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, 2026.

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.)
9350 Kirby Drive, Suite 300 **Houston, Texas** (Address of principal executive offices)	**77054** (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 November 16, 2026, 8,989,475 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, 2026

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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, clinical trials, manufacturing, 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 period over which we estimate our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital expenditure requirements;
- 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 and progress of manufacturing of our drug product candidates;
- 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;
- our ability to maintain compliance with the continued listing requirements of the Nasdaq Capital Market;
- the impact of laws and regulations; and
- the risks described in this Quarterly Report under Part II, Item 1A, “Risk Factors,” in our Annual Report (as defined below) under Item 1A, “Risk Factors,” and our other filings with the SEC.

We have based these forward-looking statements largely on our current expectations and projections about our business, the industry in which we operate and financial trends that we believe may affect our business, financial condition, results of operations and prospects, and these forward-looking statements are not guarantees of future performance or development. These forward-looking statements 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, 2025, as amended, 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, 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

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

	September 30, 2026	December 31, 2025
	(unaudited)	
Assets		
Current assets		
Cash and cash equivalents	$ 1,168	$ 4,894
Research and development supplies and other current assets	2,991	—
Prepaid expenses	618	1,455
Total current assets	4,777	6,349
Property and equipment, net	661	842
Operating lease right-of-use asset, net	1,265	2,380
Other assets	48	48
Total assets	$ 6,751	$ 9,619
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable and accrued expenses	$ 3,667	$ 945
Operating lease liability, short-term	264	706
SEPA put option liability	—	108
Total current liabilities	3,931	1,759
Operating lease liability, long-term	1,011	1,704
Total liabilities	4,942	3,463
Stockholders' equity		
Preferred Stock, $0.00001 par value; 10,000,000 shares authorized as of September 30, 2026 and December 31, 2025	—	—
Preferred Stock, $0.00001 par value; 2,500 Series C Preferred shares authorized; 125 shares issued and outstanding as of September 30, 2026 and December 31, 2025	—	—
Voting Common Stock, $0.00001 par value; 300,000,000 shares authorized as of September 30, 2026 and December 31, 2025; 8,332,312 shares and 3,325,986 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively	1	1
Additional paid-in capital	69,137	60,319
Accumulated deficit	(67,329)	(54,164)
Total stockholders' equity	1,809	6,156
Total liabilities and stockholders' equity	$ 6,751	$ 9,619

On March 30, 2026, the Company effected a reverse split of the Company's issued and outstanding common stock. The reverse split was at a ratio of one share for every 20 shares previously held with no change in the par value per share. The reverse split did not change the number of authorized shares of common stock. All common stock share and per share data, and exercise price data for applicable common stock equivalents, included in these unaudited condensed consolidated financial statements have been retroactively adjusted to reflect the reverse split.

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 share and per share data)

	For the Three Months Ended September 30,		For the Nine Months Ended September 30,	
	2026	**2025**	**2026**	**2025**
Operating expenses:				
Research and development	$ 2,075	$ 2,789	$ 6,686	$ 6,610
General, administrative and other	1,996	2,249	6,486	7,449
Total operating expenses	4,071	5,038	13,172	14,059
Loss from operations	(4,071)	(5,038)	(13,172)	(14,059)
Other income/(expense):				
Change in fair value of SEPA put option liability	9	33	63	23
Change in fair value of convertible debt	—	(846)	—	(963)
Other expense	(2)	—	(96)	(625)
Interest income	20	73	55	222
Interest expense	(4)	—	(15)	—
Total other income/(expense)	23	(740)	7	(1,343)
Net loss	$ (4,048)	$ (5,778)	$ (13,165)	$ (15,402)
Net loss per share, basic and diluted	$ (0.38)	$ (2.68)	$ (1.91)	$ (7.80)
Weighted-average shares outstanding, basic and diluted	10,588,204	2,153,627	6,902,856	1,974,386

On March 30, 2026, the Company effected a reverse split of the Company's issued and outstanding common stock. The reverse split was at a ratio of one share for every 20 shares previously held with no change in the par value per share. The reverse split did not change the number of authorized shares of common stock. All common stock share and per share data, and exercise price data for applicable common stock equivalents, included in these unaudited condensed consolidated financial statements have been retroactively adjusted to reflect the reverse split.

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

FibroBiologics, Inc.
Condensed Consolidated Statements of Changes in Stockholders' Equity
For the Three and Nine Months Ended September 30, 2026 and 2025
(unaudited, in thousands, except shares)

	Series C Preferred Stock		Voting Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balance – December 31, 2025	**125**	**$ —**	**3,325,986**	**$ 1**	**$ 60,319**	**$ (54,164)**	**$ 6,156**
Issuance of Voting Common Stock	—	—	133,108	—	750	—	750
Exercise of pre-funded warrants	—	—	53,750	—	—	—	—
Issuance of fractional shares from reverse stock split	—	—	343	—	—	—	—
Stock-based compensation expense	—	—	—	—	694	—	694
Net loss	—	—	—	—	—	(5,000)	(5,000)
Balance (Unaudited) - March 31, 2026	**125**	**$ —**	**3,513,187**	**$ 1**	**$ 61,763**	**$ (59,164)**	**$ 2,600**
Issuance of Voting Common Stock	—	—	1,323,433	—	2,862	—	2,862
Issuance of pre-funded warrants	—	—	—	—	2,584		2,584
Exercise of pre-funded warrants	—	—	1,243,940	—	—	—	—
Stock-based compensation expense	—	—	—	—	707	—	707
Net loss	—	—	—	—	—	(4,117)	(4,117)
Balance (Unaudited) - June 30, 2026	**125**	**$ —**	**6,080,560**	**$ 1**	**$ 67,916**	**$ (63,281)**	**$ 4,636**
Issuance of Voting Common Stock	—	—	334,119	—	550	—	550
Exercise of pre-funded warrants	—	—	1,917,633	—	—	—	—
Stock-based compensation expense	—	—	—	—	671	—	671
Net loss	—	—	—	—	—	(4,048)	(4,048)
Balance (Unaudited) – September 30, 2026	**125**	**$ —**	**8,332,312**	**$ 1**	**$ 69,137**	**$ (67,329)**	**$ 1,809**

	Series C Preferred Stock		Voting Common Stock		Additional Paid-in	Accumulated	Total Stockholders'
	Shares	Amount	Shares	Amount	Capital	Deficit	Equity
Balance – December 31, 2024	**125**	**$ —**	**1,754,286**	**$ —**	**$ 38,253**	**$ (35,518)**	**$ 2,735**
Issuance of Voting Common Stock for commitment fee payable	—	—	5,950	—	250	—	250
Conversion of Short-term convertible note payable into Voting Common Stock	—	—	117,530	—	3,780	—	3,780
Stock-based compensation expense	—	—	—	—	551	—	551
Net loss	—	—	—	—	—	(4,966)	(4,966)
Balance (Unaudited) - March 31, 2025	**125**	**$ —**	**1,877,766**	**$ —**	**$ 42,834**	**$ (40,484)**	**$ 2,350**
Conversion of Short-term convertible debt into Voting Common Stock	—	—	156,358	—	2,439	—	2,439
Stock-based compensation expense	—	—	—	—	729	—	729
Net loss	—	—	—	—	—	(4,658)	(4,658)
Balance (Unaudited) - June 30, 2025	**125**	**$ —**	**2,034,124**	**$ —**	**$ 46,002**	**$ (45,142)**	**$ 860**
Conversion of Short-term convertible debt into Voting Common Stock	—	—	370,076	—	4,339	—	4,339
Stock-based compensation expense	—	—	—	—	704	—	704
Net loss	—	—	—	—	—	(5,778)	(5,778)
Balance (Unaudited) – September 30, 2025	**125**	**$ —**	**2,404,200**	**$ —**	**$ 51,045**	**$ (50,920)**	**$ 125**

On March 30, 2026, the Company effected a reverse split of the Company's issued and outstanding common stock. The reverse split was at a ratio of one share for every 20 shares previously held with no change in the par value per share. The reverse split did not change the number of authorized shares of common stock. All common stock share and per share data, and exercise price data for applicable common stock equivalents, included in these unaudited condensed consolidated financial statements have been retroactively adjusted to reflect the reverse split.

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,	
	2026	**2025**
Cash flows from operating activities		
Net loss	$ (13,165)	$ (15,402)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in fair value of SEPA put option liability	(63)	(23)
Change in fair value of convertible debt	—	963
Non-cash original discount on convertible debt	—	625
Stock-based compensation expense	2,072	1,984
Gain on termination of operating lease	(32)	—
Amortization of operating lease right-of-use asset	322	420
Depreciation expense	198	178
Changes in operating assets and liabilities:		
Research and development supplies and other current assets	(2,991)	—
Prepaid expenses	837	(148)
Accounts payable and accrued expenses	2,722	(1,378)
Other current assets	—	18
Other assets	—	(48)
Operating lease liability	(310)	(420)
Net cash used in operating activities	(10,410)	(13,231)
Cash flows from investing activities		
Purchases of property and equipment	(18)	(262)
Net cash used in investing activities	(18)	(262)
Cash flows from financing activities		
Proceeds from short-term convertible debt	327	4,375
Repayments of short-term borrowing	(327)	—
Proceeds from issuance of pre-funded warrants, net of direct costs	2,584	—
Proceeds from issuance of common stock, net of direct costs	4,118	—
Net cash provided by financing activities	6,702	4,375
Net decrease in cash and cash equivalents	(3,726)	(9,118)
Cash and cash equivalents, beginning of period	4,894	13,985
Cash and cash equivalents, end of period	$ 1,168	$ 4,867
Supplemental disclosure of cash flow information:		
Cash paid for income taxes	$ —	$ —
Cash paid for interest	$ 15	$ 5
Supplemental disclosure of non-cash investing and financing activities:		
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, 2026

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 a clinical-stage biotechnology company headquartered in Houston, Texas, developing innovative treatments for chronic diseases using fibroblast cells. The Company's primary focus is the initiation and progression of preclinical studies and clinical-stage U.S. Food and Drug Administration trials related to fibroblast treatments for wound healing, psoriasis, multiple sclerosis, degenerative disc disease, certain cancers, and potential human longevity applications including thymic involution reversal using a thymic organoid. Prior to Inception, preclinical research and development related to these disease pathways took place under the parent company, SpinalCyte, LLC (the "Parent").

Formation of Wholly-Owned Subsidiary

On June 12, 2025, the Company formed a wholly-owned subsidiary, FibroBiologics Australia Pty Ltd. This entity acts 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, 2026, the Company had an accumulated deficit of $67.3 million and cash and cash equivalents of $1.2 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 condensed consolidated financial statements. While management has implemented plans to obtain additional funding, 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 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 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. 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 and other income and expenses.

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, 2026, unaudited condensed consolidated statements of operations for the three and nine months ended September 30, 2026 and 2025, unaudited condensed consolidated statements of changes in stockholders' equity for the three and nine months ended September 30, 2026 and 2025, and unaudited condensed consolidated statements of cash flows for the nine months ended September 30, 2026 and 2025, and the accompanying notes 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, 2025 as filed with the SEC on February 24, 2026 (as amended on March 13, 2026) (the "Annual Report"), 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, 2026, the results of operations for the three and nine months ended September 30, 2026 and 2025, the unaudited condensed consolidated statements of changes in stockholders' equity for the three and nine months ended September 30, 2026 and 2025, and the unaudited condensed consolidated statements of cash flows for the nine months ended September 30, 2026 and 2025. The December 31, 2025 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 8 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 the 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 8) 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 consolidated 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 $1.2 million and $4.9 million of cash and cash equivalents as of September 30, 2026 and December 31, 2025, respectively.

Research and development supplies and other current assets

Materials acquired to be used in clinical research, that have an alternative future use, are capitalized when the materials are acquired, and included in research and development supplies. These supplies are recognized as expense as they are consumed through use for testing or clinical activities, or have spoiled. The costs of materials that were acquired for a particular research and development activity and have no alternative future use are expensed in the period acquired.

Research and development supplies purchased, valued at cost, and capitalized for future use were $2.6 million and $0 at September 30, 2026 and December 31, 2025, respectively.

Other current assets consists of a loan receivable. See Note 4.

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, 2026 and 2025.

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 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 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 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 statement 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. If an equity classified instrument is subsequently required to be reclassified as a liability, an amount reflective of that instrument's fair value would be reclassified to a liability at that time.

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 $0.6 million for the three and nine months ended September 30, 2026, respectively. 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.

Stock-Based Compensation

The Company recognizes compensation costs related to stock options granted to employees and non-employees 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 shares of the Company's common stock, par value $0.00001 per share (the "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.

Reverse Stock Split

On March 30, 2026, the Company effected a reverse split of the Company's issued and outstanding common stock, (the "March 2026 Reverse Split"). The March 2026 Reverse Split was at a ratio of one share for every 20 shares previously held with no change in the par value per share. The March 2026 Reverse Split did not change the number of authorized shares of common stock. Pursuant to the Company's Amended and Restated Certificate of Incorporation, as amended, the outstanding shares of Series C Preferred Stock were proportionately adjusted following the March 2026 Reverse Split. The adjustment to the outstanding shares of Series C Preferred Stock did not change the number of authorized shares of Series C Preferred Stock.

Recently Issued Accounting Pronouncements

In November 2024, the Financial Accounting Standards Board issued Accounting Standards Update ("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 condensed consolidated 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)	2026	2025	2026	2025
Numerator:				
Net loss	$ (4,048)	$ (5,778)	$ (13,165)	$ (15,402)
Denominator:				
Weighted-average shares outstanding, basic and diluted	10,588,204	2,153,627	6,902,856	1,974,386
Net loss per share, basic and diluted	$ (0.38)	$ (2.68)	$ (1.91)	$ (7.80)

For the three and nine months ended September 30, 2026 and 2025, the Company reported net losses and, accordingly, potential common shares were not included since such inclusion would have been anti-dilutive. In accordance with ASC 260-10-45-13, the Company's 2,538,760 unexercised pre-funded warrants are considered outstanding in the context of basic earnings per share.

4. Research and Development Supplies and Other Current Assets

The Company's research and development supplies consist of materials that are currently being manufactured at its contract development and manufacturing organization and are valued at cost, and capitalized for future use. These supplies were $2.6 million and $0 at September 30, 2026 and December 31, 2025, respectively.

Other current assets consist of a $0.4 million note receivable from a shareholder of the Company, Golden Knight Incorporated, LP (the "Note"). The Note is due on January 14, 2027 and has an interest rate of 3.63%. The Company accounts for the note receivable under ASC 310, *Receivables*. As the note is short-term in nature with a one year maturity, and there is an applicable federal interest rate applied, and the Company expects full repayment at the end of the term, the note is classified as an asset rather than as equity.

5. Property and Equipment

Property and equipment, net consist of the following:

(in thousands)	September 30, 2026	December 31, 2025
Laboratory equipment	$ 1,215	$ 1,198
Computer equipment, software, and other	93	92
Total property and equipment at cost	1,308	1,290
Less: Accumulated depreciation	(647)	(448)
Property and equipment, net	$ 661	$ 842

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 approximately $66,000 and $65,000 for the three months ended September 30, 2026 and 2025, respectively, and was $198,000 and $178,000 for the nine months ended September 30, 2026 and 2025, respectively.

6. 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. Cash equivalents include instruments such as money market accounts and other short-term treasuries.

	Fair Value Measurement as of September 30, 2026			
(in thousands)	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	$ 102	$ —	$ —	$ 102
Total assets fair value	$ 102	$ —	$ —	$ 102
Liabilities:				
SEPA put option liability	$ —	$ —	$ —	$ —
Total liabilities fair value	$ —	$ —	$ —	$ —

	Fair Value Measurement as of December 31, 2025			
(in thousands)	Level 1	Level 2	Level 3	Total
Assets:				
Cash equivalents	$ 2,860	$ —	$ —	$ 2,860
Total assets fair value	$ 2,860	$ —	$ —	$ 2,860
Liabilities:				
SEPA put option liability	$ —	$ —	$ 108	$ 108
Total liabilities fair value	$ —	$ —	$ 108	$ 108

The following table summarizes the activity related to Level 3 financial liabilities for the nine months ended September 30, 2026:

(in thousands)	SEPA Put Option Liability
Fair value at December 31, 2025	$ 108
Change in fair value of SEPA put option liability	(63)
Sales under SEPA Agreement	(45)
Fair value at September 30, 2026	$ —

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 Company entered in the SEPA on December 30, 2024 and 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 December 30, 2024 note was fully converted in June 2025, the June 16, 2025 note was fully converted in October 2025, and the December 20, 2024 note was paid off in November 2025 and the total of the fair values of these notes at September 30, 2025 was $4.6 million. Assumptions used in the valuation model at September 30, 2025 for these notes included the closing bid price of $11.00, a term of one year, an annual risk-free rate of 4.3%, and a volatility of 60%, and at December 31, 2024 for both notes included the closing bid price of $2.00, a term of 0.22 years, an annual risk free rate of 4.01%, and a volatility of 57%.

As further described in Note 8, upon entering into the SEPA, the Company 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.

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, 2026.

7. Stockholders' Equity

The Company's Amended and Restated Certificate of Incorporation was amended on March 30, 2026, to effect the March 2026 Reverse Split.

Authorized Capital - As of September 30, 2026, the Company authorized 300,000,000 shares of Common Stock and 10,000,000 shares of preferred stock, of which 2,500 were designated shares of Series C preferred stock.

In March 2026, the Company sold 133,108 shares using the SEPA for proceeds of $0.7 million. For further information, see Note 8.

On April 2, 2026, the Company sold in a registered offering (i) 1,028,788 shares of Common Stock, (ii) pre-funded warrants to purchase up to 1,243,940 shares of Common Stock, and (iii) warrants to purchase up to 2,272,728 shares of Common Stock. The combined public offering price for each share of Common Stock, together with an accompanying warrant to purchase one share of Common Stock, was $1.32, and the combined public offering price for each pre-funded warrant, together with an accompanying warrant to purchase one share of Common Stock, was $1.31999 (equal to the offering price, minus $0.00001, the exercise price of each pre-funded warrant). The exercise price of the warrants is $1.32 per share. The net proceeds to the Company from the offering were approximately $2.5 million, after deducting placement agent fees and offering expenses payable by the Company. In connection with the offering, the Company issued to the placement agent (or its designees) warrants to purchase up to 159,091 shares of Common Stock, at an exercise price of $1.65 per share. The placement agent warrants will expire five years from March 31, 2026. Except as provided above, the placement agent warrants have substantially the same terms as the warrants.

On May 1, 2026, the Company entered into an At-The-Market Offering Agreement, or the Sales Agreement, with H.C. Wainwright & Co., LLC, or Wainwright, pursuant to which the Company may offer and sell shares of Common Stock having up to an aggregate sales price of up to $7.5 million, or the ATM Program. Any shares of Common Stock sold will be issued pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-284663). The Company will pay Wainwright compensation for sales of Common Stock sold pursuant to the Sales Agreement of 3.0% of the gross proceeds of any shares of Common Stock sold under the Sales Agreement. During the nine months ended September 30, 2026, the Company sold 330,256 shares at an average price of $1.14 for net proceeds of $0.4 million utilizing its ATM Program.

On June 25, 2026, the Company entered into a securities purchase agreement with an accredited investor for a private placement offering, pursuant to which the Company received gross proceeds of $3,000,000, before deducting placement agent fees and other offering expenses, in consideration of (i) pre-funded warrants to purchase up to 4,081,633 shares of Common Stock, (ii) warrants to purchase up to 4,081,633 shares of Common Stock at an exercise price of $0.735 per share that expire 18 months from September 17, 2026 (the "Short-term Warrants") and (iii) warrants to purchase up to 4,081,633 shares of Common Stock at an exercise price of $0.735 per share that expire 5 years from September 17, 2026 (the "Long-term Warrants" and together with the Short-term Warrants, the "Warrants"), at a purchase price of $0.735 per share (the "Offering Price") of Common Stock (or $0.73499 per pre-funded warrant in lieu thereof (equal to the Offering Price, minus $0.00001, the exercise price of each pre-funded warrant)) and associated Warrants. The offering closed on June 29, 2026. In addition, the Company issued warrants to purchase up to 285,714 shares of Common Stock at an exercise price of $0.9188 per share to the Placement Agent, or its designees, which have substantially the same terms as the Long-term Warrants described above except for the exercise price.

On September 15, 2026, the Company entered into a securities purchase agreement with Hamid Khoja, Ph.D., the Company's Chief Scientific Officer, relating to the issuance and sale of 298,508 shares of Common Stock, and accompanying warrants to purchase up to 298,508 shares of Common Stock, in a private placement. Pursuant to the securities purchase agreement, the Company issued the 298,508 shares of Common Stock and the accompanying warrants at an offering price of $1.675 per share and accompanying warrant, which was equal to the consolidated closing bid price of the Common Stock on The Nasdaq Capital Market on September 14, 2026 of $1.55 per share plus $0.125 per warrant. The gross proceeds to the Company were approximately $0.5 million, before deducting estimated expenses payable by the Company. The warrants have an exercise price of $1.55 per share. The warrants expire on the five-year anniversary of the date of issuance and contain cashless exercise provisions.

8. Standby Equity Purchase Agreement

On December 20, 2024, the Company entered into a Standby Equity Purchase Agreement (the "SEPA"). Pursuant to the SEPA, the Company could require the investor to purchase up to $10.0 million of shares of Common Stock by delivering written notice to the investor.

Below is a summary of sales to the investor pursuant to the SEPA during the nine months ended September 30, 2026.

Date	Cash Received	Shares Issued	Price Per Share
March 12, 2026	$ 180,799	26,667	$ 7.064
March 12, 2026	$ 9,686	1,441	$ 7.000
March 18, 2026	$ 323,050	65,000	$ 5.178
March 24, 2026	$ 128,053	26,667	$ 5.002
March 24, 2026	$ 64,000	13,333	$ 5.000

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 $0.1 million at December 31, 2025. There is no liability on the condensed consolidated balance sheets as of September 30, 2026. 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*.

9. Income Taxes

The Company did not record any tax provision or benefit for the nine months ended September 30, 2026 and 2025. 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, 2026 and December 31, 2025.

10. Leases, Commitments and Contingencies

In October 2022, the Company entered into a lease agreement for office space with a term of 62 months, which was to expire on November 30, 2027. This lease was 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%. The Company entered into a termination agreement regarding its office space and terminated this lease on April 2, 2026. For consideration of $45,108, the Company and the sublandlord agreed to terminate the lease agreement and future payments owed of $826,470.

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 is accounted for as an operating lease under the ASC 842 guidance for lease accounting. A right-of-use lease asset and lease liability of $1.6 million each were recorded at inception of the lease term using a discount rate of 6.38%.

Operating lease cost for the three and nine months ended September 30, 2026 was $0.1 million and $0.4 million, respectively. Operating lease cost expense for the three and nine months ended September 30, 2025 was $0.3 million and $0.7 million, respectively. As of September 30, 2026, noncancelable lease payments under operating leases were $1.5 million.

Maturities of operating lease liability as of September 30, 2026 were as follows:

(in thousands of dollars)	
2027	$ 338
2028	346
2029	353
2030	361
2031	60
Thereafter	—
Total lease payments	1,458
Less: Imputed interest	(183)
Total lease liability	1,275
Less: Current lease liability	(264)
Total non-current lease liability	$ 1,011

11. Share-Based Compensation

The Company adopted on August 10, 2022, and the stockholders approved on August 18, 2022, the 2022 Stock Plan (the "2022 Plan"). On April 22, 2026, the Company adopted the 2026 Equity and Incentive Compensation Plan (the "Plan") and on June 22, 2026, the stockholders approved the Plan. The Plan provides for the grant of stock options (including stock options intended to be "incentive stock options" as defined in Section 422 of the Code), appreciation rights, restricted stock, RSUs, performance shares, performance units, cash incentive awards and certain other awards based on or related to shares of the Company's Common Stock.

As of September 30, 2026 there were 1,981,583 shares available for future issuance under the Plan, and as of December 31, 2025, there were 339,188 shares available for future issuance under the 2022 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)	**2026**	**2025**	**2026**	**2025**
Research and development	$ 113	$ 108	$ 331	$ 308
General, administrative and other	558	596	1,741	1,676
Total stock-based compensation expense	$ 671	$ 704	$ 2,072	$ 1,984

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, 2026, are as follows:

	Stock Options
Unrecognized stock-based compensation expense (in thousands)	$ 3,091
Expected weighted-average period compensation costs to be recognized (years)	2.0

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, 2025	285,801	$ 47.80	8.0	$ —
Granted	400,443	$ 1.19	—	$ —
Exercised	—	$ —	—	$ —
Forfeited/canceled	(33,314)	$ 4.13	—	$ —
Vested shares expired	(9,513)	$ 42.58	—	$ —
Outstanding as of September 30, 2026	643,417	$ 21.16	8.5	$ 51
Exercisable as of September 30, 2026	194,947	$ 49.89	6.6	$ —

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, 2026
Risk-free interest rate	4.27%
Expected volatility	110.53%
Expected term (years)	7.00
Expected dividend	N/A

The weighted-average grant date fair value of the options granted during the nine months ended September 30, 2026 and 2025 was $1.04 per share and $17.40 per share, respectively.

12. Warrants

As of September 30, 2026, the Company accounts for all issued and outstanding warrants to purchase common stock as equity-classified instruments based on the guidance in ASC 480 and ASC 815.

	Number of Warrants	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Life (years)
Outstanding as of December 31, 2025	1,125,228	$ 6.80	4.9
Granted	11,179,307	$ 0.89	3.7
Exercised	—	$ —	—
Forfeited/canceled	—	$ —	—
Outstanding as of September 30, 2026	12,304,535	$ 1.43	3.7
Exercisable as of September 30, 2026	12,304,535	$ 1.43	3.7

In addition to the common warrants listed above, the Company had pre-funded warrants to purchase up to an aggregate of 2,538,760 shares of Common Stock outstanding at September 30, 2026.

13. Subsequent Events

The Company terminated the SEPA, effective October 3, 2026.

On October 7, 2026, the Company entered into a securities purchase agreement with Peak One Opportunity Fund, L.P. ("Peak One"), pursuant to which the Company agreed to issue to Peak One, in a private placement offering upon the satisfaction of certain conditions, a convertible debenture in the principal amount of $1,200,000 (the "Debenture") and 125,000 restricted shares (the "Commitment Shares") of Common Stock.

The Offering closed on October 8, 2026, and the Company issued the Debenture to Peak One and the Commitment Shares to Peak One and Peak One's designee. The Debenture was sold to Peak One for a purchase price of $1,020,000, representing an original issue discount of fifteen percent (15%). In connection with the offering, the Company paid $20,000 as a non-accountable fee to Peak One to cover its accounting fees, legal fees and other transactional costs incurred in connection with the transactions contemplated by the SPA and issued the Commitment Shares to Peak One and its designee.

The Debenture matures on October 8, 2027, has a 0% interest rate, and is only convertible following an event of default at a fixed conversion price equal to $0.78 per share. Upon an event of default, the holder of the Debenture can increase the interest rate applicable to the Debenture to the lesser of eighteen percent (18%) per annum and the maximum interest rate allowable under applicable law and accelerate the full indebtedness under the Debenture, in an amount equal to one hundred twenty percent (120%) of the outstanding principal amount and accrued and unpaid interest.

Pursuant to the terms of the Debenture, (i) the Company must make interim payments of $1,080,000 on April 8, 2027, $60,000 on July 8, 2027, and $60,000 (or the remaining balance, if higher) at maturity; (ii) at the sole discretion of the holder of the Debenture, the Company agreed to use 50% of cash proceeds it receives of more than $1,500,000, in the aggregate, from any source or series of related or unrelated sources, including but not limited to the issuance of equity or debt, the conversion of outstanding warrants of the Company or subsidiary of the Company, the issuance of securities pursuant to an equity line of credit or at-the-market offering, or the sale of assets by the Company or subsidiary of the Company, to repay outstanding amounts owed under the Debenture; and (iii) the Company agreed, subject to limited exceptions, not to enter into a variable rate transaction while the Debenture remains outstanding.

The Company can redeem the Debenture at 100% of the principal amount at any time so long as no event of default shall have occurred and be continuing.

On October 23, 2026, an investor exercised 509,000 pre-funded warrants for $5.09 in proceeds and 509,000 shares of commons stock were issued.

In October 2026, the Company sold 13,244 shares at an average price of $1.21 for net proceeds of approximately $15,263 utilizing its ATM Program.

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, psoriasis, multiple sclerosis, degenerative disc disease, 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 have initiated a twelve-week Phase 1/2 clinical trial in Australia for treatment of diabetic foot ulcers.

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 also completed 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. On December 30, 2025, we filed a Phase 1/2 Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA) seeking regulatory clearance to initiate clinical trials of CYPS317. We are in the process of updating our submission to the FDA based on feedback received.

We are developing CYMS101 as an intravenously administered allogeneic fibroblast single cell, and fibroblast spheroid, cell-based therapy to treat multiple sclerosis, or 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-term or long-term impact in complete blood count tests during the 16-week monitoring period, and no short-term or long-term 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 2027 after we receive FDA clearance for our IND relating to CYPS317. 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, or DDD, 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. We successfully carried out experiments that demonstrated the ability to use the CYWC628 spheroid master cell bank for the manufacturing of a modified CybroCell™ drug product for the treatment of degenerative disc disease. We also supported animal trials confirming that the therapeutic effects of the fibroblast-derived chondrocyte spheroids derived from the CYWC628 master cell bank are significantly better to those of single-cell fibroblasts, which supported our IND clearance with the FDA for the planned Phase I clinical trial for degenerative disc disease. Based on these results, we plan to work to amend the IND clearance with the FDA to replace single-cell fibroblasts, CybroCell™, with fibroblast-derived chondrocyte spheroids derived from the CYWC628 master cell bank. A timeline for the trial will be determined in connection with discussions with the FDA.

We also have human longevity, certain cancer, and artificial pancreatic organoid research programs in the 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 complete and both are certified as released by our CDMO. This CDMO has also manufactured CYWC628 for use in our twelve-week Phase 1/2 clinical trial for treatment of diabetic foot ulcers that we are conducting 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 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 debt issuances and equity raises.

As of September 30, 2026, we had cash and cash equivalents of $1.2 million. Since our inception, we have incurred significant operating losses. We incurred net losses of $13.2 million and $15.4 million for the nine months ended September 30, 2026 and 2025, respectively. As of September 30, 2026, we had an accumulated deficit of $67.3 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:

- pursue strategic transactions and capital raising initiatives;
- 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 continue operations and ultimately generate revenue to achieve profitability will depend heavily on our ability to raise significant additional capital and on the development, approval, and subsequent commercialization of our product candidates. If we fail to raise significant capital or become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations. As a result, we will need substantial additional funding to support 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, delay our pursuit of potential in-licenses or acquisitions, or cease operations.

General Trends and Outlook

Recent Developments and Upcoming Milestones

CYWC628

We manufactured three batches of the CYWC628 drug product in accordance with FDA's Good Manufacturing Practices (cGMP), all of which have been released after successfully passing all required safety and quality testing.

We completed site onboarding as outlined in the protocol for the DFU clinical trial in Australia and began screening, enrolling and dosing patients in the second quarter of 2026, marking the transition of our DFU program into active clinical evaluation. Early operating experience has given us clear visibility into the factors influencing enrollment pace. To date, recruitment and enrollment have progressed more slowly than anticipated, partly as a result of protocol eligibility requirements and a higher than anticipated rate of pre-screen failures, and some clinical study sites have experienced limited patient pools, investigator departures and resource constraints. We are acting on these insights by strengthening patient recruitment efforts and activating additional sites to support our recruitment objectives and to maintain, or shorten, the overall timeline for the trial. As part of these efforts, we updated the protocol for the DFU clinical trial to broaden access to the study by expanding eligibility requirements. We also plan to submit additional updates to the protocol for the DFU clinical trial designed to sharpen its efficiency, including by (i) keeping the most responsive treatment arm, and removing

the lower response treatment arm of the study; (ii) focusing the 6-week interim data on the percent area reduction primary outcome; and (iii) removing the requirement that interim 6-week data be anchored to 28-40 patients per arm. We believe these revisions position the trial to generate meaningful data on a more predictable schedule and will allow us to report interim data once 14 patients from the remaining treatment arm and standard of care arms of the study have completed at least 6 weeks of treatment. If the revised protocol is approved, we plan to report safety and efficacy data from the DFU clinical trial as follows:

- determination from the safety review committee confirming that the safety and tolerability of the CYWC628 drug product is acceptable following the first two (2) weeks of treatment of the first twenty (20) randomized participants, which we expect will occur by mid-December 2026;
- six-week interim safety and primary efficacy data of the clinical trial, which we expect will occur in February 2027;
- twelve-week primary safety and efficacy data of the clinical trial, which we expect will occur in the first half of 2027;
- secondary outcome results of the study, including monitoring for wound recurrence at the same site, which we expect will occur in the second half of 2027 once all the patients in each arm of the study that remain in the study have been assessed for a 6-month follow-up; and
    - for the second period of the clinical trial, patients enrolled in the standard of care arm of the study whose wounds did not heal, and still meet the inclusion/exclusion criteria of the study, will be provided the option of receiving CYWC628 for up to 12 weeks to generate additional secondary outcome results.
- final report of the study, which will include all the primary and secondary outcomes outlined in the clinical trial, which we expect will occur in the second half of 2027.

These timelines have been extended, and may be further extended, as we resolve issues that have arisen and may continue to develop if revisions to the protocol for the DFU clinical trial are not accepted. Please see "Risk Factors – Risks Related to Manufacturing" and "– Risks Related to Development, Regulatory Approval and Commercialization" in our Annual Report and "Item 1A. Risk Factors – Risks Related to Manufacturing" and "– Risks Related to Development, Regulatory Approval and Commercialization" in this Quarterly Report.

Degenerative Disc Disease

We reported results from a preclinical study for the development of fibroblast spheroid-derived chondrocyte (FSdC) spheroids for DDD that evaluated three approaches using allogeneic human dermal fibroblasts: conventionally cultured (2D) fibroblasts, three-dimensional (3D) fibroblast spheroids, and fibroblast spheroid-derived chondrocytes (FSdC). In the study, an established model of intervertebral disc degeneration was used to assess the effects of a single injection of each cell preparation compared with a control. Treatment outcomes were monitored over 12 weeks through periodic X-ray imaging, followed by MRI and tissue analysis to evaluate changes in disc structure and degeneration.

Key findings of the preclinical study include: (i) chondrogenic differentiation of the FSdC spheroids was confirmed by positive Alcian blue staining and upregulation of the cartilage-associated genes TGFβ1, COMP, SOX9, and ACAN; (ii) all three fibroblast-treated groups had higher disc heights than vehicle controls, measured by normalized percent disc height index (%DHI) (in mixed-model analysis, the improvements were statistically significant for 2D fibroblasts ($p<0.05$), fibroblast spheroids ($p<0.05$), and FSdC spheroids ($p<0.01$)); throughout the 12-week study, the FSdC spheroid group kept significantly higher %DHI values than the other treatment groups; (iv) at 12 weeks, %DHI was 80.7% in the FSdC spheroid group versus 71.8% in controls ($p<0.05$); and (v) the treatment effects were consistent across the lumbar levels studied.

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 accrued interest expense and interest on short-term borrowing to finance D&O insurance premiums.

Statements of Operations

Results of Operations

Comparison of Three Months Ended September 30, 2026 and 2025

The following tables set forth our results of operations for the three months ended September 30, 2026 and 2025.

	Three Months Ended September 30,		Change Amount
	2026	2025	
	(unaudited, in thousands)		
Operating expenses:			
Research and development	$ 2,075	$ 2,789	$ (714)
General, administrative and other	1,996	2,249	(253)
Total operating expenses	4,071	5,038	(967)
Loss from operations	(4,071)	(5,038)	967
Other income/(expense)			
Change in fair value of SEPA put option liability	9	33	(24)
Change in fair value of convertible debt	—	(846)	846
Other expense	(2)	—	(2)
Interest income	20	73	(53)
Interest expense	(4)	—	(4)
Total other income/(expense)	23	(740)	763
Net loss	$ (4,048)	$ (5,778)	$ 1,730

Research and Development Expenses

Research and development expenses were $2.1 million and $2.8 million for the three months ended September 30, 2026 and 2025, respectively. The decrease of $0.7 million was primarily due to:

- decreased CRO costs of $0.4 million as clinical validation changed to manufacturing, and certain costs were capitalized to research and development supplies;
- decreased supplies expenses of $0.2 million;
- decreased sponsored research agreements of $0.3 million;
- increase in payroll related costs associated with new personnel of $0.2 million; and

Research and development expenses are not tracked by product candidate.

General, Administrative and Other Expenses

General, administrative and other expenses were $2.0 million and $2.2 million for the three months ended September 30, 2026 and 2025, respectively. The decrease of approximately $0.3 million was primarily due to:

- decreased personnel expenses of $0.1 million which consisted of severance and vacation accrual costs in the prior year;
- increased professional fees of $0.1 million such as legal and patent filing fees; and
- decreased facilities expenses of $0.2 million.

Change in fair value of SEPA put option liability

There was an approximate $10,000 change in the fair value of the SEPA put option liability during the three months ended September 30, 2026 due to the cancellation of the SEPA. There was an approximate $33,000 gain in the change in the fair value of the SEPA put option liability during the three months ended September 30, 2025 resulting 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.

Other expense

There is an approximate $2,000 of other expense for the three months ended September 30, 2026 primarily for the loss on exchange rate and there was no other expense for the three months ended September 30, 2025.

Interest income

Interest income was approximately $20,000 and $0.1 million for the three months ended September 30, 2026 and 2025, respectively. Interest income is comprised of interest income and unrealized gain/losses on cash equivalents.

Interest expense

Interest expense was approximately $4,000 and $0 for the three months ended September 30, 2026 and 2025, 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, 2026 and 2025

The following tables set forth our results of operations for the nine months ended September 30, 2026 and 2025.

	Nine Months Ended September 30,		Change Amount
	2026	2025	
	(unaudited, in thousands)		
Operating expenses:			
Research and development	$ 6,686	$ 6,610	$ 76
General, administrative and other	6,486	7,449	(963)
Total operating expenses	13,172	14,059	(887)
Loss from operations	(13,172)	(14,059)	887
Other income/(expense)			
Change in fair value of SEPA put option liability	63	23	40
Change in fair value of convertible debt	—	(963)	963
Other expense	(96)	(625)	529
Interest income	55	222	(167)
Interest expense	(15)	—	(15)
Total other income/(expense)	7	(1,343)	1,350
Net loss	$ (13,165)	$ (15,402)	$ 2,237

Research and Development Expenses

Research and development expenses were $6.7 million and $6.6 million for the nine months ended September 30, 2026 and 2025, respectively. The increase of $0.1 million was primarily due to:

- increased CRO costs of $0.5 million for the clinical trial currently underway;
- increased payroll related expenses of $0.2 million; and
- decreased supplies expenses of $0.6 million.

Research and development expenses are not tracked by product candidate.

General, Administrative and Other Expenses

General, administrative and other expenses were $6.5 million and $7.4 million for the nine months ended September 30, 2026 and 2025, respectively. The decrease of approximately $1.0 million was primarily due to:

- decreased personnel expenses of $0.5 million which consisted of severance and vacation accrual costs in the prior year;
- decreased professional fees of $0.2 million such as legal and accounting fees;
- decreased travel expenses of $0.1 million;
- decreased facilities expenses of $0.3 million; and
- increased costs associated with maintaining our Nasdaq listing of $0.2 million.

Change in fair value of SEPA put option liability

The change in fair value of the SEPA put option liability was a gain of $0.1 million during the nine months ended September 30, 2026 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 fully paid off in 2025.

Other expense

There is $0.1 million of other expense for the nine months ended September 30, 2026 primarily for the gain on the lease termination and $0.6 million of non-cash original discount on convertible debt for the nine months ended September 30, 2025.

Interest income

Interest income was approximately $55,000 and $0.2 million for the nine months ended September 30, 2026 and 2025, respectively. Interest income is comprised of interest income and unrealized gain/losses on cash equivalents.

Interest expense

Interest expense was approximately $15,000 and $0 for the nine months ended September 30, 2026 and 2025, respectively, primarily related to financing our directors and officers insurance.

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, 2026, we have financed our operations primarily with various borrowings and stock offerings. As of September 30, 2026, we had cash and cash equivalents of $1.2 million and an accumulated deficit of $67.3 million.

Cash Flows

The following table sets forth a summary of our cash flows for the nine months ended September 30, 2026 and 2025.

	Nine Months Ended September 30,	
	2026	2025
	(in thousands)	
Net cash used in operating activities	$ (10,410)	$ (13,231)
Net cash used in investing activities	(18)	(262)
Net cash provided by financing activities	6,702	4,375
Net decrease in cash and cash equivalents	$ (3,726)	$ (9,118)

Cash Flows from Operating Activities

Net cash used in operating activities was $10.4 million and $13.2 million for the nine months ended September 30, 2026 and 2025, respectively, and consisted primarily of net losses of $13.2 million and $15.4 million, respectively. Noncash expenses consisting of stock-based compensation expense of $2.1 million, and amortization of operating lease right-of-use asset of $0.3 million partially offset the net loss, while a decrease in prepaid expenses of $0.8 million, an increase in accounts payable and accrued expenses of $2.7 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, 2026. In addition, we issued a note receivable of $0.4 million. For the nine months ended September 30, 2025, 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 an increase 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.

Cash Flows from Investing Activities

Net cash used in investing activities was $0.0 million and approximately $0.3 million for the nine months ended September 30, 2026 and 2025, respectively, and consisted primarily of laboratory equipment purchases.

Cash Flows from Financing Activities

Net cash provided by financing activities was $6.7 million and $4.4 million for the nine months ended September 30, 2026 and 2025, respectively. During the nine months ended September 30, 2026, we issued stock under the SEPA for $0.8 million and stock from our ATM of $0.4 million. We

also sold stock in a registered offering for net proceeds of $2.6 million and private placements for net proceeds of $3.2 million. In addition, we received proceeds from a loan for D&O costs of $0.3 million and repaid $0.3 million.

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, 2026, we had an accumulated deficit of $67.3 million and cash and cash equivalents of $1.2 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, or cease operations. During the nine months ended September 30, 2026, 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 decreasing 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 utilizing certain capital raising options, 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 10, “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 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. During the preparation of our financial statements for the year ended December 31, 2025, our management identified a material weakness in our internal control over financial reporting due to a lack of segregation of duties. A material weakness is defined as a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

Specifically, our management identified a material weakness in our internal controls within the financial reporting function that resulted from an ineffective design and implementation of controls over proper segregation of duties for the period of time covered by our consolidated financial statements prior to our Chief Financial Officer joining us in June 2025 when all financial functions were handled by a single individual, and afterward, through September 30, 2026, 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 our Chief Financial Officer in June 2025, we continue to make valuable changes to our accounting and financial reporting processes and internal controls. The Company's plan is to add additional accounting staff, strengthen 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, 2026, 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, 2026, 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 decreasing 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, including ceasing operations, and you could lose all or part of your investment in us.

We may acquire companies, product candidates or products or engage in strategic transactions, which could divert our management's attention and cause us to incur various costs and expenses.

We may acquire or invest in companies, product candidates or products that we believe could complement or expand our business or otherwise offer growth opportunities or capital. The pursuit of potential acquisitions or investments may divert the attention of management and has caused, and in the future may cause, us to incur various costs and expenses in identifying, investigating, and pursuing them, whether or not they are consummated. We may not be able to identify desirable acquisitions or investments or be successful in completing or realizing anticipated benefits from such transactions. In addition, the acquisition of companies, product candidates and products is a highly competitive area, and many other companies are pursuing the same or similar product candidates to those that we may consider attractive. Larger companies with more well-established and diverse revenue streams may have a competitive advantage over us due to their size, financial resources and more extensive clinical development and commercialization capabilities. In addition, we have received, and may receive, inquiries relating to potential strategic transactions, including collaborations, licenses, and acquisitions. Such potential transactions may divert the attention of management and may cause us to incur various costs and expenses in investigating and evaluating such transactions, whether or not they are consummated.

Risks Related to Development, Regulatory Approval and Commercialization

We may encounter substantial delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.

Before obtaining marketing approval from the FDA, the EMA, or other comparable foreign regulatory authorities for the sale of our product candidates, we must complete preclinical development and extensive clinical trials to demonstrate the safety and efficacy of our product candidates. Clinical testing is expensive, difficult to design and implement, can take many years to complete and its ultimate outcome is uncertain. A failure of one or more clinical trials can occur at any stage of the process. The outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later clinical trials.

We do not know whether our future clinical trials will begin on time, whether our ongoing trials and/or future trials will enroll patients on time, or whether our ongoing and/or future clinical trials will be completed on schedule or at all. We may experience delays in completing our clinical trials or preclinical studies and initiating or completing additional clinical trials or preclinical studies, including as a result of regulators not allowing or delay in allowing clinical trials to proceed under an IND or similar foreign authorization, or not approving or delaying approval for any clinical trial grant or similar approval we need to initiate a clinical trial. Clinical trials can be delayed for a variety of reasons, including delays related to:

- the FDA, the EMA or other comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- obtaining regulatory authorizations to commence a trial or reaching a consensus with regulatory authorities on trial design;
- challenges or delays in recruiting principal investigators or study sites to lead our clinical trials;
- any failure or delay in reaching an agreement with CROs and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining approval from one or more independent IRBs;
- IRBs refusing to approve, suspending or terminating the trial at an investigational site, precluding enrollment of additional subjects, or withdrawing their approval of the trial;
- delays in enrollment due to travel or quarantine policies, or other factors related to pandemics or other events outside our control;
- changes to clinical trial protocol and obtaining related regulatory authorizations;
- clinical sites deviating from trial protocol or dropping out of a trial;
- manufacturing sufficient quantities of a product candidate or obtaining sufficient quantities of combination therapies for use in clinical trials;
- subjects failing to enroll or remain in our trial at the rate we expect, or failing to return for post-treatment follow-up;
- subjects choosing an alternative treatment for the indication for which we are developing our product candidates, or participating in competing clinical trials;
- lack of adequate funding to continue the clinical trial;
- subjects experiencing severe or unexpected product-related adverse effects;
- occurrence of serious adverse events in trials of the same class of agents conducted by other companies;
- selection of clinical endpoints that require prolonged periods of clinical observation or analysis of the resulting data;
- a facility manufacturing our product candidates or any of their components being ordered by the FDA, the EMA, or comparable foreign regulatory authorities to temporarily or permanently shut down due to violations of cGMP regulations or other applicable requirements, or infections or cross-contaminations of product candidates in the manufacturing process;
- any changes to our manufacturing process that may be necessary or desired;
- third-party clinical investigators losing the licenses or permits necessary to perform our clinical trials, not performing our clinical trials on our anticipated schedule or consistent with the clinical trial protocol, GCP or other regulatory requirements;
- third-party contractors not performing data collection or analysis in a timely or accurate manner;
- third-party contractors becoming debarred or suspended or otherwise penalized by the FDA, the EMA or other government or regulatory authorities for violations of regulatory requirements, in which case we may need to find a substitute contractor, and we may not be able to use some or all of the data produced by such contractors in support of our marketing applications; or
- approval policies or regulations of the FDA, EMA or other comparable regulatory authorities significantly changing in a manner rendering our clinical data insufficient for approval.

Several of the above factors are arising as we progress our CYWC628 twelve-week Phase1/2 clinical trial in Australia for the treatment of DFUs. For example, to date, recruitment and enrollment of patients have progressed more slowly than anticipated, partly as a result of protocol eligibility requirements and a higher than anticipated rate of pre-screen failures, and some clinical study sites have experienced limited patient pools, investigator departures, and resource constraints. We are acting on these insights by strengthening patient recruitment efforts and activating additional sites to support our recruitment objectives and to maintain, or shorten, the overall timeline for the trial. As part of these efforts, we updated the protocol for the DFU clinical trial to broaden access to the study by expanding eligibility requirements. We also plan to submit additional updates to the protocol for the DFU clinical trial designed to sharpen its efficiency, including by (i) keeping the most responsive treatment arm, and removing the lower response treatment arm of the study; (ii) focusing the 6-week interim data on the percent area reduction primary outcome; and (iii) removing the requirement that interim data be anchored to 28-40 patients per arm. If we are unable to remedy these issues, or receive regulatory approval for the protocol changes, we may experience delays in completing our CYWC628 clinical trial or be unable to complete the trial.

Conducting clinical trials in foreign countries, as we are doing for CYWC628 and may do for our other product candidates, presents additional risks that may delay completion of our clinical trials. These risks include the failure of enrolled patients in foreign countries to adhere to clinical protocol as

a result of differences in healthcare services or cultural customs, managing additional administrative burdens associated with foreign regulatory schemes, as well as political and economic risks relevant to such foreign countries.

Additionally, if the results of our clinical trials are inconclusive or if there are safety concerns or serious adverse events associated with our product candidates, we may:

- be delayed in obtaining marketing approval, if at all;
- obtain approval for indications or patient populations that are not as broad as intended or desired;
- obtain approval with labeling that includes significant use or distribution restrictions or safety warnings;
- be required to perform additional clinical trials to support approval or be subject to additional post-marketing testing requirements;
- be subject to the addition of labeling statements, such as warnings or contraindications;
- be sued; or
- experience damage to our reputation.

Our development costs will also increase if we experience delays in testing or obtaining marketing approvals. We do not know whether any of our preclinical studies or clinical trials will begin as planned, need to be restructured or be completed on schedule, if at all. Any delay in, or termination of, our clinical trials will delay the submission of a BLA to the FDA or similar applications with comparable foreign regulatory authorities and, ultimately, our ability to commercialize our product candidates, if approved, and generate product revenue. Even if our clinical trials are completed as planned, we cannot be certain that their results will support our claims for differentiation or the effectiveness or safety of our product candidate. The FDA and comparable foreign regulatory authorities have substantial discretion in the review and approval process and may disagree that our data support the claims we propose. Negative or inconclusive results from our clinical trials or preclinical studies could mandate repeated or additional clinical trials and, to the extent we choose to conduct clinical trials in other indications, could result in changes to or delays in clinical trials of our product candidates in such other indications. Our failure to successfully initiate and complete clinical trials and to demonstrate the efficacy and safety necessary to obtain regulatory approval to market our product candidates would significantly harm our business.

Moreover, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA, the EMA, or other comparable foreign regulatory authorities. The FDA, the EMA or other comparable foreign regulatory authorities may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA, the EMA or other comparable foreign regulatory authorities may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA, the EMA, or other comparable foreign regulatory authorities, as the case may be, and may ultimately lead to the denial of marketing approval of one or more of our product candidates.

If we experience delays in the completion of, or termination of, any clinical trial of our product candidates, the commercial prospects of our product candidates will be harmed, and our ability to generate product revenues from any of these product candidates will be delayed. Moreover, any delays in completing our clinical trials will increase our costs, slow down our product candidate development and approval process and jeopardize our ability to commence product sales and generate revenues.

In addition, many of the factors that cause, or lead to, termination or suspension of, or a delay in the commencement or completion of, clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Any delays to our clinical trials that occur as a result could shorten any period during which we may have the exclusive right to commercialize our product candidates and our competitors may be able to bring products to market before we do, and the commercial viability of our product candidates could be significantly reduced. Any of these occurrences may harm our business, financial condition, and prospects significantly.

Risks Related to Manufacturing

Manufacturing cell therapy products is complex and subject to both human and systemic risks. Our third-party manufacturers and suppliers 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 and suppliers 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, mechanical malfunctions, equipment failures, and availability of qualified personnel, as well as compliance with strictly enforced federal, state, and foreign regulations. For example, (i) timelines for our planned twelve-week Phase 1/2 clinical trial utilizing CYWC628 for treatment of diabetic foot ulcers in Australia were extended as we worked 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 began the manufacture of CYWC628 for the clinical trial, and (ii) lower than expected yields from the manufacture of the three batches of the CYWC628 drug product have required, and may require us to spend significant financial resources to manufacture additional batches of the CYWC628 drug product, as needed, in order to complete the DFU 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 or suppliers, 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, (i) timelines for our planned twelve-week Phase 1/2 clinical trial utilizing CYWC628 for treatment of diabetic foot ulcers in Australia were extended as we worked 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 began the manufacture of CYWC628 for the clinical trial and (ii) lower than expected yields from the manufacture of the three batches of the CYWC628 drug product have required, and may require us to spend significant financial resources to manufacture additional batches of the CYWC628 drug product, as needed, in order to complete the DFU 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, (i) we encountered process issues with the manufacturing training run of CYWC628 and needed to increase the number of aseptic process simulation runs needed to confirm sterility of the manufacturing process before we began the manufacture of CYWC628 for the clinical trial, and (ii) lower than expected yields from the manufacture of the three batches of the CYWC628 drug product have required, and may require us to spend significant financial resources to manufacture additional batches of the CYWC628 drug product, as needed, in order to complete the DFU 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 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, (i) we worked with our CDMO to resolve process issues with the manufacturing training runs of CYWC628 and increase the number of aseptic process simulation runs needed to confirm sterility of the manufacturing process before we began the manufacture of CYWC628 for our planned twelve-week Phase 1/2 clinical trial utilizing CYWC628 for treatment of diabetic foot ulcers in Australia, and (ii) lower than expected yields from the manufacture of the three batches of the CYWC628 drug product have required, and may require us to spend significant financial resources to manufacture additional batches of the CYWC628 drug product, as needed, in order to complete the DFU trial. If these issues are not resolved, we will be unable to manufacture the required batches of CYWC628 to complete our 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 and suppliers to produce our product candidates. In the event that we or any of our third-party manufacturers or suppliers 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. We remain subject to the $1 minimum bid price requirement and continued listing requirements for the Nasdaq Capital Market, including the new market value of listed securities of $5 million requirement approved by the SEC on July 22, 2026 (which is not afforded a cure period to regain compliance), and no assurance can be given that we will be able to satisfy these requirements. If we fail to meet any of these requirements, our securities may be delisted from Nasdaq.

On July 1, 2025, we received a notification letter from the Nasdaq Listing Qualifications Staff, or the 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 as required for continued listing on the Nasdaq Capital Market under Nasdaq Listing Rule 5550(a)(2), or the Bid-Price Rule. 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, or the MVLS Rule. On December 30, 2025, we received a notification indicating that the Staff planned to delist our securities due to our continued non-compliance with the Bid-Price Rule as of December 29, 2025, unless we timely requested a hearing before the Nasdaq Hearings Panel, or the Panel. We timely requested a hearing before the Panel. On February 3, 2026, we received formal notice from the Staff that, based on our continued non-compliance with the MVLS Rule, the deficiency served as an additional basis for the delisting of our common stock. The notice indicated that, in addition to the deficiency under the Bid Price Rule, the Panel would consider our plan to regain compliance with the MVLS Rule in their decision regarding our request for continued listing on the Nasdaq Capital Market. At our hearing before the Panel, we presented our plan to regain compliance with both the Bid-Price Rule and the MVLS Rule. On February 12, 2026, we received a determination from the Panel granting our request for the continued listing of our common stock on the Nasdaq Capital Market, subject to our satisfying (i) the equity standard of $2.5 million required under Rule 5550(b)(1), or the Equity Rule, as an alternative to the MVLS Rule on or before February 27, 2026, (ii) the Bid Price Rule on or before April 13, 2026, and (iii) all other applicable criteria for continued listing on Nasdaq on or before April 13, 2026.

On March 9, 2026, we received notice from Nasdaq that we had demonstrated compliance with the Equity Rule in lieu of the MVLS Rule. The compliance determination also noted that we remained subject to a Mandatory Panel Monitor with respect to the Equity Rule for a period of one year from March 9, 2026. If within that one-year monitoring period we fail to satisfy the Equity Rule, we will not be permitted to provide the Staff with a compliance plan nor would the Staff be permitted to grant additional time to us to regain compliance. Instead, the Staff will issue a delist determination, at which time we may request a new hearing before a Nasdaq Hearings Panel. Such request would stay any delisting action by Nasdaq at least pending the conclusion of the hearing process.

On April 17, 2026, we received formal notice from Nasdaq that we have demonstrated compliance with the Bid-Price Rule and all other applicable criteria for continued listing on the Nasdaq Capital Market. Accordingly, the previously disclosed listing matters have been closed. We were also informed that we will remain subject to a Mandatory Panel Monitor for a period of one year from April 17, 2026. If within that one-year monitoring period we fail to maintain compliance with the Bid Price Rule, we will not be afforded a cure period to regain compliance with the Bid Price Rule. Instead, Staff will issue a delist determination, at which time we may request a new hearing before a Nasdaq Hearings Panel. Such request would stay any further delisting action by Nasdaq at least pending the conclusion of the hearing process.

On July 22, 2026, we received a Staff Determination letter, or the Staff Determination, from Nasdaq notifying us that the Staff had determined to delist our securities from the Nasdaq Capital Market. The Staff Determination stated that the bid price of our listed securities had closed at less than $1.00 per share over the previous 30 consecutive business days, from June 8, 2026 through July 21, 2026, and that, as a result, we are not in compliance with the Bid Price Rule. The Staff Determination further stated that, although companies are normally afforded a 180-calendar day period to demonstrate compliance with the Bid Price Rule, we are not eligible for any such compliance period pursuant to Nasdaq Listing Rule 5810(c)(3)(A)(iv) due to the fact that we effected a reverse stock split over the prior one-year period. Unless we requested an appeal of this determination by July 29, 2026, Nasdaq staff had determined that our securities would be scheduled for delisting from The Nasdaq Capital Market and would be suspended at the opening of business on July 31, 2026. We timely requested a hearing before a Nasdaq Hearings Panel to appeal the Staff's determination. The timely hearing request stayed any further delisting actions through the hearing process. On August 25, 2026, we received formal notice from Nasdaq that we have regained compliance with the Bid-Price Rule and that we are therefore in compliance with the Nasdaq Capital Market's listing requirements. Consequently, the hearing before the Nasdaq Hearings Panel was cancelled and our common stock continues to be listed and traded on the Nasdaq Capital Market.

At September 30, 2026, we reported stockholders' equity of $1.8 million, which means we are no longer in compliance with the Equity Rule. We expect to receive a delist determination letter from the Staff, which we intend to appeal by requesting a hearing before a Nasdaq Hearings Panel. We expect that a timely hearing request will stay any further delisting actions through the hearing process. At the hearing, we expect to present our plan to regain compliance with Nasdaq's continued listing requirements. There can be no assurance that we will be successful in our appeal, that the Nasdaq Hearings Panel will grant our request for continued listing, or that we will be able to regain or maintain compliance with any applicable Nasdaq listing requirements.

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 are deficient under the Nasdaq continued listing standards and fail to regain compliance with such 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 not listed or quoted on an exchange or over-the-counter system, this can constitute an event of default under our outstanding debenture and would preclude us from utilizing our ATM facility. 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, 2026. 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 September 15, 2026, the Company entered into a securities purchase agreement with Hamid Khoja, Ph.D., the Company's Chief Scientific Officer, relating to the issuance and sale of 298,508 shares of Common Stock, and accompanying warrants to purchase up to 298,508 shares of Common Stock, in a private placement. Pursuant to the securities purchase agreement, the Company issued the 298,508 shares of Common Stock and the accompanying warrants at an offering price of $1.675 per share and accompanying warrant, which was equal to the consolidated closing bid price of the Common Stock on The Nasdaq Capital Market on September 14, 2026 of $1.55 per share plus $0.125 per warrant. The gross proceeds to the Company were approximately $0.5 million, before deducting estimated expenses payable by the Company. The warrants have an exercise price of $1.55 per share. The warrants expire on the five-year anniversary of the date of issuance and contain cashless exercise provisions.

Below is a summary of shares sold to YA II PN, LTD., or Yorkville, pursuant to the standby equity purchase agreement, or the SEPA, dated December 20, 2024, with Yorkville, during the nine months ended September 30, 2026. Shares were sold at a 4% discount to the applicable market price.

Date	Cash Received	Shares Issued	Price Per Share
March 12, 2026	$ 180,799	26,667	$ 7.064
March 12, 2026	$ 9,686	1,441	$ 7.000
March 18, 2026	$ 323,050	65,000	$ 5.178
March 24, 2026	$ 128,053	26,667	$ 5.002
March 24, 2026	$ 64,000	13,333	$ 5.000

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 the Registrant.	8-K	001-41934	3.1	June 13, 2025
3.3	Amendment to Amended and Restated Certificate of Incorporation of the Registrant	8-K	001-41934	3.1	April 3, 2026
3.4	Second Amended and Restated Bylaws of the Registrant	8-K	001-41934	3.1	April 17, 2026
4.1+	Form of Common Stock Purchase Warrant issued September 15, 2026	8-K	001-41934	4.1	September 15, 2026
4.2	Convertible Debenture issued October 8, 2026	8-K	001-41934	10.2	October 8, 2026
10.1+	Securities Purchase Agreement, dated September 15, 2026, between FibroBiologics, Inc. and Hamid Khoja, Ph.D.	8-K	001-41934	10.1	September 15, 2026
10.2	Securities Purchase Agreement, dated October 7, 2026, between FibroBiologics, Inc. and Peak One Opportunity Fund, L.P.	8-K	001-41934	10.1	October 8, 2026
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).				

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

SIGNATURE

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

FIBROBIOLOGICS, INC.

Date: November 16, 2026

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, 2026 of FibroBiologics, Inc. (the "registrant");

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

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

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

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

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

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

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

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

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

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

Date: November 16, 2026

/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, 2026 of FibroBiologics, Inc. (the "registrant");

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

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

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

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

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

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

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

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

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

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

Date: November 16, 2026

/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, 2026, 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: November 16, 2026