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

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d)**
OF THE SECURITIES EXCHANGE ACT OF 1934
For the quarterly period ended September 30, 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 October 31, 2025, 51,456,077 shares of FibroBiologics, Inc.'s Common Stock, $0.00001 par value per share, were outstanding.

FibroBiologics, Inc.

Quarterly Report on Form 10-Q
For the Quarter Ended September 30, 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 Consolidated Balance Sheets
(in thousands, except shares and per share data)

	September 30, 2025	December 31, 2024
	(unaudited)	
Assets		
Current assets		
Cash and cash equivalents	$ 4,867	$ 13,985
Prepaid expenses	373	225
Other current assets	—	18
Total current assets	5,240	14,228
Property and equipment, net	908	824
Operating lease right-of-use asset, net	2,548	1,393
Other assets	48	—
Total assets	$ 8,744	$ 16,445
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable and accrued expenses	$ 1,069	$ 2,697
Operating lease liability, short-term	643	401
SEPA put option liability	437	460
Short-term convertible debt	4,573	9,168
Total current liabilities	6,722	12,726
Operating lease liability, long-term	1,897	984
Total liabilities	8,619	13,710
Stockholders' equity		
Preferred Stock, $0.00001 par value; 10,000,000 shares authorized as of September 30, 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 September 30, 2025 and December 31, 2024	—	—
Voting Common Stock, $0.00001 par value; 300,000,000 shares and 100,000,000 shares authorized as of September 30, 2025 and December 31, 2024, respectively; 48,263,979 shares and 35,085,718 shares issued and outstanding as of September 30, 2025 and December 31, 2024, respectively	—	—
Additional paid-in capital	51,045	38,253
Accumulated deficit	(50,920)	(35,518)
Total stockholders' equity	125	2,735
Total liabilities and stockholders' equity	$ 8,744	$ 16,445

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

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2025	**2024**	**2025**	**2024**
Operating expenses:				
Research and development	$ 2,789	$ 1,213	$ 6,610	$ 3,148
General, administrative and other	2,249	2,139	7,449	6,877
Total operating expenses	5,038	3,352	14,059	10,025
Loss from operations	(5,038)	(3,352)	(14,059)	(10,025)
Other income/(expense):				
Change in fair value of warrant liability	—	1,927	—	4,349
Change in fair value of forward contract liability	—	849	—	(650)
Change in fair value of SEPA put option liability	33	—	23	—
Change in fair value of convertible debt	(846)	—	(963)	—
Commitment fee expenses	—	—	—	(1,941)
Other income/(expense)	—	2	(625)	31
Interest income	73	79	222	188
Interest expense	—	(5)	—	(14)
Total other income/(expense)	(740)	2,852	(1,343)	1,963
Net loss	$ (5,778)	$ (500)	$ (15,402)	$ (8,062)
Net loss per share, basic and diluted	$ (0.13)	$ (0.01)	$ (0.39)	$ (0.25)
Weighted-average shares outstanding, basic and diluted	43,072,542	33,516,656	39,487,728	32,457,473

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

FibroBiologics, Inc.
Condensed Consolidated Statements of Changes in Stockholders' Equity/(Deficit)
For the Three and Nine Months Ended September 30, 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 debt 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**
Conversion of Short-term convertible debt into Voting Common Stock	—	—	—	—	—	—	—	—	—	—	3,127,156	—	2,439	—	2,439
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	729	—	729
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	(4,658)	(4,658)
Balance (Unaudited) – June 30, 2025	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**2,500**	**$ —**	**—**	**$ —**	**40,862,456**	**$ —**	**$ 46,002**	**$ (45,142)**	**$ 860**
Conversion of Short-term convertible debt into Voting Common Stock	—	—	—	—	—	—	—	—	—	—	7,401,523	—	4,339	—	4,339
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	704	—	704
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	(5,778)	(5,778)
Balance (Unaudited) – September 30, 2025	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**2,500**	**$ —**	**—**	**$ —**	**48,263,979**	**$ —**	**$ 51,045**	**$ (50,920)**	**$ 125**

	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)**
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	578	—	578
Net income	—	—	—	—	—	—	—	—	—	—	—	—	—	898	898
Balance (Unaudited) – June 30, 2024	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**2,500**	**$ —**	**—**	**$ —**	**32,719,125**	**$ —**	**$ 29,532**	**$ (31,919)**	**$ (2,387)**
Sale of Common Stock	—	—	—	—	—	—	—	—	—	—	1,198,836	$ —	5,052	—	5,052
Stock-based compensation expense	—	—	—	—	—	—	—	—	—	—	—	—	572	—	572
Net loss	—	—	—	—	—	—	—	—	—	—	—	—	—	(500)	(500)
Balance (Unaudited) – September 30, 2024	**—**	**$ —**	**—**	**$ —**	**—**	**$ —**	**2,500**	**$ —**	**—**	**$ —**	**33,917,961**	**$ —**	**$ 35,156**	**$ (32,419)**	**$ 2,737**

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

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

	For the Nine Months Ended September 30,	
	2025	**2024**
Cash flows from operating activities		
Net loss	$ (15,402)	$ (8,062)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of warrant liability	—	(4,349)
Change in fair value of forward contract liability	—	650
Change in fair value of SEPA put option liability	(23)	—
Change in fair value of convertible debt	963	—
Non-cash original discount on convertible debt	625	—
Stock-based compensation expense	1,984	1,675
Amortization of operating lease right-of-use asset	420	310
Depreciation expense	178	110
Changes in operating assets and liabilities:		
Prepaid expenses	(148)	(317)
Accounts payable and accrued expenses	(1,378)	(265)
Commitment fee payable	—	1,863
Other current assets	18	(2)
Other assets	(48)	—
Payable to Parent	—	(141)
Operating lease liability	(420)	(300)
Net cash used in operating activities	(13,231)	(8,828)
Cash flows from investing activities		
Purchases of property and equipment	(262)	(85)
Net cash used in investing activities	(262)	(85)
Cash flows from financing activities		
Proceeds from short-term convertible debt	4,375	574
Repayments of short-term borrowing	—	(459)
Proceeds from issuance of common stock, net of direct costs	—	7,462
Net cash provided by financing activities	4,375	7,577
Net decrease in cash and cash equivalents	(9,118)	(1,336)
Cash and cash equivalents, beginning of period	13,985	9,163
Cash and cash equivalents, end of period	$ 4,867	$ 7,827
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	$ —	$ —
Cash paid for interest	$ 5	$ 14
Supplemental disclosure of non-cash investing and financing activities:		
Settlement of forward contract liability for sale of shares to GEM pursuant to Draw Down and Closing Notices	$ —	$ 409
Right of use asset obtained in exchange for operating lease liability	$ 1,575	$ —
Issuance of Voting Common Stock for commitment fee payable	$ 250	$ —
Conversion of Short-term convertible debt into shares of common stock	$ 10,558	$ —

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

FibroBiologics, Inc.
Notes to the Unaudited Condensed Consolidated Financial Statements
September 30, 2025

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.

Formation of Wholly-Owned Subsidiary

On June 12, 2025, the Company formed a wholly-owned subsidiary, FibroBiologics Australia Pty Ltd. This entity will act as the local sponsor for the Company's twelve-week Phase 1/2 clinical trial utilizing CYWC628 for treatment of diabetic foot ulcers in Australia.

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 September 30, 2025, the Company had an accumulated deficit of $50.9 million and cash and cash equivalents of $4.9 million. 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 consolidated 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 $13.1 million for the issuance of $15.0 million of short-term convertible notes principal. Pursuant to the SEPA, and upon the satisfaction of the conditions to the investor's purchase obligations set forth therein, the Company may require the investor to purchase up to an additional $10.0 million of shares of Common Stock. While management has implemented plans to obtain additional funding, including through the SEPA, these plans are not sufficient to alleviate the substantial doubt about the Company's ability to continue as a going concern. 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 consolidated financial statements do not include any adjustments that might be necessary if the Company is unable to continue as a going concern.

Segments

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 consolidated balance sheets as total assets. The CODM evaluates performance and allocates resources based on net income (loss) that also is reported on the condensed consolidated statements of operations as net loss, and cash used in operations as reported on the condensed consolidated statements of cash flows. The significant expenses regularly reviewed by the CODM are consistent with those reported on the Company's condensed consolidated 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.

2. Summary of Significant Accounting Policies

Basis of Presentation

The accompanying unaudited condensed consolidated 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 consolidated balance sheet as of September 30, 2025, unaudited condensed consolidated statements of operations for the three and nine months ended September 30, 2025 and 2024, unaudited condensed consolidated statements of changes in stockholders' equity/(deficit) for the three and nine months ended September 30, 2025 and 2024, and unaudited condensed consolidated statements of cash flows for the nine months ended September 30, 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 consolidated 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 consolidated financial statements have been prepared on the same basis as the annual consolidated financial statements and, in the opinion of management, reflect all adjustments (consisting of normal recurring adjustments) necessary to state fairly the Company's financial position as of September 30, 2025, the results of operations for the three and nine months ended September 30, 2025 and 2024, the unaudited condensed consolidated statements of changes in stockholders' equity/(deficit) for the three and nine months ended September 30, 2025 and 2024, and the unaudited condensed consolidated statements of cash flows for the nine months ended September 30, 2025 and 2024. The December 31, 2024 condensed consolidated 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.

Interim results are not necessarily indicative of results for an entire year or for any future period.

Principles of Consolidation

The accompanying unaudited consolidated condensed financial statements, which include the accounts of the Company and its wholly-owned subsidiary, FibroBiologics Australia Pty Ltd, have been prepared in accordance with GAAP for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. All significant intercompany balances and transactions are eliminated in consolidation.

Use of Estimates

The preparation of the unaudited condensed consolidated 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 consolidated 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 consolidated financial statements; therefore, actual results could differ from those estimates and assumptions. The most significant estimates include the warrant liability, fair value of forward contract liability, SEPA put option liability, fair value of the short-term convertible debt, and stock-based compensation.

Fair Value Option of Accounting

The Company has elected the option under Accounting Standards Codification ("ASC") 825-10, *Financial Instruments* ("ASC 825"), to measure its short-term convertible debt 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 condensed consolidated statements of operations at each subsequent reporting date. Up-front 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 condensed cosolidated 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 $250,000. Any loss incurred or a lack of access to such funds could have a significant adverse impact on the Company's financial condition, results of operations and cash flows.

Risks and Uncertainties

The Company is subject to certain risks and uncertainties, including, but not limited to, changes in any of the following areas that the Company believes could have a material adverse effect on the future financial position or results of operations: the timing of, and the Company's ability to advance its current and future product candidates into and through clinical development; costs and timelines associated with the manufacture of clinical supplies of the Company's product candidates; regulatory approval and market acceptance of its product candidates; performance of third-party contract research organizations ("CROs") and contract 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 $4.9 million and $14.0 million cash equivalents as of September 30, 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 condensed consolidated 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 and nine months ended September 30, 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 consolidated balance sheets.

The Company has elected in accordance with 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 consolidated 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 are recorded at fair value on the unaudited condensed consolidated 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 consolidated 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 consolidated 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 $0.3 million and $0.7 million for the three and nine months ended September 30, 2025, 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 consolidated 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 consolidated statements of operations.

In July 2025, the One Big Beautiful Bill Act (the "Tax Act") was enacted, introducing a series of corporate tax changes in the U.S., including 100% bonus depreciation on qualified property and full expensing for research and development expenditures. The impacts of the Tax Act are reflected in the Company's results for the fiscal quarter ended September 30, 2025, and there was no material impact to income tax expense or effective tax rate.

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 Common Stock underlying stock-based awards has been determined by the 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 Common Stock was based upon most recently available third-party valuations of Common Stock and the board of directors' assessment of additional objective and subjective factors that it believed were relevant and which may have changed from the date of the most recent valuation through the date of the grant. These third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants' Accounting and Valuation Guide, Valuation of Privately-Held-Company Equity Securities Issued as Compensation (the Practice Aid). After completion of the Direct Listing, a public trading market for Common Stock has been established so the fair value of 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 Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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 has determined that there is no impact that the adoption of ASU 2023-09 has had on its condensed consolidated 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 condensed consolidated 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 September 30,		Nine Months Ended September 30,	
(in thousands, except share and per share amounts)	2025	2024	2025	2024
Numerator:				
Net loss	$ (5,778)	$ (500)	$ (15,402)	$ (8,062)
Denominator:				
Weighted-average number of common shares outstanding, basic and diluted	43,072,542	33,516,656	39,487,728	32,457,473
Net loss per common share attributable to common stockholders, basic and diluted	$ (0.13)	$ (0.01)	$ (0.39)	$ (0.25)

As further described in Note 7, during the nine months ended September 30, 2025, the Company issued 118,991 shares of Common Stock to satisfy the $250,000 commitment fee payable, and $9.7 million of short-term convertible notes were converted into 13,059,270 shares of Common Stock. As of September 30, 2025, the estimated number of shares of Common Stock that would have been issued upon conversion of the remaining $5.3 million of principal was 9,877,251 shares of Common Stock. For the three and nine months ended September 30, 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)	September 30, 2025	December 31, 2024
Laboratory equipment	$ 1,198	$ 981
Computer equipment, software, and other	92	47
Total property and equipment at cost	1,290	1,028
Less: Accumulated depreciation	(382)	(204)
Property and equipment, net	$ 908	$ 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 $65,000 and $38,000 for the three months ended September 30, 2025 and 2024, respectively, and $178,000 and $110,000 for the nine months ended September 30, 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 September 30, 2025			
(in thousands)	**Level 1**	**Level 2**	**Level 3**	**Total**
Assets:				
Cash equivalents	$ 4,594	$ —	$ —	$ 4,594
Total assets fair value	$ 4,594	$ —	$ —	$ 4,594
Liabilities:				
SEPA put option liability	$ —	$ —	$ 437	$ 437
Short-term convertible debt	—	—	4,573	4,573
Total liabilities fair value	$ —	$ —	$ 5,010	$ 5,010

	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 debt	—	—	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 nine months ended September 30, 2025:

(in thousands)	**Short-term Convertible Debt**	**SEPA Put Option Liability**
Fair value at December 31, 2024	$ 9,168	$ 460
Change in fair value of SEPA put option liability	—	(23)
Addition of short-term convertible debt	5,000	—
Conversions of convertible debt into shares of common stock	(10,558)	—
Change in fair value of convertible debt	963	—
Fair value at September 30, 2025	$ 4,573	$ 437

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

(in thousands)	**Liability Instrument**	**Forward Contract Liability**	**Warrant Liability**
Fair value at December 31, 2023	$ 7,236	$ —	$ —
Bifurcation of the liability instrument upon Direct Listing	(7,236)	—	7,236
Increase in forward contract liability for Draw Down Notice on June 27, 2024	—	1,500	13,727
Change in fair value of Forward contract liability	—	(1,259)	—
Increase in Warrant liability at issuance January 31, 2024	—	—	—
Change in fair value of Warrant liability	—	—	(18,076)
Fair value at September 30, 2024	$ —	$ 241	$ 2,887

As further described in Note 7, the Company issued short-term convertible debt on December 20, 2024 and December 30, 2024 with a total principal balance of $10.0 million and recorded those notes at their initial fair values totaling $9.3 million. On June 16, 2025, the Company issued short-term convertible debt with a principal balance of $5.0 million and recorded those notes at their initial fair value of $4.5 million. The total of the fair values of these notes at September 30, 2025 and December 31, 2024 was $4.6 million and $9.2 million, 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 models at issuance on June 16, 2025 included the closing bid price of $0.80, a term of one year, an annual risk-free rate of 4.3%, and a volatility of 60%. Assumptions used in the valuation model at September 30, 2025 for all notes included the closing bid price of $0.55, a term of 0.22 year, an annual risk free rate of 4.01%, and a volatility of 57%, and at December 31, 2024 for the 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, subject to the satisfaction of the conditions to the investor's purchase obligations set forth therein, to require the investor to purchase up to an additional $10.0 million of shares of Common Stock by delivering written notice to the investor. As of December 20, 2024 and December 31, 2024, the fair value of the SEPA put option liability was $0.5 million and $0.5 million, 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. As of June 16, 2025, the fair value of the SEPA put option liability was $0.5 million. The fair value of this SEPA put option liability was determined using a Monte Carlo simulation valuation model. For the valuation on September 30, 2025, inputs used in the model included a stock price of $0.55 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 $5.0 million, a simulation term of 0.26 years, volatility of 103%, and a 3.97% risk-free rate.

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

There were no transfers in or out of Level 1, Level 2 or Level 3 assets and liabilities for the nine months ended September 30, 2025 and for the year ended December 31, 2024.

6. Stockholders' Equity/(Deficit)

Authorized Capital - As of September 30, 2025, the Company authorized 300,000,000 shares of Common Stock and 10,000,000 shares of preferred stock, of which 2,500 were shares of Series C preferred stock. As of December 31, 2024, the Company had 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.

In June 2025, the Company amended and restated its certificate of incorporation with the State of Delaware to increase its authorized Common Stock, par value $0.00001 per share, from 100,000,000 shares to 300,000,000 shares.

7. Standby Equity Purchase Agreement

On December 20, 2024, the Company entered into the Standby Equity Purchase Agreement (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 million, 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 $4.3 million on December 20, 2024 from the first tranche of short-term convertible notes with $5.0 million principal (the "First Note"). The Company received net proceeds of $4.4 million on December 30, 2024 from the second tranche of short-term convertible notes with $5.0 million principal (the "Second Note"). The Company received net proceeds of $4.4 million on June 16, 2025 from the third tranche of short-term convertible notes with $5.0 million principal (the "Third Note"). 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).

The Third Note is convertible at a conversion price equal to the lower of (i) $0.98 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).

Below is a summary of conversions during the nine months ended September 30, 2025.

Date	Tranche	Principal Amount	Shares Issued	Price Per Share
January 23, 2025	Second Note	$ 900,000	552,113	$ 1.6301
January 27, 2025	Second Note	$ 500,000	317,238	$ 1.5761
January 29, 2025	Second Note	$ 500,000	334,336	$ 1.4955
February 7, 2025	Second Note	$ 1,100,000	732,941	$ 1.5008
February 21, 2025	Second Note	$ 250,000	232,169	$ 1.0768
March 4, 2025	Second Note	$ 350,000	361,794	$ 0.9674
April 11, 2025	Second Note	$ 200,000	263,643	$ 0.7586
April 15, 2025	Second Note	$ 200,000	263,643	$ 0.7586
May 15, 2025	Second Note	$ 300,000	388,450	$ 0.7723
June 2, 2025	Second Note	$ 100,000	147,579	$ 0.6776
June 3, 2025	Second Note	$ 300,000	442,739	$ 0.6776
June 20, 2025	Second Note	$ 100,000	144,216	$ 0.6934
June 24, 2025	Second Note	$ 200,000	295,377	$ 0.6771
June 26, 2026	Third Note	$ 300,000	443,066	$ 0.6771
June 27, 2025	Third Note	$ 500,000	738,443	$ 0.6771
July 15, 2025	Third Note	$ 300,000	533,428	$ 0.5624
July 28, 2025	Third Note	$ 300,000	493,258	$ 0.6082
August 1, 2025	Third Note	$ 600,000	1,035,911	$ 0.5792
August 18, 2025	Third Note	$ 300,000	571,537	$ 0.5249
August 25, 2025	Third Note	$ 300,000	544,959	$ 0.5505
September 9, 2025	Third Note	$ 300,000	566,572	$ 0.5295
September 16, 2025	Third Note	$ 300,000	597,133	$ 0.5024
September 25, 2025	Third Note	$ 400,000	815,660	$ 0.4904
September 30, 2025	Third Note	$ 1,100,000	2,243,065	$ 0.4904

The Company recognized a net loss of $0.9 million during the nine months ended September 30, 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 $10.0 million of shares of Common Stock by delivering written notice to the investor.

The Company paid the investor a structuring fee of $25,000, which was expensed immediately, and agreed to pay the investor a commitment fee totaling $0.3 million (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 $0.5 million at inception of the agreement on December 20, 2024, and at December 31, 2024, and at $0.4 million at September 30, 2025. The SEPA put option liability is recognized as a current liability on the condensed balance sheets as of September 30, 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 condensed consolidated 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 September 30, 2025 and December 31, 2024 because there were no notices for the sale of the Company's Common Stock as of September 30, 2025 and December 31, 2024.

8. Income Taxes

The Company did not record any tax provision or benefit for the nine months ended September 30, 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 September 30, 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 $2.3 million 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 had a term of 12 months and monthly rent of $6,000 and was 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 $7,000. 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 $8,000. 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 $7,000. The Company terminated this lease effective April 30, 2025.

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 $32,000 per month. 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 $1.6 million each were recorded at inception of the lease term using a discount rate of 6.38%.

Rent expense for the nine months ended September 30, 2025 and 2024 was $0.7 million and $0.5 million, respectively. As of September 30, 2025, noncancelable lease payments under operating leases were $2.9 million.

Maturities of operating lease liability as of September 30, 2025 were as follows:

(in thousands of dollars)	
2026	$ 795
2027	891
2028	440
2029	353
2030	361
Thereafter	61
Total lease payments	2,901
Less: Imputed interest	(361)
Total lease liability	2,540
Less: Current lease liability	(643)
Total non-current lease liability	$ 1,897

10. Stock-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.

As of September 30, 2025 and December 31, 2024, respectively, there were 6,783,761 and 7,934,836 shares available for future issuance under the Plan.

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

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
(in thousands of dollars)	**2025**	**2024**	**2025**	**2024**
Research and development	$ 108	$ 82	$ 308	$ 248
General and administrative	596	490	1,676	1,383
Total stock-based compensation expense	$ 704	$ 572	$ 1,984	$ 1,631

In addition to the $1.6 million stock-based compensation expense for stock options for the nine months ended September 30, 2024, a $45,000 stock-based compensation expense was recognized for the grant of 2,500 shares of Series C Preferred Stock to the CEO during the nine months ended September 30, 2024.

Unrecognized stock-based compensation costs related to unvested awards and the weighted-average period over which the costs are expected to be recognized as of September 30, 2025, are as follows:

	Stock Options
Unrecognized stock-based compensation expense (in thousands)	$ 5,553
Expected weighted-average period compensation costs to be recognized (years)	2.4

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	1,391,000	$ 1.00	7.0	$ —
Exercised	—	$ —	—	$ —
Forfeited/canceled	(239,925)	$ 2.83	—	$ —
Outstanding as of September 30, 2025	5,716,239	$ 2.39	8.2	$ —
Exercisable as of September 30, 2025	2,351,451	$ 2.68	7.4	$ —

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:	Nine Months Ended September 30, 2025	Nine Months Ended September 30, 2024
Risk-free interest rate	4.13% - 4.25%	3.7% - 4.3%
Expected volatility	108% - 111%	97% - 101%
Expected term (years)	7.0	5.5 to 7.0
Expected dividend	0%	0%

The weighted-average grant date fair value of the options granted during the nine months ended September 30, 2025 and 2024 was $0.87 per share and $9.70 per share, respectively.

11. Related Party Transactions

During the three and nine months ended September 30, 2025, the Company paid an aggregate of $0 and $62,400, respectively, to a member of its Board of Directors pursuant to a consulting agreement effective May 15, 2025. Under the terms of the agreement, the director provides strategic advisory services to the Company, including support for finance and capital raising activities. The statement of work under this agreement pursuant to which these services were provided has expired.

12. Subsequent Events

On October 14, 2025, the investor converted $200,000 in principal amount of the Tranche 3 Note and the Company issued to the investor 482,741 shares of Common Stock at a $0.4143 conversion price per share.

On October 15, 2025, the investor converted $100,000 in principal amount of the Tranche 3 Note and the Company issued to the investor 246,305 shares of Common Stock at a $0.406 conversion price per share.

On October 16, 2025, the investor converted $200,000 in principal amount of the Tranche 1 Note and the Company issued to the investor 492,610 shares of Common Stock at a $0.406 conversion price per share.

On October 20, 2025, the investor converted $200,000 in principal amount of the Tranche 1 Note and the Company issued to the investor 492,610 shares of Common Stock at a $0.406 conversion price per share.

On October 21, 2025, the investor converted $300,000 in principal amount of the Tranche 1 Note and the Company issued to the investor 738,916 shares of Common Stock at a $0.406 conversion price per share.

On October 27, 2025, the investor converted $300,000 in principal amount of the Tranche 1 Note and the Company issued to the investor 738,916 shares of Common Stock at a $0.406 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, certain cancers, and potential human longevity applications including thymic involution reversal using a thymic organoid. Our most advanced product candidates are CYWC628, CYPS317, CYMS101 and CybroCell™.

We have completed our IND-enabling pre-clinical studies for the development of 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, and statistically significant improvement in the quality of the healed wounds in comparison with both a marketed wound care product and control.

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 in the fourth quarter of 2025. 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 preliminary IND-enabling pre-clinical studies utilizing chronic and acute psoriasis mouse models to assess the potential use of intravenous administration of fibroblast spheroids for the treatment of psoriasis. We are continuing our IND-enabling animal model studies to determine the optimal efficacious dose range and the durability of treatment for mild to moderate, and moderate to severe, psoriasis, which we expect to complete in the fourth quarter of 2025. We plan to file an IND following completion of these studies if the results support continued development.

We also have human longevity, certain cancers, and artificial pancreatic organoid research programs in the very early stages of research and development. 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 will 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 April 2021 separation from SpinalCyte, LLC (also known as FibroGenesis), our activities have consisted primarily of (i) corporate and strategic planning, (ii) recruiting and retaining personnel, (iii) financing our operations, (iv) prosecuting, maintaining and expanding our intellectual property portfolio, and (v) conducting preclinical and other research and development related to our product candidates. These activities allow us to continue building our fibroblast cell-based 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 $15.0 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 $13.1 million in proceeds from the issuance of additional convertible promissory notes.

As of September 30, 2025, we had cash and cash equivalents of $4.9 million. Since our inception, we have incurred significant operating losses. We incurred net losses of $15.4 million and $8.1 million for the nine months ended September 30, 2025 and 2024, respectively. As of September 30, 2025, we had an accumulated deficit of $50.9 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 our support short-term and 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 expect to initiate our twelve-week Phase 1/2 clinical trial utilizing CYWC628 for treatment of diabetic foot ulcers in Australia in the first quarter of 2026 and we expect to complete the clinical trial in the third quarter of 2026. These timelines have been extended as we work to resolve process issues with the manufacturing training runs and increase the number of aseptic process simulation runs needed to confirm sterility of the manufacturing process before we begin the manufacturing of CYWC628 for the clinical trial. Please see “Risk Factors – Risks Related to Manufacturing” in our Annual Report and “Item 1A. Risk Factors – Risks Related to Manufacturing” in this Quarterly Report.

CybroCell™

We successfully carried out experiments that demonstrated the ability to use the CYWC628 spheroid master cell bank for the manufacturing of the CybroCell™ drug product. Animal trials are currently underway to confirm that the therapeutic effects of the CYWC628 spheroids are similar to those of single-cell fibroblasts, which supported our IND clearance with the FDA for the planned Phase I clinical trial. If the animal trial results demonstrate similarity of therapeutic effects, we will work to amend the IND clearance with the FDA to replace single-cell fibroblasts with CYWC628 spheroids. 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, including preparing and amending regulatory filings related to our product candidates;
- 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 costs of preparing and amending regulatory filings related to our product candidates;
- 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 interest on short-term borrowing to finance D&O insurance premiums.

Statements of Operations

Results of Operations

Comparison of Three Months Ended September 30, 2025 and 2024

The following tables set forth our results of operations for the three months ended September 30, 2025 and 2024.

	Three Months Ended September 30,		Change Amount
	2025	2024	
	(unaudited, in thousands)		
Operating expenses:			
Research and development	$ 2,789	$ 1,213	$ 1,576
General, administrative and other	2,249	2,139	110
Total operating expenses	5,038	3,352	1,686
Loss from operations	(5,038)	(3,352)	(1,686)
Other income/(expense)			
Change in fair value of warrant liability	—	1,927	(1,927)
Change in fair value of forward contract liability	—	849	(849)
Change in fair value of SEPA put option liability	33	—	33
Change in fair value of convertible debt	(846)	—	(846)
Other income/(expense)	—	2	(2)
Interest income	73	79	(6)
Interest expense	—	(5)	5
Total other income/(expense)	(740)	2,852	(3,592)
Net loss	$ (5,778)	$ (500)	$ (5,278)

Research and Development Expenses

Research and development expenses were $2.8 million and $1.2 million for the three months ended September 30, 2025 and 2024, respectively. The increase of $1.6 million was primarily due to:

- increased CRO costs of $1.2 million to prepare for a clinical trial;
- increased contract research costs of $0.3 million; and
- increased personnel related expenses of $0.1 million due to hiring additional research scientists.

Research and development expenses are not tracked by product candidate.

General, Administrative and Other Expenses

General, administrative and other expenses were $2.2 million and $2.1 million for the three months ended September 30, 2025 and 2024, respectively. The increase of $0.1 million was primarily due to:

- increased expenses of $0.1 million for added personnel in 2025, which includes stock-based compensation expense;

Change in fair value of warrant liability

Change in fair value of warrant liability was $0 and a gain of $1.9 million for the three months ended September 30, 2025 and 2024, respectively. The liability instrument to investors under the GEM SPA was comprised of the contingent warrant liability and contingent put option.

Change in fair value of forward contract liability

Change in fair value of forward contract liability was $0 and $0.8 million for the three months ended September 30, 2025 and 2024, respectively. A forward contract liability to sell shares to the investor at 90% of the average daily closing price per share over the Draw Down Pricing Period is recorded each time we issue a Draw Down Notice to GEM under the Share Purchase Agreement. The forward contract liability is remeasured at the end of each quarter, if open, and again upon receipt of the Closing Notice from the investor. The forward contract liability is eliminated upon receipt of the Closing Notice and funds from the investor.

Change in fair value of 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 $10.0 million 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 $0.4 million and $0.5 million at September 30, 2025 and December 31, 2024, respectively. The change in fair value of the SEPA put option liability was a gain of $0.0 million during the three months ended September 30, 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 June 2025 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 September 30, 2025 with a $0.8 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 $3.9 million of convertible debt into shares of Common Stock during the three months ended September 30, 2025. We recognized an approximate $0.4 million 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.

Other income/(expense)

There is no other expense for the three months ended September 30, 2025 and $2,000 in other income for the three months ended September 30, 2024.

Interest income

Interest income was $0.1 million and $0.1 million for the three months ended September 30, 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 $5,000 for the three months ended September 30, 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.

Comparison of Nine Months Ended September 30, 2025 and 2024

The following tables set forth our results of operations for the nine months ended September 30, 2025 and 2024.

	Nine Months Ended September 30,		Change Amount
	2025	2024	
	(unaudited, in thousands)		
Operating expenses:			
Research and development	$ 6,610	$ 3,148	$ 3,462
General, administrative and other	7,449	6,877	572
Total operating expenses	14,059	10,025	4,034
Loss from operations	(14,059)	(10,025)	(4,034)
Other income/(expense)			
Change in fair value of warrant liability	—	4,349	(4,349)
Change in fair value of forward contract liability	—	(650)	650
Change in fair value of SEPA put option liability	23	—	23
Change in fair value of convertible debt	(963)	—	(963)
Commitment fee expenses	—	(1,941)	1,941
Other income/(expense)	(625)	31	(656)
Interest income	222	188	34
Interest expense	—	(14)	14
Total other income/(expense)	(1,343)	1,963	(3,306)
Net loss	$ (15,402)	$ (8,062)	$ (7,340)

Research and Development Expenses

Research and development expenses were $6.6 million and $3.1 million for the nine months ended September 30, 2025 and 2024, respectively. The increase of $3.5 million was primarily due to:

- increased contract research costs of $0.4 million for cell manufacturing activities;
- increased CRO costs of $2.1 million to prepare for a clinical trial;
- increased lab facilities expense of $0.2 million for lab rent;
- increased personnel related expenses of $0.3 million due to hiring additional research scientists; and
- increased research materials and supplies expenses of $0.5 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 $7.4 million and $6.9 million for the nine months ended September 30, 2025 and 2024, respectively. The increase of $0.6 million was primarily due to:

- increased expenses of $.7 million for added personnel in 2025, which includes stock-based compensation expense;
- increased professional fees of $0.2 million for accounting, legal and marketing expenses;
- increased travel expenses of $0.1 million; and
- decreased Direct Listing related expenses of $0.4 million

Change in fair value of warrant liability

Change in fair value of warrant liability was $0 and $4.3 million for the nine months ended September 30, 2025 and 2024, respectively. The liability instrument to investors under the GEM SPA was comprised of the contingent warrant liability and contingent put option.

Change in fair value of forward contract liability

Change in fair value of forward contract liability was $0 and $0.7 million for the nine months ended September 30, 2025 and 2024, respectively. We issued a Draw Down Notice to GEM under the Share Purchase Agreement on June 27, 2024, which created the forward contract liability to sell shares to the investor at 90% of the average daily closing price per share over the Draw Down Pricing Period. The $0.7 million loss during the nine months ended September 30, 2024 is based upon the estimated fair value of the forward contract liability for the Draw Down Notice issued, as remeasured at September 30, 2024, and was marked to market upon receipt of the Closing Notice from the investor.

Change in fair value of SEPA put option liability

The change in fair value of the SEPA put option liability was a loss of $0.0 million during the nine months ended September 30, 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 June 2025 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 September 30, 2025 with a $1.0 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 $9.7 million of convertible debt into shares of Common Stock during the nine months ended September 30, 2025. We recognized an approximate $0.9 million 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.

Other income/(expense)

Other expense for the nine months ended September 30, 2025 consists of $0.6 million of non-cash original discount on convertible debt and $30,000 in interest income for the nine months ended September 30, 2024.

Commitment fee expense

Commitment fee expense was $0 and $1.9 million for the nine months ended September 30, 2025 and 2024, respectively. A $2.0 million commitment fee pursuant to the GEM SPA became payable to GEM upon completion of the Direct Listing in January 2024. The commitment fee was 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 nine months ended September 30, 2024, which made $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 $0.2 million for both the nine months ended September 30, 2025 and 2024. Interest income is comprised of interest income and unrealized gain/losses on cash equivalents.

Interest expense

Interest expense was $0 and $0 for the nine months ended September 30, 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 September 30, 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 September 30, 2025, we have received aggregate proceeds of $15.0 million from sales of our convertible notes, $18.6 million from the sales of preferred stock, $10.4 million from the issuance of Common Stock and $13.1 million from the issuance of additional convertible promissory notes under the SEPA. As of September 30, 2025, we had cash and cash equivalents of $4.9 million and an accumulated deficit of $50.9 million. As of September 30, 2025, we had $5.3 million principal balance of outstanding debt with a fair value of $4.6 million.

Cash Flows

The following table sets forth a summary of our cash flows for the nine months ended September 30, 2025 and 2024.

	Nine Months Ended September 30,	
	2025	2024
	(in thousands)	
Net cash used in operating activities	$ (13,231)	$ (8,828)
Net cash used in investing activities	(262)	(85)
Net cash provided by financing activities	4,375	7,577
Net decrease in cash and cash equivalents	$ (9,118)	$ (1,336)

Cash Flows from Operating Activities

Net cash used in operating activities was $13.2 million and $8.8 million for the nine months ended September 30, 2025 and 2024, respectively, and consisted primarily of net losses of $15.4 million and $8.1 million, respectively. Noncash expenses consisting of change in fair value of convertible debt of $1.0 million, stock-based compensation expense of $2.0 million, and amortization of operating lease right-of-use asset of $0.4 million partially offset the net loss, while a decrease in prepaid expenses of $0.1 million, a decrease in accounts payable and accrued expenses of $1.4 million, and a decrease in operating lease liability of $0.4 million added to the cash used in operations in the nine months ended September 30, 2025. Noncash losses on stock-based compensation expense of $1.7 million and change in fair value of forward contract liability of $0.7 million, and amortization of operating lease right-of-use asset of $0.3 million, and change in commitment fee payable of $1.9 million partially offset the net loss, while noncash gain on change in fair value of liability instrument of $4.3 million, an increase in prepaid expenses of $0.3 million, a decrease in accounts payable and accrued expenses of $0.3 million, a decrease in payable to Parent of $0.1 million, and a decrease in operating lease liability of $0.3 million added to the cash used in operations in the nine months ended September 30, 2024.

Cash Flows from Investing Activities

Net cash used in investing activities was $0.3 million and $0.1 million for the nine months ended September 30, 2025 and 2024, respectively, and consisted primarily of laboratory equipment purchases.

Cash Flows from Financing Activities

Net cash provided by financing activities was $4.4 million and $7.6 million for the nine months ended September 30, 2025 and 2024, respectively. During the nine months ended September 30, 2025, the Company issued short-term convertible debt with a principal balance of $5.0 million net cash of $4.4 million. During the nine months ended September 30, 2024, we entered into a $0.6 million short-term borrowing agreement to finance the D&O insurance policy premiums and repaid $0.5 million of the principal borrowed, and we raised $7.5 million of net proceeds from the sale of common stock under the GEM SPA.

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 September 30, 2025, we had an accumulated deficit of $50.9 million and cash and cash equivalents of $4.9 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. During the nine months ended September 30, 2025, we have implemented measures to reduce operating expenses including delaying certain research and development project spend while prioritizing near term pipeline projects, limiting finance, legal and administrative costs, and pursuing options to limit spend on office space. 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 nine months ended September 30, 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 September 30, 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 September 30, 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 and funding allows.

Changes in Internal Control over Financial Reporting

There has been no change in the Company's internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) that occurred during the three months ended September 30, 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. During the nine months ended September 30, 2025, we have implemented measures to reduce operating expenses including delaying certain research and development project spend while prioritizing near term pipeline projects, limiting finance, legal and administrative costs, and pursuing options to limit spend on office space. If we are unable to continue as a going concern, we will be forced to further 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.

Risks Related to Manufacturing

Manufacturing cell therapy products is complex and subject to both human and systemic risks. Our third-party manufacturers or we may encounter difficulties in production and sourcing and may be subject to variations and supply constraints of critical components. If we or any of our third-party manufacturers encounter such difficulties, our ability to supply our product candidates for clinical trials or our products for patients, if approved, could be delayed or prevented.

The manufacture of biologic cell therapy product candidates, and products, if approved, is complex and requires significant expertise and capital investment, including developing advanced manufacturing techniques and process controls. Manufacturers of biologic products often encounter difficulties in production and sourcing, particularly in scaling up or out, validating the production process, and assuring high reliability of the manufacturing processes (including the absence of contamination), in light of variations and supply constraints of critical components. These problems include logistics and shipping, difficulties with production costs and yields, quality control, including consistency, stability, purity, and efficacy of the product, product testing, operator error, and availability of qualified personnel, as well as compliance with strictly enforced federal, state, and foreign regulations. For example, timelines for our planned twelve-week Phase 1/2 clinical trial utilizing CYWC628 for treatment of diabetic foot ulcers in Australia have been extended as we work with our CDMO to resolve process issues with the manufacturing training runs and increase the number of aseptic process simulation runs needed to confirm sterility of the manufacturing process before we begin the manufacture of CYWC628 for the clinical trial. Furthermore, if contaminants are discovered in our supply of our product candidates or in the manufacturing facilities, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure you that any stability, purity, and efficacy failures, deficiencies, or other issues relating to manufacturing our product candidates will not occur in the future.

Additionally, our product candidates are derived from cells collected from humans. Such cells may vary in type and quality as the donors may vary in age, medical history, and many other factors. We have strict specifications for donor cell material and our product candidates. The donor cell material variability may exceed our manufacturing process capability or deviate from the specified ranges and result in failure in the production of the cell therapy product, lower quality batches, or even require adjustments to the specifications approved by authorities. The donor cell material may also be variable in factors that we currently may not be able to detect with the analytical methods used or may not know how to measure. We may also discover failures with the material after production. As a result, we may not be able to deliver the quality and consistency of our cell therapy products that we need or may need to re-collect cell material which can increase costs and/or cause delay, result in recalls, adversely impact patient outcomes and otherwise harm our clinical trials, reputation, business, and prospects.

We may fail to manage the logistics of collecting and shipping patient material to the manufacturing site, shipping the product candidate back to the relevant parties, and experiencing delays or shortages of certain clinical or commercial-grade supplies and components. Logistical and shipment delays and problems caused by us, our vendors, or other factors not in our control, including business interruptions, global supply chain issues, and weather, could prevent or delay the delivery of product candidates to patients. Additionally, we have to maintain a complex chain of identity and chain of custody with respect to donor material as it moves to the manufacturing facility, through the manufacturing processes, and ultimately to a patient. Failure to maintain a chain of identity and chain of custody could result in patient death, loss of product, or regulatory action.

Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including clinical holds, fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, seizures or voluntary recalls of product candidates, operating restrictions, and criminal prosecutions, any of which could significantly affect supplies of our product candidates. The facilities used by our contract manufacturers to manufacture our product candidates must be evaluated by the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with cGMPs. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, the EMA, or other comparable regulatory authorities, we may not be able to secure and/or maintain regulatory approval for our product candidates manufactured at these facilities. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA finds deficiencies or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Contract manufacturers may face manufacturing or quality control problems causing drug substance production and shipment delays or a situation where the contractor may not be able to maintain compliance with the applicable cGMP requirements. Any failure to comply with cGMP requirements or other FDA, EMA and comparable foreign regulatory requirements could adversely affect our clinical research activities and our ability to develop our product candidates and market our products, if approved.

The production of our cell banks and product candidates by a contract development manufacturing organization may fail and result in delays, additional costs, or technical failure.

We have contracted with CDMOs for the production of our master cell banks and working cell banks for our fibroblast cell-based product candidates to enable clinical trials. If the CDMO is unable to produce our master cell banks, working cell banks and our fibroblast cell-based product candidates to enable clinical trials, we may encounter delays, additional costs, or technical failure of one or more of our product candidates. For example, timelines for our planned twelve-week Phase 1/2 clinical trial utilizing CYWC628 for treatment of diabetic foot ulcers in Australia have been extended as we work with our CDMO to resolve process issues with the manufacturing training run and increase the number of aseptic process simulation runs needed to confirm sterility of the manufacturing process before we begin the manufacture of CYWC628 for the clinical trial.

Our reliance on third parties reduces our control over our product candidate development activities but does not relieve us of our responsibility to ensure compliance with all required legal, regulatory and industry standards. For example, the FDA and other regulatory authorities require that our product candidates and any products that we may eventually commercialize be manufactured according to cGMP requirements. Any failure by our third-party manufacturers to comply with cGMP or maintain a compliance status acceptable to the FDA or other regulatory authorities or failure to scale up manufacturing processes, including any failure to deliver sufficient quantities of product candidates in a timely manner, could lead to a delay in, or failure to obtain, regulatory approval of any of our product candidates.

If we were to need an alternate CDMO, we would incur added costs and delays in identifying and qualifying any such replacement. In addition, we expect to order drug product and services on a statement of work or purchase order basis and do not plan to enter into long-term dedicated capacity or minimum supply arrangements with any commercial manufacturer. We may not be able to timely secure needed supply arrangements on satisfactory terms, or at all. Our failure to secure these arrangements as needed could have a material adverse effect on our ability to complete the development of our product candidates or, to commercialize them, if approved. We may be unable to conclude agreements for commercial supply with third-party manufacturers or may be unable to do so on acceptable terms. There may be difficulties in scaling up to commercial quantities and formulation of our product candidates, and the costs of manufacturing could be prohibitive.

Changes in the methods of product candidate manufacturing or formulation may result in additional costs or delay.

As product candidates proceed through preclinical studies to late-stage clinical trials towards potential marketing approval and commercialization, it is common that various aspects of the development program, such as manufacturing methods, formulation, materials, and processes, are altered along the way in an effort to optimize processes and product characteristics. Such alterations can also occur due to changes in manufacturers. Such changes carry the risk that they will not achieve their intended objectives. Any such changes could cause our product candidates to perform differently and affect the results of planned clinical trials or other future clinical trials conducted with product candidates produced using the modified manufacturing methods, materials, and processes. Such changes may also require additional testing, FDA notification or FDA approval. This could delay the completion of clinical trials, require the conduct of bridging clinical trials or the repetition of one or more clinical trials beyond those we currently anticipate, increase clinical trial costs, delay approval of our product candidates and jeopardize our ability to commercialize our product candidates if approved. In addition, we may be required to make significant changes to our upstream and downstream processes across our pipeline, which could delay the development of future product candidates. For example, we encountered process issues with the manufacturing training run of CYWC628 and will need to increase the number of aseptic process simulation runs needed to confirm sterility of the manufacturing process before we begin the manufacture of CYWC628 for the clinical trial. These issues have caused us to extend the timelines for the initiation and completion of our planned twelve-week Phase 1/2 clinical trial utilizing CYWC628 for treatment of diabetic foot ulcers in Australia. If changes are needed to the manufacturing methods for CYWC628 as a result of these issues, the timing for the initiation and completion of our clinical trial in Australia may be further delayed.

We rely on third parties for our manufacturing process and may, in the future, depend on third-party manufacturers for our product candidates, and this increases the risk related to the timely and sufficient production of our product candidates.

We do not have complete control over all aspects of the manufacturing process of, and are dependent on, our contract manufacturing partners for compliance with cGMP regulations for manufacturing our cell therapy product candidates. Third-party manufacturers may be unable to comply with cGMP regulations or similar regulatory requirements outside the United States. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, the EMA, or other regulatory authorities, we will not be able to produce our product candidates. In addition, we do not have control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. For example, we are currently working with our CDMO to resolve process issues with the manufacturing training runs of CYWC628 and to increase the number of aseptic process simulation runs needed to confirm sterility of the manufacturing process before we begin the manufacture of CYWC628 for our planned twelve-week Phase 1/2 clinical trial utilizing CYWC628 for treatment of diabetic foot ulcers in Australia. If these issues are not resolved, we will be unable to manufacture CYWC628 for our planned clinical trial in a timely manner. If the FDA, the EMA, or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain marketing approval for or market our product candidates, if approved. Our failure, or the failure of our third-party manufacturers, to comply with applicable regulations could result in sanctions being imposed on us, including fines, injunctions, civil penalties, delays, suspension or withdrawal of approvals, license revocation, seizures or recalls of product candidates, operating restrictions and criminal prosecutions, any of which could significantly and adversely affect supplies of our product candidates and harm our business and results of operations. Furthermore, the raw materials for our product candidates may be sourced, in some cases, from a single-source supplier. If we were to experience an unexpected loss of supply of any of our product candidates or any of our future product candidates for any reason, whether as a result of manufacturing, supply, or storage issues or otherwise, we could experience delays, disruptions, suspensions, or terminations of, or be required to restart or repeat, any pending or ongoing clinical trials.

We currently rely on third-party manufacturers to produce our product candidates. In the event that we or any of our third-party manufacturers fail to comply with such requirements or to perform with certain requirements in relation to quality, timing, or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to enter into an agreement with another third party, which we may not be able to do on commercially reasonable terms, if at all. In particular, any replacement of our third-party manufacturers could require significant effort and expertise because there may be a limited number of qualified replacements. In some cases, the technical skills or technology required to manufacture our product candidates may be unique or proprietary to us or the third-party manufacturer. We may have difficulty transferring such skills or technology to another third party, and a feasible alternative may not exist. In addition, certain of our product candidates and our own proprietary methods have never been produced or implemented outside of our company. Therefore, we may experience delays in our development programs if we attempt to establish new third-party manufacturing arrangements for these product candidates or methods. These factors would increase our reliance on such manufacturers or require us to obtain a license from such manufacturers in order to have another third party manufacture our product candidates. If we are required to or voluntarily stop manufacturing our product candidates for any reason, we will be required to verify that the new manufacturer maintains facilities and procedures that comply with quality standards and with all applicable regulations and guidelines and that the product produced is equivalent to that produced in our facility. The delays associated with the verification of a new manufacturer and equivalent product could negatively affect our ability to develop product candidates in a timely manner or within budget.

Our or a third party's failure to execute our manufacturing requirements, do so on commercially reasonable terms and timelines, and comply with cGMP requirements could adversely affect our business in a number of ways, including:

- inability to meet our product specifications and quality requirements consistently;
- inability to initiate or continue clinical trials of our product candidates under development;
- delays in submitting regulatory applications or receiving marketing approvals for our product candidates, if at all;
- inability to commercialize any product candidates that receive marketing approval on a timely basis;
- loss of the cooperation of future collaborators;
- subjecting third-party manufacturing facilities or our manufacturing facilities to additional inspections by regulatory authorities;
- requirements to cease development or to recall batches of our product candidates; and
- in the event of approval to market and commercialize our product candidates, an inability to meet commercial demands for our product candidates or any future product candidates.

Risks Related to Ownership of Our Common Stock

Failure to maintain compliance with the applicable Nasdaq continued listing requirements could result in our common stock being delisted, which could limit stockholders' ability to trade our common stock.

As a listed company on Nasdaq, we are required to meet certain financial, public float, bid price and liquidity standards on an ongoing basis to continue the listing of our common stock. If we fail to meet these continued listing requirements, our common stock may be subject to delisting, which could materially impact the liquidity of our common stock making it more challenging to buy and sell shares of our common stock. On April 1, 2025, the listing of our common stock was moved from the Nasdaq Global Market to the Nasdaq Capital Market. We requested this move to allow us to satisfy less stringent financial, liquidity, and market capitalization requirements to continue the listing of our common stock. For example, the market value requirement of the Nasdaq Capital Market is $35 million versus $50 million for the Nasdaq Global Market and the stockholders' equity requirement

for the Nasdaq Capital Market is $2.5 million versus $10 million for the Nasdaq Global Market. Following the transfer, we remain subject to the $1 minimum bid price requirement and continued listing requirements for the Nasdaq Capital Market, and no assurance can be given that we will be able to satisfy these requirements. If we fail to meet any of these requirements after the transfer, our securities may be delisted from Nasdaq.

On July 1, 2025, we received a notification letter from the Nasdaq Listing Qualifications Staff notifying us that the closing bid price of our shares of common stock was below the minimum closing bid price of $1.00 per share during the previous 30 consecutive trading days, or the Notice, as required for continued listing on the Nasdaq Capital Market under Nasdaq Listing Rule 5550(a)(2).

In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we have been provided an initial period of 180 calendar days, or until December 29, 2025, to regain compliance with this requirement. To regain compliance, the closing bid price of our common stock must be $1.00 per share or more for a minimum of 10 consecutive business days at any time before December 29, 2025. If we do not regain compliance with Rule 5550(a)(2) by December 29, 2025, we may be eligible for an additional 180 calendar day compliance period. To qualify, we will be required to meet the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, except the bid price requirement, and will need to provide written notice to Nasdaq of our intention to cure the deficiency during the second compliance period. If it appears to the Staff that we will not be able to cure the deficiency, or if we are otherwise not eligible, Nasdaq will notify us that our securities will be subject to delisting. In the event of such notification, we may appeal the Staff's determination to delist our securities, but there can be no assurance the Staff will grant our request for continued listing.

Additionally, on August 4, 2025, we received a notification letter from the Staff notifying us that we do not meet the requirement in Nasdaq Listing Rule 5550(b)(2) to maintain a minimum market value of listed securities, or MVLS, of $35.0 million that is required for continued listing on The Nasdaq Capital Market.

In accordance with Nasdaq Listing Rule 5810(c)(3)(C), we have a period of 180 calendar days, or until February 2, 2026, to regain compliance with this requirement. To regain compliance, our MVLS must close at $35.0 million or more for a minimum of 10 consecutive business days at any time before February 2, 2026. If we do not regain compliance with Rule 5550(b)(2) by February 2, 2026, Nasdaq will notify us that our securities are subject to delisting. In the event of such notification, we may appeal the Staff's determination to delist our securities, but there can be no assurance the Staff will grant our request for continued listing.

We continue to actively monitor our performance with respect to the listing standards and will consider available options to resolve any deficiency and maintain compliance with the Nasdaq rules. There can be no assurance that we will be able to maintain compliance or, if we fall out of compliance, regain compliance with any deficiency, or if we implement an option that regains our compliance, maintain compliance thereafter. If we fail to regain compliance with the Nasdaq continued listing standards, our common stock will be subject to delisting from Nasdaq.

Without a Nasdaq market listing, stockholders may have a difficult time getting a quote for the sale or purchase of our common stock, the sale or purchase of our common stock would likely be made more difficult and the trading volume and liquidity of our common stock could decline. Delisting from Nasdaq could also result in negative publicity and could also make it more difficult for us to raise additional capital. The absence of such a listing may adversely affect the acceptance of our common stock as currency or the value accorded by other parties. Further, if we are delisted, we would lose federal pre-emption of state securities laws as it relates to our securities and thus also incur additional costs under state blue sky laws in connection with any sales of our securities. These requirements could severely limit the market liquidity of our common stock and the ability of our stockholders to sell our common stock in the secondary market. If our common stock is delisted by Nasdaq, our common stock may be eligible to trade on an over-the-counter quotation system, such as the OTCQB market, where an investor may find it more difficult to sell our common stock or obtain accurate quotations as to the market value of our common stock. We cannot assure you that our common stock, if delisted from Nasdaq, will be listed on another national securities exchange or quoted on an over-the counter quotation system. If our common stock is delisted, it may come within the definition of "penny stock" as defined in the Exchange Act and would be covered by Rule 15g-9 of the Exchange Act. Rule 15g-9 imposes additional sales practice requirements on broker-dealers who sell securities to persons other than established customers and accredited investors. For transactions covered by Rule 15g-9, the broker-dealer must make a special suitability determination for the purchaser and receive the purchaser's written agreement to the transaction prior to the sale. Consequently, Rule 15g-9, if it were to become applicable, would affect the ability or willingness of broker-dealers to sell our securities, and accordingly would affect the ability of stockholders to sell their securities in the public market. These additional procedures could also limit our ability to raise additional capital in the future.

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

The following sets forth information regarding all unregistered securities we sold during the nine months ended September 30, 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, 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.

Below is a summary of conversions during the nine months ended September 30, 2025 by the Investor of short-term convertible notes issued to the Investor under the SEPA:

Date	Tranche	Principal Amount	Shares Issued	Price Per Share
January 23, 2025	Second Note	$ 900,000	552,113	$ 1.6301
January 27, 2025	Second Note	$ 500,000	317,238	$ 1.5761
January 29, 2025	Second Note	$ 500,000	334,336	$ 1.4955
February 7, 2025	Second Note	$ 1,100,000	732,941	$ 1.5008
February 21, 2025	Second Note	$ 250,000	232,169	$ 1.0768
March 4, 2025	Second Note	$ 350,000	361,794	$ 0.9674
April 11, 2025	Second Note	$ 200,000	263,643	$ 0.7586
April 15, 2025	Second Note	$ 200,000	263,643	$ 0.7586
May 15, 2025	Second Note	$ 300,000	388,450	$ 0.7723
June 2, 2025	Second Note	$ 100,000	147,579	$ 0.6776
June 3, 2025	Second Note	$ 300,000	442,739	$ 0.6776
June 20, 2025	Second Note	$ 100,000	144,216	$ 0.6934
June 24, 2025	Second Note	$ 200,000	295,377	$ 0.6771
June 26, 2026	Third Note	$ 300,000	443,066	$ 0.6771
June 27, 2025	Third Note	$ 500,000	738,443	$ 0.6771
July 15, 2025	Third Note	$ 300,000	533,428	$ 0.5624
July 28, 2025	Third Note	$ 300,000	493,258	$ 0.6082
August 1, 2025	Third Note	$ 600,000	1,035,911	$ 0.5792
August 18, 2025	Third Note	$ 300,000	571,537	$ 0.5249
August 25, 2025	Third Note	$ 300,000	544,959	$ 0.5505
September 9, 2025	Third Note	$ 300,000	566,572	$ 0.5295
September 16, 2025	Third Note	$ 300,000	597,133	$ 0.5024
September 25, 2025	Third Note	$ 400,000	815,660	$ 0.4904
September 30, 2025	Third Note	$ 1,100,000	2,243,065	$ 0.4904

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	Amendment to Amended and Restated Certificate of Incorporation of FibroBiologics, Inc.	8-K	001-41934	3.1	June 13, 2025
3.3	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: October 31, 2025

By: */s/ Jason D. Davis*
Jason D. Davis
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 September 30, 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: October 31, 2025

/s/ Pete O'Heeron
Pete O'Heeron
Chief Executive Officer
Principal Executive Officer

Exhibit 31.2

CERTIFICATION

I, Jason D. Davis, certify that:

1. I have reviewed this quarterly report on Form 10-Q for the period ended September 30, 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: October 31, 2025

/s/ Jason D. Davis
Jason D. Davis
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 September 30, 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 Jason D. Davis, 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/ Jason D. Davis
Jason D. Davis
Chief Financial Officer

Date: October 31, 2025