with the FDA.

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 and, even if we do, we may never generate revenue that is significant enough for us to achieve profitability.

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 of 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;
- the cost of hiring additional personnel;
- 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 expect to continue incurring additional expenses as a result of operating as a public company, including expenses related to compliance with the rules and regulations of the SEC and Nasdaq, insurance, 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, interest on short-term borrowing to finance D&O insurance premiums, and amortization of discount on our convertible notes.

Statements of Operations

Results of Operations

Comparison of Three Months Ended March 31, 2025 and 2024

The following tables set forth our results of operations for the three months ended March 31, 2025 and 2024.

	Three Months Ended March 31,		Change Amount
	2025	2024	
	(unaudited, in thousands)		
Operating expenses**:**			
Research and development	$ 1,780	$ 960	$ 820
General, administrative and other	2,751	2,490	261
Total operating expenses	4,531	3,450	1,081
Loss from operations	(4,531)	(3,450)	(1,081)
Other income/(expense)			
Change in fair value of warrant liability	—	(3,104)	3,104
Change in fair value of SEPA put option liability	(83)	—	(83)
Change in fair value of convertible debt	(451)	—	(451)
Commitment fee expense	—	(1,941)	1,941
Interest income	99	39	60
Interest expense	—	(4)	4
Net loss	$ (4,966)	$ (8,460)	$ 3,494

Research and Development Expenses

Research and development expenses were $1.8 million and $1.0 million for the three months ended March 31, 2025 and 2024, respectively. The increase of $0.8 million was primarily due to:

- increased chemistry, manufacturing and control costs of $0.2 million for cell manufacturing activities;
- increased CRO costs of $0.1 million to prepare for a clinical trial;
- increased personnel related expenses of $0.2 million due to hiring additional research scientists; and
- increased research materials and supplies expenses of $0.3 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 $2.8 million and $2.5 million for the three months ended March 31, 2025 and 2024, respectively. The increase of $0.3 million was primarily due to:

- increased expenses of $0.3 million for added personnel in 2024.

Change in fair value of warrant liability

Change in fair value of warrant liability was a loss of $0 and $3.1 million for the three months ended March 31, 2025 and 2024, respectively. The liability instrument to investors under the GEM SPA was comprised of the contingent warrant liability and contingent put option. The $3.1 million loss during the three months ended March 31, 2024 resulted from the mark to market of the warrant liability, which occurred at the end of each reporting period until the warrant liability was derecognized in December 2024.

Change in fair value of SEPA put option liability

On December 20, 2024, we entered into a Standby Equity Purchase Agreement (the "SEPA") with a certain investor. Pursuant to the SEPA, and subject to certain conditions, we have the right, from time to time, until December 20, 2026, to require the investor to purchase up to an additional $10,000 thousand of shares of Common Stock by delivering written notice to the investor. The SEPA was accounted for as a liability under ASC 815 because it includes an embedded put option and an embedded forward option. The SEPA put option liability was recognized at inception, and its fair value was estimated at $543 thousand and $460 thousand at March 31,2 025 and December 31, 2024, respectively. The change in fair value of the SEPA put option liability was a loss of $0.1 million during the quarter ended March 31, 2025 and resulted primarily from changes in stock price and other assumptions used in the valuation model.

Change in fair value of convertible debt

We received advances in the form of convertible notes pursuant to the SEPA in December 2024 and elected to account for the short-term convertible notes under the fair value option. Under the fair value option, all costs associated with raising the funds were expensed immediately. The convertible notes were adjusted to their fair values at March 31, 2025 with a $0.3 million loss resulting from the increase in fair value.

Gain/(loss) on issuance of common stock in exchange for convertible debt, net

The investor converted $3,600 thousand of convertible debt into shares of Common Stock during the three months ended March 31, 2025. We recognized a $180 thousand net loss on these conversions, which results from the difference between the quoted market price per share used to record the issuance of Common Stock and the conversion price per share.

Commitment fee expense

Commitment fee expense was $0 and $1.9 million for the three months ended March 31, 2025 and 2024, 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 would have been due.

Interest income

Interest income was $0.1 million and $0.0 million for the three months ended March 31, 2025 and 2024, respectively. Interest income is comprised of interest income and unrealized gain/losses on cash equivalents.

Interest expense

Interest expense was $0 and $0.0 million for the three months ended March 31, 2025 and 2024, respectively.

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

Through March 31, 2025, we have financed our operations primarily with investment from FibroGenesis, proceeds from borrowings under our convertible loan agreements, proceeds from the issuance of preferred stock, and proceeds from the sale of Common Stock through the GEM SPA and the SEPA. From inception through March 31, 2025, we have received aggregate proceeds of approximately $15.0 million from sales of our convertible notes, $18.6 million from the sales of preferred stock, and $10.4 million from the issuance of Common Stock. As of March 31, 2025, we had cash and cash equivalents of approximately $8.7 million and an accumulated deficit of approximately $42.8 million. As of March 31, 2025, we had $6.4 million principal balance of outstanding debt with a fair value of $5.8 million.

Cash Flows

The following table sets forth a summary of our cash flows for the three months ended March 31, 2025 and 2024.

	Three Months Ended March 31,	
	2025	**2024**
	(in thousands)	
Net cash used in operating activities	$ (5,275)	$ (4,275)
Net cash used in investing activities	(43)	(8)
Net cash provided by financing activities	—	3,278
Net increase/(decrease) in cash and cash equivalents	$ (5,318)	$ (1,005)

Cash Flows from Operating Activities

Net cash used in operating activities was $5.3 million and $4.3 million for the three months ended March 31, 2025 and 2024, respectively, and consisted primarily of net losses of $5.0 million and $8.5 million, respectively. Noncash expenses consisting of change in fair value of convertible debt of $0.3 million, change in fair value of SEPA put option liability of $0.1 million, net loss on issuance of Common Stock in exchange for convertible debt of $0.2 million, stock-based compensation expense of $0.6 million, and amortization of operating lease right-of-use asset of $0.1 million partially offset the net loss, while an increase in prepaid expenses of $0.4 million, a decrease in accounts payable and accrued expenses of $1.0 million, and a decrease in operating lease liability of $0.1 million added to the cash used in operations in the three months ended March 31, 2025. Noncash expenses consisting of change in fair value of liability instrument of $3.1 million, change in commitment fee payable of $2.0 million, stock-based compensation expense of $0.5 million, and amortization of operating lease right-of-use asset of $0.1 million partially offset the net loss, while an increase in prepaid expenses of $0.7 million, a decrease in accounts payable and accrued expenses of $0.6 million, a decrease in payable to Parent of $0.1 million, and a decrease in operating lease liability of $0.1 million added to the cash used in operations in the three months ended March 31, 2024.

Cash Flows from Investing Activities

Net cash used in investing activities was approximately $0.0 million and $0.0 million for the three months ended March 31, 2025 and 2024, respectively, and consisted primarily of laboratory equipment purchases.

Cash Flows from Financing Activities

Net cash provided by financing activities was approximately $0 and $3.3 million for the three months ended March 31, 2025 and 2024, respectively. During the three months ended March 31, 2024, we entered into a $0.6 million short-term borrowing agreement to finance the D&O insurance policy premiums and repaid $0.1 million of the principal borrowed, and we raised $2.8 million of net proceeds from the sale of Common Stock under the GEM SPA.

Funding Requirements

We have incurred operating losses since our formation and expect such losses to continue in the future as we build infrastructure, develop intellectual property and conduct research and development activities. Moreover, we have incurred, and expect to continue to incur, additional costs associated with operating as a public company. We do not have any products approved for sale, and we have never generated any revenue from product sales. We have primarily relied on a combination of angel investors, private debt placements, convertible debt issuances, and sales of equity to fund our operations. As of March 31, 2025, we had an accumulated deficit of $42.8 million and cash and cash equivalents of $8.7 million. 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. Unless and until such time that revenue and net income are generated, we will need to continue to raise additional capital. These factors raise substantial doubt about our ability to continue as a going concern for one year from the issuance of the financial statements included in this Quarterly Report. 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, and do not include any adjustments that might be necessary if we are unable to continue as a going concern.

Our ability to continue as a going concern is dependent on our ability to raise additional capital. 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 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.

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;
- 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.

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. 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.

Contractual Obligations and Commitments

We have material cash requirements and other contractual obligations related to our office and lab rent (as described in Note 9, “Leases, Commitments and Contingencies” to the financial statements in this Quarterly Report).

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 the Annual Report.

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 three months ended March 31, 2025, 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 prior to our then-Chief Financial Officer joining us in June 2022 when all financial functions were handled by a single individual, and afterward, through March 31, 2025, 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

With the addition of a chief financial officer and the changes made to our accounting and financial reporting processes and internal controls during the last half of fiscal year 2022 and through March 31, 2025, we have strengthened our internal controls and 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 March 31, 2025, 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 the Annual Report.

Risks Related to Our Financial Condition and Capital Requirements

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

We have incurred recurring operating losses and negative cash flows from operating activities since inception and expect to continue incurring operating losses and negative cash flows in the future. In connection with the preparation of our 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 the 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 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 financial statements 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 March 31, 2025. 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 January 7, 2025, we satisfied the commitment fee due under the SEPA with YA II PN, LTD., or the Investor, by issuing 118,991 shares of our Common Stock to the Investor at a $2.1010 price per share.

On January 23, 2025, the Investor converted $900,000 in principal amount of convertible promissory notes we issued under the SEPA, or the Notes, and we issued to the Investor 552,113 shares of Common Stock at a $1.6301 conversion price per share.

On January 27, 2025, the Investor converted $500,000 in principal amount of the Notes and we issued to the Investor 317,238 shares of Common Stock at a $1.5761 conversion price per share.

On January 29, 2025, the Investor converted $500,000 in principal amount of the Notes and we issued to the Investor 334,336 shares of Common Stock at a $1.4955 conversion price per share.

On February 7, 2025, the Investor converted $1,100,000 in principal amount of the Notes and we issued to the Investor 732,941 shares of Common Stock at a $1.5008 conversion price per share.

On February 21, 2025, the Investor converted $250,000 in principal amount of the Notes and we issued to the Investor 232,169 shares of Common Stock at a $1.0768 conversion price per share.

On March 4, 2025, the Investor converted $350,000 in principal amount of the Notes and we issued to the Investor 361,794 shares of Common Stock at a $0.9674 conversion price per share.

On April 11, 2025, the Investor converted $200,000 in principal amount of the Notes and we issued to the Investor 263,643 shares of Common Stock at a $0.7586 conversion price per share.

On April 15, 2025, the Investor converted $200,000 in principal amount of the Notes and we issued to the Investor 263,643 shares of Common Stock at a $0.7586 conversion price per share.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

Director and Officer Trading Plans and Arrangements
None of our directors or "officers," as defined in Rule 16a-1(f) under the Securities Exchange Act of 1934, adopted or terminated a Rule 10b5-1 trading plan or arrangement or a non-Rule 10b5-1 trading plan or arrangement, as defined in Item 408(c) of Regulation S-K, during the fiscal quarter covered by this report.

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
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).				

* 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: May 14, 2025

By: */s/ Robert E. Hoffman*
Robert E. Hoffman
Interim Chief Financial Officer
(*Duly Authorized Officer and Principal Financial Officer*)

Exhibit 31.1

CERTIFICATION

I, Pete O'Heeron, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended March 31, 2025 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: May 14, 2025

/s/ Pete O'Heeron

Pete O'Heeron
Chief Executive Officer
Principal Executive Officer

Exhibit 31.2

CERTIFICATION

I, Robert E. Hoffman, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended March 31, 2025 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: May 14, 2025

/s/ Robert E. Hoffman
Robert E. Hoffman
Interim Chief Financial Officer
Principal Financial Officer

Exhibit 32.1

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 March 31, 2025, 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: May 14 ,2025