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

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2024

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to

Commission File Number: 001-39619

Kiromic BioPharma, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**46-4762913**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
7707 Fannin Street, Suite 200, Houston, TX	**77054**
(Address of Principal Executive Offices)	Zip Code

(832) 968-4888
(Registrant's telephone number)

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

Title of Each Class	**Trading symbol**	**Name of Exchange on which registered**
Common Shares, par value $0.001 per share	KRBP	The OTCQB 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 ☒

As of November 6, 2024, there were 1,545,920 shares of the registrant's common stock outstanding.

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Cautionary Note on Forward-Looking Statements

Various statements made in this Quarterly Report on Form 10-Q are forward-looking and involve risks and uncertainties. All statements that address activities, events or developments that we intend, expect or believe may occur in the future are forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. Such statements give our current expectations or forecasts of future events and are not statements of historical or current facts. These statements include, among others, statements about:

- Our goals and strategies.
- Our future business development, financial condition and results of operations.
- Our expected timing of human clinical trials and other related milestones.
- Expected changes in our revenue, costs or expenditures.
- Our ability to obtain financing in amounts sufficient to fund our operations and continue as a going concern and avoid seeking protection under Chapters 7 or 11 of the United States Bankruptcy Code.
- Difficulties or delays in the product development process, including the results of preclinical studies or clinical trials.
- Difficulties or delays in the regulatory approval process.
- Manufacturing, sales, marketing and distribution of any of our products that may be successfully developed and approved for commercialization.
- Growth of and competition trends in our industry.
- Our expectations regarding demand for, and market acceptance of, our products.
- Our expectations regarding our relationships with investors, institutional funding partners and other parties we collaborate with.
- Fluctuations in general economic and business conditions in the markets in which we operate.
- Our ability to raise capital when needed.
- Relevant government policies and regulations relating to our industry.
- The outcome of any pending or threatened litigation.
- Our results from preclinical studies and early-stage clinical trials may not be predictive of results from late-stage or other clinical trials.

Forward-looking statements also include statements other than statements of current or historical fact, including, without limitation, all statements related to any expectations of revenues, expenses, cash flows, earnings or losses from operations, cash required to maintain current and planned operations, capital or other financial items; any statements of the plans, strategies and objectives of management for future operations; any plans or expectations with respect to product research, development and commercialization, including regulatory approvals; any other statements of expectations, plans, intentions or beliefs; and any statements of assumptions underlying any of the foregoing. We often, although not always, identify forward-looking statements by using words or phrases such as “may," "could," "will," "should," "would," "expect," "plan," "intend," "anticipate," "believe," "estimate," "predict," "potential," "project" or "continue".

The following are some of the factors that could cause actual results to differ materially from the anticipated results or other expectations expressed, anticipated or implied in our forward-looking statements:

- The effectiveness and timeliness of our preclinical studies and clinical trials, and the usefulness of the data.
- Our expectations regarding the timing and clinical development of our product candidates.
- Our ability to achieve profitable operations and access to needed capital.
- Fluctuations in our operating results.
- The success of current and future license and collaboration agreements.
- Our dependence on contract research organizations, vendors and investigators.
- Effects of competition and other developments affecting development of products.
- Market acceptance of our products.
- Protection of intellectual property and avoiding intellectual property infringement.
- Product liability.
- Other factors described in our filings with the SEC.

We cannot guarantee that the results and other expectations expressed, anticipated or implied in any forward-looking statement will be realized. The risks set forth under Item 1A of our Annual Report on Form 10-K for the fiscal year ended December 31, 2023, and subsequent quarterly reports on Form 10-Q describe major risks to our business, and you should read and interpret any forward-looking statements together with these risks. A variety of factors, including these risks, could cause our actual results and other expectations to differ materially from the anticipated results or other expectations expressed, anticipated or implied in our forward-looking statements. Should known or unknown risks materialize, or should underlying assumptions prove inaccurate, actual results could differ materially from past results and those anticipated, estimated or projected in the forward-looking statements. You should bear this in mind as you consider any forward-looking statements.

Our forward-looking statements speak only as of the dates on which they are made. We do not undertake any obligation to publicly update or revise our forward-looking statements even if experience or future changes makes it clear that any projected results expressed or implied in such statements will not be realized, except as may be required by law.

PART I —FINANCIAL INFORMATION

Item 1. Financial Statements

KIROMIC BIOPHARMA, INC.
Condensed Consolidated Balance Sheets
(Unaudited)
(In thousands, except share and per share amounts)

	September 30, 2024	December 31, 2023
Assets:		
Current Assets:		
Cash and cash equivalents	$ 2,924	$ 3,204
Restricted cash	132	—
Prepaid expenses and other current assets	1,247	1,226
Total current assets	4,303	4,430
Property and equipment, net	4,847	6,175
Operating lease right-of-use asset, net	1,074	1,543
Other assets	21	21
Total Assets	$ 10,245	$ 12,169
Liabilities and Stockholders' Deficit:		
Current Liabilities:		
Senior secured convertible promissory notes	$ 13,640	$ 14,000
Accounts payable	1,693	2,136
Accrued expenses and other current liabilities	1,666	1,673
Interest payable	1,460	1,938
Operating lease liability - short term	670	631
Total current liabilities	19,129	20,378
Operating lease liability - long term	404	912
Total Liabilities	19,533	21,290
Commitments and contingencies (Note 8)		
Stockholders' Deficit:		
Preferred Stock, $0.0001 par value: 60,000,000 shares authorized, 33,835 and 14,000 issued and outstanding, with a liquidation preference of $40,312 and $16,205, as of September 30, 2024 and December 31, 2023, respectively	—	—
Common stock, $0.001 par value: 300,000,000 shares authorized as of September 30, 2024 and December 31, 2023; 1,545,920 and 1,258,460 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively	1	1
Additional paid-in capital	134,015	113,775
Accumulated deficit	(143,304)	(122,897)
Total Stockholders' Deficit	(9,288)	(9,121)
Total Liabilities and Stockholders' Deficit	$ 10,245	$ 12,169

See accompanying notes to the condensed consolidated financial statements

KIROMIC BIOPHARMA, INC.
Condensed Consolidated Statements of Operations
(Unaudited)
(In thousands, except share and per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 4,228	$ 2,677	$ 11,385	$ 6,719
General and administrative	2,375	2,875	6,684	7,903
Total operating expenses	6,603	5,552	18,069	14,622
Loss from operations	(6,603)	(5,552)	(18,069)	(14,622)
Other expense:				
Interest expense	(935)	(440)	(2,957)	(1,219)
Litigation settlement	—	40	—	(1,730)
Other income	103	1,758	619	1,313
Total other expense	(832)	1,358	(2,338)	(1,636)
Net loss	$ (7,435)	$ (4,194)	$ (20,407)	$ (16,258)
Net loss per preferred share, basic and diluted	$ (272.82)	$ (254.26)	$ (963.64)	$ (1,294.31)
Net loss per common share, basic and diluted	$ (0.65)	$ (1.52)	$ (2.06)	$ (8.43)
Weighted average preferred shares outstanding, basic and diluted	30,968	12,891	22,793	7,011
Weighted average common shares outstanding, basic and diluted	1,545,920	1,189,989	1,432,787	1,040,190

See accompanying notes to the condensed consolidated financial statements

KIROMIC BIOPHARMA, INC.
Condensed Consolidated Statements of Stockholders' Deficit
(Unaudited)
(In thousands, except share amounts)

	Preferred Stock		Common Stock				
	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Total
Balance at December 31, 2023	14,000	$ —	1,258,460	$ 1	$ 113,775	$ (122,897)	$ (9,121)
Common stock discount amortization	—	—	—	—	86	—	86
Warrants underlying common stock issuance	—	—	—	—	(86)	—	(86)
Released restricted stock units	—	—	29,775	—	—	—	—
Issuance of convertible preferred stock	8,000	—	—	—	8,000	—	8,000
Stock compensation expense	—	—	—	—	57	—	57
Net loss	—	—	—	—	—	(6,147)	(6,147)
Balance at March 31, 2024	22,000	$ —	1,288,235	$ 1	$ 121,832	$ (129,044)	$ (7,211)
Common stock discount amortization	—	—	—	—	86	—	86
Warrants underlying common stock issuance	—	—	—	—	(86)	—	(86)
Released restricted stock awards	—	—	254,185	—	—	—	—
Issuance of convertible preferred stock	8,838	—	—	—	8,838	—	8,838
Stock compensation expense	—	—	—	—	29	—	29
Net loss	—	—	—	—	—	(6,825)	(6,825)
Balance at June 30, 2024	30,838	$ —	1,542,420	$ 1	$ 130,699	$ (135,869)	$ (5,169)
Common stock discount amortization	—	—	—	—	70	—	70
Warrants underlying common stock issuance	—	—	—	—	(70)	—	(70)
Released restricted stock units	—	—	3,500	—	—	—	—
Issuance of convertible preferred stock	2,997	—	—	—	2,997	—	2,997
Stock compensation expense	—	—	—	—	319	—	319
Net loss	—	—	—	—	—	(7,435)	(7,435)
Balance at September 30, 2024	33,835	$ —	1,545,920	$ 1	$ 134,015	$ (143,304)	$ (9,288)

See accompanying notes to the condensed consolidated financial statements

KIROMIC BIOPHARMA, INC.
Condensed Consolidated Statements of Stockholders' Deficit
(Unaudited)
(In thousands, except share amounts)

	Preferred Stock		Common Stock				
	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Total
Balance at December 31, 2022	—	$ —	648,384	$ 1	$ 96,172	$ (101,948)	$ (5,775)
Common stock discount amortization	—	—	—	—	85	—	85
Warrants underlying common stock issuance	—	—	—	—	(85)	—	(85)
Released restricted stock units	—	—	1,773	—	—	—	—
Conversion of subordinated convertible notes into shares of common stock	—	—	329,086	—	2,914	—	2,914
Stock compensation expense	—	—	—	—	21	—	21
Net loss	—	—	—	—	—	(5,300)	(5,300)
Balance at March 31, 2023	—	$ —	979,243	$ 1	$ 99,107	$ (107,248)	$ (8,140)
Common stock discount amortization	—	—	—	—	86	—	86
Warrants underlying common stock issuance	—	—	—	—	(86)	—	(86)
Issuance of convertible preferred stock	8,000	—	—	—	8,000	—	8,000
Commitments shares issuance from standby equity purchase agreement	—		197,017	—	659	—	659
Stock issuance costs	—	—	—	—	(85)	—	(85)
Stock compensation expense	—	—	—	—	35	—	35
Net loss	—	—	—	—	—	(6,764)	(6,764)
Balance at June 30, 2023	8,000	$ —	1,176,260	$ 1	$ 107,716	$ (114,012)	$ (6,295)
Common stock discount amortization	—	—	—	—	87	—	87
Warrants underlying common stock issuance	—	—	—	—	(87)	—	(87)
Released restricted stock units	—	—	—	—	—	—	—
Issuance of convertible preferred stock	6,000	—	—	—	6,000	—	6,000
Stock issuance costs	—	—	—	—	(26)	—	(26)
Stock compensation expense	—	—	—	—	26	—	26
Net loss	—	—	—	—	—	(4,194)	(4,194)
Balance at September 30, 2023	14,000	$ —	1,176,260	$ 1	$ 113,716	$ (118,206)	$ (4,488)

See accompanying notes to the condensed consolidated financial statements

KIROMIC BIOPHARMA, INC.
Condensed Consolidated Statements of Cash Flows
(Unaudited)
(In thousands)

	Nine Months Ended September 30,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (20,407)	$ (16,258)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation	1,666	1,666
Operating lease non-cash expense	469	425
Stock compensation expense	405	83
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(20)	(512)
Accounts payable	(443)	(2,884)
Interest payable	2,996	1,181
Accrued litigation liability	—	1,088
Accrued expenses and other current liabilities	(7)	(168)
Operating lease liability	(469)	(437)
Net cash used for operating activities	(15,810)	(15,816)
Cash flows from investing activities:		
Purchases of property and equipment	(338)	(98)
Net cash used for investing activities	(338)	(98)
Cash flows from financing activities:		
Proceeds from senior secured convertible note payable	16,000	19,600
Proceeds from issuance of common stock	—	659
Stock issuance costs	—	(110)
Borrowings from note payable	400	—
Repayments of note payable	(400)	(500)
Net cash provided by financing activities	16,000	19,649
Net change in cash and cash equivalents and restricted cash	(148)	3,735
Cash and cash equivalents and restricted cash:		
Beginning of period	3,204	645
End of period	$ 3,056	$ 4,380
Supplemental disclosures of cash flow information:		
Cash paid for interest on note payable	$ 13	$ 39
Non-cash investing and financing activities:		
Exchange of 25% senior convertible promissory notes and accrued interest into convertible preferred stock	$ 17,600	$ 14,000
Conversion of accrued interest into subordinated convertible promissory note	$ 1,240	$ —
Conversion of accrued interest into convertible preferred stock	$ 2,235	$ —
Conversion of subordinated convertible promissory notes into common stock	$ —	$ 2,914
Stock issuance costs in accounts payable	$ —	$ 1
Property and equipment in accounts payable	$ —	$ 13
Deferred financing costs forgiven	$ —	$ 365

The following table presents a reconciliation of cash, cash equivalents and restricted cash reported on the balance sheet that sums the total of the same such amounts shown in the statement of cash flows.

	September 30, 2024	**September 30, 2023**
Cash and cash equivalents	$ 2,924	$ 4,380
Restricted cash	132	—
Total cash and cash equivalents and restricted cash	$ 3,056	$ 4,380

See accompanying notes to the condensed consolidated financial statements

KIROMIC BIOPHARMA, INC.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. ORGANIZATION

Nature of Business

Kiromic BioPharma, Inc. and subsidiaries (the "Company" or "We") are a clinical stage, fully integrated biotherapeutics company formed under the Texas Business Organizations Code in December 2012. We maintain offices in Houston, Texas. We have not generated any revenue to date.

We are an allogeneic Gamma Delta T-cell therapy company featuring unique, proprietary end-to-end bioinformatic, AI targeting and manufacturing technologies to address solid tumors. Our end-to-end approach consists of target discovery and validation, product development, and on-site current Good Manufacturing Practices ("cGMP") which we believe will allow us to leverage a new framework for the next generation of cell therapies.

From a development standpoint, we utilize innovative non-engineered and engineered allogeneic Gamma Delta T (GDT) cell technologies and are developing proprietary, virus-free cell engineering methods to develop novel therapies for solid tumors that we believe will be effective and cost-efficient. Deltacel™ (Deltacel) is our first off-the-shelf, non-engineered GDT cell-based product currently in a Phase 1 clinical stage. Our Isocel™ ("Isocel") and Procel™ ("Procel") product candidates consist of allogeneic, engineered, off-the-shelf GDT cells and they are currently in the preclinical development stage. Our Isocel product candidate consists of engineered GDTs that target Mesothelin Isoform 2 ("Iso-Meso"), a target that we have discovered and prioritized using our Diamond AI bio-informatic platform. Our Procel product candidate consists of engineered GDTs that target PD-L1. Our Deltacel product candidate consists of non-engineered GDTs which we expand, enrich, and activate *ex-vivo* through a proprietary process, and it is intended to treat solid tumors regardless of the specific tumor antigen expression. Isocel consists of engineered GDTs targeting solid tumors expressing a tumor-specific variant (Isoform) of Mesothelin ("Iso-Meso"), while Procel consists of engineered GDTs targeting PD-L1 positive tumors.

We have a total of five clinical programs to study our key product candidates:

1) Deltacel-01: This clinical trial is active, and will evaluate Deltacel in combination with low-dose targeted radiation for patients with stage 4 non-small cell lung cancer (NSCLC). Deltacel was granted Fast-Track Designation status by the FDA in August 2024. This trial has entered the second part, dose-expansion phase, in September 2024.

2) Isocel combination: This clinical trial will evaluate Isocel in combination with low-dose radiation for patients with Mesothelin Isoform 2 positive solid malignancies.

3) Alexis-ISO-1: This clinical trial will evaluate Isocel in patients with Mesothelin Isoform 2 positive solid malignancies.

4) Procel combination: This clinical trial will evaluate Procel in combination with low-dose radiation for patients with PD-L1 positive solid malignancies.

5) Alexis-PRO-1: This clinical trial will evaluate Procel in patients with PD-L1 positive solid malignancies.

Depending on pre-clinical evidence, we might submit 1 IND for Isocel and 1 for Procel, for a total of two new INDs to study our product candidates either with or without low-dose radiation.

Going Concern— These consolidated financial statements have been prepared in accordance with generally accepted accounting principles applicable to a going concern, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business.

The Company has incurred significant losses and negative cash flows from operations since inception and expects to incur additional losses until such time that it can generate significant revenue from the commercialization of its product candidates. The Company had negative cash flow from operations of $15.8 million for the nine months ended September 30, 2024, and an accumulated deficit of $143.3 million as of September 30, 2024. To date, the Company has relied on equity and debt financing to fund its operations. The Company's product candidates are still in the early stages of clinical trials and development, and substantial additional financing will be needed by the Company to fund its operations and ongoing research and development efforts prior to the commercialization, if any, of its product candidates. The Company does not have sufficient cash on hand or available liquidity to meet its obligations through the twelve months following the date the condensed consolidated financial statements are issued. This condition raises substantial doubt about the Company's ability to continue as a going concern.

Given its projected operating requirements and its existing cash and cash equivalents, management's plans include evaluating different strategies to obtain the required funding for future operations. These plans may include, but are not limited to, additional funding from private or public equity or debt offerings with current or new investors. However, there can be no assurance that the Company will be able to secure such additional financing, or if available, that it will be sufficient to meet its needs or on favorable terms. Therefore, the plans cannot be deemed probable of being implemented. As a result, the Company has concluded management's plans do not alleviate substantial doubt about the Company's ability to continue as a going concern. In the event the Company is unable to secure financing sufficient to allow it to meet its obligations as they become due, the Company may need to file a voluntary petition for relief under the United States Bankruptcy Code in order to implement a restructuring plan or liquidation.

The condensed consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying condensed consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("GAAP") for interim financial information (Accounting Standards Codification ("ASC") 270, Interim Reporting) and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information necessary for a full presentation of financial position, results of operations, and cash flows in conformity with GAAP. Operating results for interim periods are not necessarily indicative of results that may be expected for the fiscal year as a whole. In the opinion of management, the condensed consolidated financial statements reflect all adjustments (consisting of normal recurring adjustments) considered necessary for a fair presentation of the results of the Company for the periods presented.

Certain information and footnote disclosures normally included in financial statements prepared in accordance with GAAP have been condensed or omitted. These interim financial statements should be read in conjunction with the consolidated financial statements and notes thereto included in our Form 10-K for the year ended December 31, 2023. The results of operations for the period ended September 30, 2024, are not necessarily indicative of the operating results that may be expected for a full year. The consolidated balance sheet as of December 31, 2023, contains financial information taken from the audited Company consolidated financial statements as of that date.

All intercompany balances were eliminated upon consolidation.

Use of Estimates—The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. Actual results could differ from those estimates. Significant estimates include determination of the fair value of common stock and related stock-based compensation, warrants to purchase common stock underlying shares of Series B Preferred Stock and public offering common stock, and estimating services incurred by third-party service providers used to recognize research and development expense.

Concentrations of Credit Risk and Other Uncertainties—Financial instruments that potentially subject the Company to concentration of credit risk consist of cash and cash equivalents. Substantially all of the Company's cash and cash equivalents were deposited in accounts at a small number of national financial institutions. Account balances may at times exceed federally insured limits. The Company has not incurred losses related to these cash and cash equivalents deposited at financial institutions and management believes that the Company is not exposed to significant credit risk due to the financial strength of the depository institutions in which the cash is held.

The Company is subject to certain risks and uncertainties from changes in any of the following areas that the Company believes could have a material adverse effect on future financial position or results of operations: the ability to obtain regulatory approval and market acceptance of, and reimbursement for, the Company's product candidates; the performance of third-party clinical research organizations and manufacturers; protection of the intellectual property; litigation or claims against the Company based on intellectual property, patent, product, regulatory or other factors; the Company's ability to attract and retain employees necessary to support commercial success; and changes in the industry or customer requirements including the emergence of competitive products with new capabilities.

Restricted Cash— Restricted cash of $132 thousand and zero as of September 30, 2024 and December 31, 2023, respectively, consists primarily of bank deposits that collateralize our obligations to vendors.

Property and Equipment—Property and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful lives of the assets ranging from 1 to 8 years. Major replacements and improvements are capitalized as leasehold improvements, while general repairs and maintenance are expensed as incurred. Estimated useful lives of leasehold improvements are the shorter of the remaining lease term or the estimated useful economic life of the specific asset.

Impairment of Long-Lived Assets—The Company reviews its long-lived assets, including property and equipment, for impairment indicators. If indicators are noted, the Company compares the carrying amount of the asset to its estimated undiscounted cash flows. If the carrying amount exceeds its estimated undiscounted cash flows, an impairment loss is recognized to adjust the long-lived asset to fair value. There have been no impairment losses on the Company's long-lived assets since inception.

Income Taxes—The Company files federal and state income tax returns, utilizing the accrual basis of accounting. Income taxes are provided for the tax effects of transactions reported in the condensed consolidated financial statements and consist of taxes currently due and deferred taxes. Certain transactions of the Company may be subject to accounting methods for income tax purposes, which differ from the accounting methods used in preparing these condensed consolidated financial statements in accordance with GAAP. Accordingly, the net income or loss of the Company reported for income tax purposes may differ from the balances reported for those same items in the accompanying condensed consolidated financial statements.

Deferred tax assets and liabilities are recognized for the future tax consequences attributable between the financial statement carrying amounts of existing assets and liabilities and their respective tax basis. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which such temporary differences are expected to be recovered or settled. The Company records valuation allowances to reduce deferred income tax assets to the amount that is more likely than not to be realized.

The Company records uncertain tax positions in accordance with Accounting Standard Codification ("ASC 740"), *Income Taxes*, on the basis of a two-step process in which (1) the Company determines whether it is more-likely-than-not that the tax positions will be sustained on the basis of the technical merits of the position and (2) for those tax positions that meet the more-likely-than-not recognition threshold, the Company recognizes the largest amount of tax benefit that is more than 50 percent likely to be realized upon ultimate settlement with the related tax authority. The Company recognizes interest and penalties related to unrecognized tax benefits on the income tax expense line in the accompanying condensed consolidated statements of operations. No such interest or penalties were recognized during the three and nine months ended September 30, 2024 or 2023.

Research and Development Expense—The Company expenses research and development costs as incurred. Research and development expenses include personnel and personnel-related costs, costs associated with the Company's pre-clinical development activities including costs of outside consultants and contractors, the submission and maintenance of regulatory filings, equipment and supplies used in developing products prior to market approval and an allocation of certain overhead costs such as facility and related expenses.

The Company accrues and expenses costs of services provided by contract research organizations in connection with preclinical studies and contract manufacturing organizations engaged to manufacture clinical trial material, costs of licensing technology, and costs of services provided by research organizations and service providers. Upfront payments and milestone payments made for the licensing of technology are expensed as research and development in the period in which they are incurred if the technology is not expected to have any alternative future uses other than the specific research and development project for which it was intended. Nonrefundable advance payments 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 rather than when the payment is made.

Nonvested Stock Options, Restricted Stock Units and Awards—Pursuant to the Company's 2017 Stock Incentive Plan (the "2017 Plan") and the Omnibus 2021 Equity Incentive Plan (the "2021 Plan"), the Company has the ability to issue a variety of share-based payments and incentives to board members, employees, and non-employees through grants of nonvested stock options, restricted stock units ("RSUs") and restricted stock awards ("RSAs").

The vesting conditions for stock options and RSUs include annual and monthly vesting. Annual vesting conditions are for three years or more. Monthly vesting conditions range from 10 to 48 months. When nonvested options are vested, they become exercisable over a 10-year period from grant date.

The vesting conditions for RSAs include cliff vesting conditions. Certain RSUs vest with a range of 6 to 12 months. When RSUs vest, they are released to the grantee within sixty days.

Stock-Based Compensation—The Company records stock compensation expense related to the 2017 Equity Incentive Plan (the "2017 Plan") and the Omnibus 2021 Equity Incentive Plan (the "2021 Plan") in accordance with ASC 718, *Compensation—Stock Compensation*. The Company measures and recognizes stock compensation expense for all stock-based awards, including stock options, based on estimated fair values recognized using cliff vesting or the straight-line method over the requisite service period. The fair value of stock options is estimated on the grant date using the Black-Scholes option-valuation model (the "Black-Scholes model"). The calculation of stock-based compensation expense requires that the Company make assumptions and judgments about the variables used in the Black-Scholes model, including the fair value of the Company's common stock, expected term, expected volatility of the underlying common stock, and risk-free interest rate. Forfeitures are accounted for when they occur.

The Company estimates the grant date fair value of stock options using the Black-Scholes model and the assumptions used to value such stock options are determined as follows:

Expected Term. The expected term represents the period that the Company's stock options are expected to be outstanding. Due to limitations on the sale or transfer of the Company's common stock under the lock-up agreements and market standoff components of the stock option agreements, the Company does not believe its historical exercise pattern is indicative of the pattern it will experience after restricted periods expire. The Company uses the simplified method to calculate the expected term, which is the average of the contractual term and vesting period.

Risk-Free Interest Rate. The Company bases the risk-free interest rate used in the Black-Scholes model on the implied yield available on U.S. Treasury zero-coupon issues with a term equivalent to that of the expected term of the stock options for each stock option group.

Volatility. The Company determines the price volatility based on the historical volatilities of industry peers as it has limited trading history for its common stock price. The Company intends to continue to consistently apply this process using the same or a similar peer group of public companies, until a sufficient amount of historical information regarding the volatility of its own common stock price becomes available, or unless circumstances change such that the identified peer companies are no longer similar, in which case other suitable peer companies whose common stock prices are publicly available would be utilized in the calculation.

Dividend Yield. The expected dividend assumption is based on the Company's current expectations about its anticipated dividend policy. To date, the Company has not declared any dividends and, therefore, the Company has used an expected dividend yield of zero.

Common Stock Valuations. The closing price listed on the OTCQB Capital Market or previously the NASDAQ Capital Market for the Company's common stock on the date of the grant is used as the common stock valuation.

Segment Data—The Company manages its operations as a single segment for the purposes of assessing performance and making operating decisions.

Recently Issued Accounting Pronouncements—From time to time, Accounting Standards Updates ("ASU") are issued by the Financial Accounting Standards Board ("FASB") or other standard setting bodies and adopted by the Company as of the specified effective date.

Accounting Standards Not Yet Adopted

Segments. In November 2023, the FASB issued ASU No. 2023-07, "Improvements to Reportable Segment Disclosures (Topic 280)". ASU 2023-07 modifies reportable segment disclosure requirements, primarily through enhanced disclosures about segment expenses categorized as significant or regularly provided to the Chief Operating Decision Maker (CODM). In addition, the amendments enhance interim disclosure requirements, clarify circumstances in which an entity can disclose multiple segment measures of profit or loss, and contain other disclosure requirements. The purpose of the amendments is to enable investors to better understand an entity's overall performance and assess potential future cash flows. This ASU is effective for annual periods beginning after December 15, 2023, and interim periods within annual periods beginning after December 15, 2024, with early adoption permitted. The Company currently operates as one reportable segment and does not believe there will be a material impact on the related disclosures in the consolidated financial statements.

Income Taxes. In December 2023, the FASB issued ASU No. 2023-09, "Improvements to Income Tax Disclosures (Topic 740)". ASU 2023-09 requires enhanced disclosures on income taxes paid, adds disaggregation of continuing operations before income taxes between foreign and domestic earnings and defines specific categories for the reconciliation of jurisdictional tax rate to effective tax rate. This ASU is effective for fiscal years

beginning after December 15, 2024, and can be applied on a prospective basis. The Company is currently evaluating the impact this new standard will have on the related disclosures in the consolidated financial statements.

3. NET LOSS PER COMMON STOCK SHARE

Basic and diluted net loss per common share is determined by dividing net loss less deemed dividends by the weighted-average common shares outstanding during the period. For all periods presented the common shares underlying the stock options, RSUs and warrants have been excluded from the calculation because their effect would be anti-dilutive. Therefore, the weighted-average common shares outstanding used to calculate both basic and diluted loss per common shares is the same. The following table illustrates the computation of basic and diluted loss per share:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands)	2024	2023	2024	2023
Net loss	$ (7,435)	$ (4,194)	(20,407)	(16,258)
Less: Initial Public Offering Common Stock discount amortization	(8)	(25)	(58)	(75)
Less: Public Offering Common Stock discount amortization	(62)	(62)	(184)	(183)
Less: Undeclared dividends attributable to convertible preferred stock	(1,951)	(808)	(4,272)	(1,323)
Net loss attributable to common shareholders	$ (9,457)	$ (5,089)	(24,922)	(17,839)

	Three Months Ended September 30, 2024		Three Months Ended September 30, 2023	
(In thousands, except share and per share amounts)	Common Stock	Preferred Stock	Common Stock	Preferred Stock
Net loss per share, basic and diluted				
Allocation of undistributed net loss	$ (1,008)	$ (8,449)	$ (1,811)	$ (3,278)
Weighted average shares outstanding, basic and diluted	1,545,920	30,968	1,189,989	12,891
Basic and diluted net loss per share	$ (0.65)	$ (272.82)	$ (1.52)	$ (254.26)

	Nine Months Ended September 30, 2024		Nine Months Ended September 30, 2023	
	Common Stock	Preferred Stock	Common Stock	Preferred Stock
Net loss per share, basic and diluted				
Allocation of undistributed net loss	$ (2,957)	$ (21,965)	$ (8,765)	$ (9,074)
Weighted average shares outstanding, basic and diluted	1,432,787	22,793	1,040,190	7,011
Basic and diluted net loss per share	$ (2.06)	$ (963.64)	$ (8.43)	$ (1,294.31)

For the three months ended September 30, 2024, there were 56,239 restricted stock units and 15,416 warrants that were excluded from the computations of diluted weighted-average shares of common stock because they were anti-dilutive.

During the nine months ended September 30, 2024, the Company entered into three exchange agreements (the "Exchange Agreements"). The first agreement reclassified convertible promissory notes with $8.0 million of principal into 8,000 shares of Series D convertible voting preferred stock (the “Series D Stock”). The second agreement reclassified (i) convertible promissory notes with $7.2 million of principal and (ii) accrued interest of $1.63 million for a total of $8.8 million into 8,837.58 shares of Series D Stock. The third agreement reclassified (i) convertible promissory notes with $2.4 million of principal and (ii) accrued interest of $0.59 million for a total of $3.0 million into 2,997 shares of Series E Stock. See Note 10 - Stockholder’s Equity for details concerning the Series D and Series E Stock.

4. PROPERTY AND EQUIPMENT, NET

Property and equipment, net consisted of the following:

(In thousands)	September 30, 2024	December 31, 2023
Equipment	$ 3,336	$ 3,126
Leasehold improvements	7,372	7,372
Office furniture, fixtures, and equipment	137	137
Software	589	360
Construction in progress	—	101
	11,434	11,096
Less: Accumulated depreciation	(6,587)	(4,921)
Total	$ 4,847	$ 6,175

Depreciation expense was $552 thousand and $560 thousand for the three months ended September 30, 2024 and 2023, respectively. Depreciation expense was $1,666 thousand and $1,666 thousand for the nine months ended September 30, 2024 and 2023, respectively. Depreciation expense is allocated between research and development and general and administrative operating expenses on the condensed consolidated statements of operations.

5. ACCRUED EXPENSES AND OTHER CURRENT LIABILITIES

Accrued expenses and other current liabilities consisted of the following as of:

(In thousands)	September 30, 2024	December 31, 2023
Accrued litigation and settlements	$ 130	$ 448
Accrued compensation	1,116	865
Accrued consulting and outside services	420	360
Total	$ 1,666	$ 1,673

6. NOTE PAYABLE

In January 2024, the Company entered into a financing arrangement for its Director and Officer Insurance policy. The total amount financed was approximately $400 thousand with an annual interest rate of 4.93%, to be paid over a period of eleven months. As of September 30, 2024 and December 31, 2023, the payable balance on the financed amount was zero.

7. SENIOR SECURED CONVERTIBLE PROMISSORY NOTE

The Company began issuing senior secured convertible promissory notes (each a “CPN” and together the “Notes”) during 2022.

Through September 30, 2024, the Company has issued twenty-two notes totaling $45.2 million, of which $17.2 million were issued during the nine months ended September 30, 2024. The notes are each 25% Senior Secured Convertible Promissory Notes with largely consistent terms including a stated interest rate of 25% per year; and a one-year maturity. The Notes are convertible at varying conversion prices.

The stated interest rates for these notes increase to 27% per annum or the highest rate then allowed under applicable law (whichever is lower) upon the occurrence of an event of default, including the failure by the Company to make payment of principal or interest due under the related note on the respective maturity date, and any commencement by the Company of a case under any applicable bankruptcy or insolvency law.

In April 2023, July 2023, March 2024, June 2024 and September 2024, the Company executed an exchange agreement to reclassify $8.0 million, $6.0 million, $8.0 million of the Notes' principal, and $8.8 million and $3.0 million of the Notes' principal and interest into shares of convertible preferred stock, respectively. See Note 10— Stockholders' Equity for further discussion.

Senior secured convertible promissory notes consisted of the following:

(In thousands)

Issue Date	Maturity Date	September 30, 2024	December 31, 2023
06/26/2023	06/26/2024	$ —	$ 2,400
07/25/2023	07/25/2024	—	2,400
08/25/2023	08/25/2024	—	2,400
09/27/2023	09/27/2024	—	2,400
11/02/2023	11/02/2024	2,400	2,400
12/12/2023	12/12/2024	—	2,000
04/02/2024	04/02/2025	2,000	—
05/02/2024	05/02/2025	2,000	—
06/03/2024	06/03/2025	2,000	—
06/21/2024	06/21/2025	1,240	—
07/03/2024	07/03/2025	2,000	—
08/01/2024	08/01/2025	2,000	—
Total senior secured convertible promissory notes		$ 13,640	$ 14,000

8. COMMITMENTS AND CONTINGENCIES

License Agreements—

The Company has entered into a number of licensing arrangements for various intellectual property and licensed patent rights for technologies being developed for commercial sale. As part of these arrangements, the Company is subject to contingent milestone payments in accordance with agreed-upon development objectives, as well as future royalty payments on product sales of the underlying assets. As of September 30, 2024, and December 31, 2023, the Company has not incurred any milestone or royalty liabilities related to these license agreements.

Legal Proceedings—

Jason Terrel Claim

On March 22, 2021, Jason Terrell (“Terrell”), a former consultant and director of the Company, commenced an action against us in the Court of Chancery of the State of Delaware, C.A. No. 2021-0248-MTZ (the “Action”). In the Action, Terrell seeks a declaratory judgment that we are obligated to issue him (i) options to purchase 16,667 shares of our common stock at a price of $15.00 per share pursuant to an alleged 2014 consulting agreement, and (ii) options to purchase an additional 16,667 shares of common stock at a price of $5.10 per share pursuant to an alleged January 2017 non-employee director options agreement.

On January 31, 2024, the Chancery Court issued a letter opinion that dismissed Terrell’s claims based on the contract-interpretation grounds the Company originally advanced back in 2021, as well as the Delaware Supreme Court’s determination that the third options agreement was not unconscionable. On March 11, 2024, the Chancery Court entered a stipulated form of Final Order and Judgment, dismissing Terrell’s claims consistent with the Chancery Court’s January 31, 2024, letter opinion. Terrell thereafter commenced an appeal of the dismissal to the Delaware Supreme Court. Pursuant to the briefing schedule ordered by the Delaware Supreme Court, Terrell filed its opening appellate brief on May 9, 2024; and the Company filed its answering brief on June 25, 2024. Oral argument in the Delaware Supreme Court appeal took place on October 30, 2024, and the parties are awaiting the Court's decision.

Karp and Podmore Class Actions

On August 5, 2022, Ronald H. Karp, filed a class action complaint in the United States District Court for the Southern District of New York (the “Karp Class Action”) in connection with a public offering by the Company that closed on or about July 2, 2021, and asserting claims against the Company and certain current and former officers and directors of the Company for alleged violations of Sections 11, 12, and 15 of the Securities Act of 1933 in connection with the purchase of common stock through the Company’s public offering that closed on July 2, 2021 and Section 10(b) of the Exchange Act of 1934 and Rule 10b-5 promulgated thereunder in connection with the certain statements and acts made by the defendants between June 25, 2021 and August 13, 2021. On October 3, 2022, Joseph Podmore filed a class action complaint in the United States District Court for the Southern District of New York (the “Podmore Class Action”) raising similar claims.

The Karp Class Action and the Podmore Class Action were consolidated and are collectively referred to as the “Class Action”. Please refer to the Settlement of the Class Action described more fully below.

Settlement in Principle of the Class Action

On August 7, 2023, we entered into a term sheet with the plaintiffs in the Class Action, to settle in principle (and globally resolve) the Class Action. We subsequently reached agreement with the plaintiffs in the Class Action on all settlement materials and terms including with respect to payment of up to $2,300,000 and, on September 29, 2023, counsel for plaintiffs submitted the proposed settlement materials to the Court for approval. Of this amount, insurance covered $570,000, resulting in a net settlement of $1,730,000 owed by the Company. As of September 30, 2024, we have paid the totality of the settlement into an escrow account, of which $448,000 was payable as of December 31, 2023.

The Company regularly assesses all contingencies and believes, based on information presently known, the Company is not involved in any other matters that would have a material effect on the Company’s financial position, results of operations and cash flows.

9. LEASES

The Company leases real estate for office and warehouse space under non-cancelable operating leases, with a total rentable space of 149,000 square feet. The Company intends to use the full lease term under the existing lease agreement which is currently set to expire on April 30, 2026. As of September 30, 2024, the Company is not able to determine if any renewal options will be exercised.

There are no variable payments associated with the lease agreements, as the rent payments are predetermined on a fixed schedule.

The following table indicates the balance sheet line items that include the right-of-use assets and lease liabilities for our operating lease:

(In thousands)	September 30, 2024	December 31, 2023
	Operating lease	Operating lease
Right-of-Use Asset		
Operating lease, net	$ 1,074	$ 1,543
Total right-of use asset, net	$ 1,074	$ 1,543
Lease Liabilities		
Operating lease - short term	$ (670)	$ (631)
Operating lease - long term	(404)	(912)
Total lease liabilities	$ (1,074)	$ (1,543)

For the three and nine months ended September 30, 2024 and 2023, the components of lease expense were as follows:

	Three Months Ended		Nine Months Ended	
(In thousands)	September 30, 2024	September 30, 2023	September 30, 2024	September 30, 2023
Operating lease cost allocated to research and development expense	$ 113	$ 109	$ 338	$ 288
Operating lease cost allocated to general and administrative expense	66	70	199	249
Total lease expense	$ 179	$ 179	$ 537	$ 537
Weighted-average remaining lease term	1.59	2.59	1.59	2.59
Weighted-average discount rate	7.12%	7.12%	7.12%	7.12%

As of September 30, 2024, the maturities of the Company's operating lease liabilities were as follows:

Maturity of Lease Liabilities (In thousands)	Operating lease
2024 (remaining)	$ 179
2025	725
2026	242
Total lease payments	1,146
Less: imputed interest	(72)
Present value of lease payments	$ 1,074

10. STOCKHOLDERS' EQUITY

Common Stock— The Company has one class of common shares outstanding. Refer to the Condensed Consolidated Balance Sheets for shares authorized, issued and outstanding as of the balance sheet dates.

Preferred Stock— As of September 30, 2024, and December 31, 2023, the Company was authorized to issue 60,000,000 shares of preferred stock (24,000,000 shares designated as Series A-1 Preferred Stock and 16,500,000 shares designated as Series B Preferred stock), none of which were issued or outstanding. Additionally, as of September 30, 2024 and December 31, 2023, the Company authorized the issuance of 14,000 and 14,000 shares of Series C Convertible Voting Preferred Stock (the "Series C Stock"), respectively, 20,000 and 0 shares of Series D Convertible Preferred Stock, 6,000 and 0 shares of Series E Convertible Preferred Stock (the "Series E Stock", the "Series D Stock" and together with the Series C Stock, the "Preferred Shares"), respectively. The Company issued 8,000 shares of Series C Stock on April 2, 2023, 6,000 shares of Series C Stock on July 18, 2023, 8,000 shares of Series D Stock on March 28, 2024, 8,837.58 shares of Series D Stock on June 21, 2024, and 2,997 shares of Series E Stock on September 27, 2024, as part of five agreements to reclassify convertible preferred notes for Preferred Shares.

As discussed in Note 3, the Company reclassified certain CPNs into convertible preferred shares by executing the Exchange Agreements. This reclassification resulted in two new classes of convertible preferred shares in 2024, the Series D and Series E Stock. The Company has three classes of convertible preferred shares issued and outstanding for both balance sheet dates presented - Series C Stock, Series D Stock and Series E Stock. The Preferred Shares are convertible, upon a notice of conversion by the holder, into shares of the Company's common stock, par value $0.001 per share at an exchange price of $6.50 per share for the Series C Stock, $2.50 for the Series D Stock and a price equal to 80% of the 5-day VWAP for the Common Stock beginning on the fifth day preceding the date of the Notice of Conversion for the Series E Stock, subject to a beneficial ownership maximum of 19.99%. The Preferred Shares are voting stock and holders are entitled to vote together with the Common Stock on an as-if-converted-to-Common-Stock basis as determined by dividing the Liquidation Preference with respect to such shares of Preferred Shares by their conversion price. Holders of Common Stock are entitled to one vote for each share of Common Stock held on all matters submitted to a vote of stockholders. Accordingly, holders of Preferred Shares are entitled to one vote for each whole share of Common Stock into which their Preferred Shares are convertible on all matters submitted to a vote of stockholders.

Cumulative Rights of Series C, D and E Stock Shareholders— The Preferred Shares accumulate undeclared dividends at an annual rate of 25%. Unpaid dividends and undeclared dividends are added to the aggregated Liquidation Preference which also includes the face value of the Preferred Shares outstanding. In the event of any liquidation of the Company, holders of Preferred Shares then outstanding shall be entitled to be paid the Liquidation Preference out of the assets of the Company available for distribution to its stockholders, before any payment shall be made to the holders of any other shares of capital.

	Dividends Earned for the period Ended September 30, 2024		**Liquidation Preference**	
(In thousands)	**Three Months Ended**	**Nine Months Ended**	**September 30, 2024**	**December 31, 2023**
Series C	$ 882	$ 2,627	$ 18,833	$ 16,205
Series D	1,061	1,637	18,474	-
Series E	8	8	3,005	-
Total	$ 1,951	$ 4,272	$ 40,312	$ 16,205

Participating Rights of Series C, D and E Stock Shareholders— In the event the Company declares a dividend, and all cumulative dividends have been distributed, the Preferred Shares participate in any remaining declared dividends to be paid equal to (on an as-if-converted-to-common-stock basis) and in the same form as dividends paid on shares of Common Stock.

Warrants—Holders of warrants (the "Warrants") grant the holder the right to purchase a specified number of shares of the Company at a specified price with an expiration date of five years. Holders of the Warrants may purchase 2,083 shares of common stock at an exercise price of $450.00 per share with an expiration date of October 14, 2025, or an additional 13,333 shares of common stock at an exercise price of $187.50 per share with an expiration date of July 1, 2026. All of the Warrants were outstanding as of September 30, 2024 and December 31, 2023.

Standby Equity Purchase Agreement Financing

On October 13, 2022, the Company entered into a Standby Equity Purchase Agreement (the "SEPA") with YA II PN, Ltd. (the "Investor"), pursuant to which the Company has the right to sell to the Investor up to $8.0 million (the "Commitment Amount") of its shares of common stock, at the Company's request any time during the commitment period commencing on October 13, 2022, and terminating on the earliest of (i) the first day of the month following the 24-month anniversary of the SEPA or (ii) the date on which the Investor has paid for shares of Common Stock equal to the Commitment Amount.

On May 24, 2023, we issued to the Investor 97,000 shares of common stock at a purchase price of $3.89, for an advance amount of $377,000.

On June 2, 2023, we issued to the Investor 100,000 shares of common stock at a purchase price of $2.82, for an advance amount of $282,100.

11. STOCK-BASED COMPENSATION

2017 Stock Incentive Plan—Restricted Stock Units

The following table summarizes the activity for all RSUs outstanding under the 2017 Plan as of September 30, 2024 and 2023:

	2024		2023	
	Shares	Weighted Average Grant Date Fair Value Per Share	Shares	Weighted Average Grant Date Fair Value Per Share
Outstanding RSUs at beginning of period	605	$ 285.36	650	$ 259.50
Granted	—	—	—	—
Vested	(52)	259.97	(246)	255.85
Cancelled and forfeited	(537)	254.10	(45)	260.10
Nonvested RSUs as of September 30	16	$ 260.08	359	$ 285.36

In addition, the weighted average remaining recognition period for the 2017 RSUs is 0.3 year as of September 30, 2024.

Total stock compensation expense recognized from stock-based compensation awards classified as restricted stock units were recognized in the condensed consolidated statements of operations for the three and nine months ended September 30, 2024 and 2023, as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands)	2024	2023	2024	2023
Research and development	$ —	$ 6	$ 9	$ 21
General and administrative	—	9	15	23
Total	$ —	$ 15	$ 24	$ 44

As of September 30, 2024, there was $3,200 unrecognized stock compensation expense related to unvested restricted stock units under the 2017 Plan.

2017 Stock Incentive Plan— Stock Options

The following table summarizes the activity for all stock options outstanding as of September 30, 2024 and 2023 under the 2017 Plan:

	2024		2023	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Options outstanding at beginning of period	18,093	$ 101.04	32,706	$ 96.24
Granted	—	—	—	—
Exercised	—	—	—	—
Cancelled and forfeited	—	—	(14,613)	88.17
Balance as of September 30	18,093	$ 101.04	18,093	$ 101.04
Options exercisable as of September 30:	18,093	$ 101.04	18,093	$ 101.04

The options have no intrinsic value as of September 30, 2024, or December 31, 2023, respectively.

There was no stock compensation expense recognized for stock options in the condensed consolidated statements of operations for the three and nine months ended September 30, 2024 and 2023.

As of September 30, 2024, there was no unrecognized stock compensation expense related to unvested stock options.

2021 Stock Incentive Plan—Restricted Stock Units

The following table summarizes the activity for all RSUs outstanding as of September 30, 2024 and 2023 under the 2021 Plan:

	2024		2023	
	Shares	Weighted Average Grant Date Fair Value Per Share	Shares	Weighted Average Grant Date Fair Value Per Share
Outstanding RSUs at beginning of period	89,206	$ 1.56	684	$ 133.20
Granted	92,444	2.57	50,843	0.62
Vested	(29,775)	4.95	(13,483)	0.62
Cancelled and forfeited	(95,652)	1.89	(621)	126.60
Nonvested RSUs as of September 30	56,223	$ 3.74	37,423	$ 20.41

In addition, the weighted average remaining recognition period for the 2021 RSUs is 2.88 years as of September 30, 2024.

Total stock compensation expense recognized from stock-based compensation awards classified as restricted stock units were recognized in the condensed consolidated statements of operations for the three and nine months ended September 30, 2024 and 2023, as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands)	2024	2023	2024	2023
Research and development	$ —	$ 10	$ 24	$ 21
General and administrative	—	2	38	17
Total	$ —	$ 12	$ 62	$ 38

As of September 30, 2024, there was $197,800 unrecognized stock compensation expense related to unvested restricted stock units under the 2021 Plan.

2021 Stock Incentive Plan—Restricted Stock Awards

In May 2024, the Company approved the grant of 254,185 restricted stock awards (RSAs) to Officers and certain directors. The RSAs were released to the participants when granted but were not vested yet as of September 30, 2024.

The following table summarizes the activity for all RSAs outstanding as of September 30, 2024 and 2023 under the 2021 Plan:

	2024		2023	
	Shares	Weighted Average Grant Date Fair Value Per Share	Shares	Weighted Average Grant Date Fair Value Per Share
Nonvested RSAs at beginning of period	—	$ —	—	$ —
Granted	254,185	2.42	—	—
Vested	—	—	—	—
Cancelled and forfeited	—	—	—	—
Nonvested RSAs as of September 30	254,185	$ 2.42	—	$ —

In addition, the weighted average remaining recognition period for the RSAs is 0.49 years as of September 30, 2024.

Total stock compensation expense recognized from stock-based compensation awards classified as restricted stock awards were recognized in the condensed consolidated statements of operations for the three and nine months ended September 30, 2024 and 2023, as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(In thousands)	2024	2023	2024	2023
Research and development	$ 107	$ —	$ 107	$ —
General and administrative	212	—	212	—
Total	$ 319	$ —	$ 319	$ —

As of September 30, 2024, there was $297,000 unrecognized stock compensation expense related to unvested restricted stock awards.

12. INCOME TAXES

The Company's effective tax rate from continuing operations was 0% for the three and nine months ended September 30, 2024 and 2023. The Company recorded no income tax provision for the three or nine months ended September 30, 2024.

The provision for income taxes during the interim reporting periods is calculated by applying an estimate of the annual effective tax rate for the full fiscal year to "ordinary" income or loss for the reporting period. Each quarter, the estimate of the annual effective tax rate is updated, and if the estimated effective tax rate changes, a cumulative adjustment is made. There is a potential for volatility of the effective tax rate due to several factors, including changes in the mix of the pre-tax income and the jurisdictions to which it relates, changes in tax laws, business reorganizations and settlements with taxing authorities.

The income tax rates vary from the US federal statutory rate of 21% primarily due to the full valuation allowance on the Company's deferred tax assets. The Company has recorded the full valuation allowance based on an evaluation of both positive and negative evidence, including latest forecasts and cumulative losses in recent years. The Company has concluded that it was more likely than not that none of its deferred tax assets would be realized.

13. SUBSEQUENT EVENTS

On November 1, 2024, the Company entered into an exchange agreement with the holder of promissory notes to reclassify $2.4 million of the Company's 25% Senior Secured Convertible Promissory Note's principal and $600 thousand accrued interest into Series E convertible preferred shares, The Series E Stock are convertible to a price equal to 80% of the 5-day VWAP for the Common Stock beginning on the fifth day preceding the date of the Notice of Conversion, subject to a beneficial ownership maximum of 19.99%.

On November 3, 2024, our Standby Equity Purchase Agreement (the "SEPA") with YA II PN, Ltd. expired.

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

The following discussion and analysis of financial condition and results of operations provides information that management believes is relevant to an assessment and understanding of our plans and financial condition. The following financial information is derived from our unaudited financial statements and should be read in conjunction with such financial statements and notes thereto included in this report and with the audited consolidated financial statements and the notes thereto included in our Form 10-K.

Our Business

Overview

Kiromic BioPharma, Inc. and subsidiaries (the "Company") is an allogeneic Gamma Delta T-cell therapy company featuring unique, proprietary, end-to-end bioinformatic, AI targeting, and manufacturing technologies to address solid tumors. Our end-to-end approach consists of target discovery and validation, product development, and on-site current Good Manufacturing Practices ("cGMP"), which we believe will allow us to leverage a new framework for the next generation of cell therapies.

We currently have three product candidates: 1) Deltacel, non-engineered GDTs, expanded and activated with proprietary technology; 2) Isocel GDTs engineered with an anti-Mesothelin isoform Chimeric Antigen Receptor; and 3) Procel, GDTs engineered with a PD-1 switch receptor.

We are developing a novel and virus-independent engineering method, which we believe will result in the submission of new IND applications. The first of these applications will study Isocel and is expected to be ready for submission to the FDA in the second half of 2025. The second will study Procel and is expected to be ready for submission to the FDA in 2026. The development of both technologies and their advancement to clinical stage are subject to sufficient financing. Depending on evidence from preclinical studies, we may study the new candidates in combination with low-dose radiation or as stand-alone therapies.

We have not generated any revenue from sales to date, and we continue to incur significant research and development and other expenses related to our ongoing operations. As a result, we are not and have never been profitable and have incurred losses in each period since we began principal business operations in 2012. As discussed in more detail below, we are currently in discussions with financing sources in an attempt to secure short-term financing to continue operations and fund other liquidity needs through the end of the year. In the absence of such financing, management anticipates that existing cash resources will not be sufficient to meet operating and liquidity needs beyond December 2024.

Recent Developments

Going Concern and Liquidity

We do not have sufficient cash on hand and available liquidity to meet our obligations through the twelve months following the date the condensed consolidated financial statements are issued. Therefore, this condition raises substantial doubt about our ability to continue as a going concern. Management's plans were updated to evaluate different strategies to obtain the required funding for future operations. These plans may include, but are not limited to, additional funding from current or new investors, inclusive of a potential public offering of equity; however, if we are unable to raise additional funding to meet working capital needs, we will be forced to delay or reduce the scope of our research programs and/or limit or cease operations. The negative cash flows and lack of financial resources raised substantial doubt as to our ability to continue as a going concern, and that substantial doubt has not been alleviated. See Note 1 to the Company's Condensed Consolidated Financial Statements, "Going Concern" for further details.

Our unrestricted cash and cash equivalents were $2.92 million as of September 30, 2024. We are currently in discussions with financing sources in an attempt to secure short-term financing to continue operations and fund other liquidity needs through 12 months after the date of the filing of this quarterly report on Form 10-Q. We are working with a financial advisor to assist us with our efforts to obtain financing. In the absence of such financing, management anticipates that existing cash resources as of September 30, 2024, will not be sufficient to meet our operating and liquidity needs beyond December 2024. However, management may further evaluate additional cost reduction actions, including additional reductions in our workforce and delay of research and development expenditures on one or more product candidates, in order to reduce our current expenditures and preserve cash. In addition, we are seeking to relist on to the NASDAQ or another major stock exchange in order to increase the liquidity of our stock. We are not able to predict whether any such cost reduction or major stock exchange listing actions will be successful.

As a result of our current liquidity position, management can provide no assurance that we will be able to obtain financing on acceptable terms, if at all. If financing is available, it may not be on favorable terms and may have a significant dilutive effect on our existing stockholders. In the event we are unable to secure financing sufficient to allow us to meet our obligations as they become due, we may need to file a voluntary petition for relief under the United States Bankruptcy Code in order to implement a restructuring plan or liquidation. See Part II, Item 1A. "Risk Factors" for further details.

Financing Update

In 2024, we executed monthly CPNs to finance our operations and executed three Exchange Agreements to strengthen our balance sheet by reclassifying CPNs to preferred shares. Please see Note 7 – Senior Secured Convertible Promissory Note, Note 10 – Stockholders' Equity and Note 13 – Subsequent Events for more information.

Clinical Update

In the second half of 2022, we started the development of Deltacel, our novel, non-engineered GDT cell product based on a proprietary methodology of expanding and activating GDT cells from healthy donors. We submitted the IND application for the Deltacel-01 trial in March 2023. On April 28, 2023, the FDA authorized us to proceed with the study. We began the clinical trial activation process during the second quarter of 2023. On October 23, 2023, we entered into a clinical trial agreement with Beverly Hills Cancer Center (BHCC) to conduct our Deltacel-01 Phase 1 Study in patients with stage 4 Non-Small Cell Lung Cancer (NSCLC).

On December 13, 2023, the first patient in the Deltacel-01 trial received the first dose of Deltacel at BHCC. So far, six patients received the Deltacel treatment. As of September 2024, we have registered a 6-month median Progression Free Survival (PFS) with a median length of follow-up of over 7 months and the longest PFS of 10 months.

None of the enrolled patients developed a dose-limiting toxicity. The Deltacel-01 study, encompassing long-term follow-up, spans up to 24 months. This trial consists of two parts: Part 1 is designed to identify the optimal dose of Deltacel. Following approval by the Safety Monitoring Committee (SMC), Part 2 (the Expansion Phase) is designed to further assess the therapy's effectiveness at the optimal dose identified in Part 1. Based on the promising survival benefits in the absence of limiting toxicities, we activated the Expansion Phase in September 2024, and the first patient in this phase started treatment in October 2024. We expect that a total of approximately 9 patients will be enrolled in the expansion phase, and that enrollment will be completed by year-end.

The following table shows a summary of the results from the first 6 subjects enrolled in the Deltacel-01 clinical trial:

Patient	**Safety**	**Six Weeks Post-treatment**	**Two Months Post-treatment**	**Four Months Post-treatment**	**Six Months Post-treatment**	**Eight Months Post-treatment**	**Ten Months Post-treatment**
1	No dose limiting toxicities	Stable disease	Tumor size reduction by 6.6% Tumor metabolism reduction by 20%	Stable disease (compared with two-month follow-up)	Stable disease (compared with four-month follow-up)	Stable Disease 20% Tumor Size Reduction	Stable Disease 27% Tumor Size Reduction
2	No dose limiting toxicities	Stable disease Complete resolution of brain lesions	Stable disease Confirmed clean brain imaging No new brain lesions	Disease progression Enrolled on emergency-use IND and re-treated			
3	No dose limiting toxicities	Stable disease	Stable disease	Stable disease	Disease progression		
4	No dose limiting toxicities	Stable disease	Stable disease	Stable Disease 3.6% Tumor Size Reduction	Stable Disease 5.3% Tumor Size Reduction		
5	No dose limiting toxicities	Stable disease	Disease progression				
6	No dose limiting toxicities	Scan not done per new protocol calendar	Stable disease				

Throughout 2024, we have activated an additional four testing sites:

- February 28, 2024, Virginia Oncology Associates, PC, located in Norfolk, VA;
- April 8, 2024, Texas Oncology, located in Tyler, TX;
- May 8, 2024, UPMC Hillman Cancer Center located in Pittsburgh, PA;
- September 19, 2024, the University of Arizona Cancer Center located in Tucson, Arizona.

On June 18, 2024, we submitted a Fast-Track Designation (FTD) Application to the FDA. The FTD status was granted on August 9, 2024. We believe this is a significant milestone for the clinical development of our Deltacel product candidate, as FTD facilitates and expedites the development and review of drugs that treat serious conditions and address unmet medical needs. This is achieved through benefits such as Accelerated Approval, Rolling Review, and Priority Review, which collectively accelerate the approval process. Therefore, we believe that receiving an FTD for our Deltacel product will significantly accelerate our pathway to approval, as FTD status can give us access to the following:

- More frequent meetings with FDA to discuss our clinical development plan and ensure the collection of appropriate data needed to support drug approval
- More frequent written communication from FDA about the design of the proposed clinical trials and use of biomarkers
- Eligibility for Accelerated Approval
- Eligibility for Priority Review
- Rolling Review, which means that we will be allowed to submit completed sections of its Biologic License Application (BLA) for review by FDA, rather than waiting until every section of the BLA is completed before the entire application can be reviewed. Without Rolling Review, BLA review does not begin until the entire application has been submitted to the FDA

On October 1, 2024, based upon our insights from the favorable results of the first phase of our trial, we submitted an IND protocol amendment to the FDA that includes changes in the study to further improve our therapeutic approach and the benefits for the patients. The changes became effective on November

1, 2024.

Depending on the response rates registered during our Deltacel-01 Phase 1 clinical trial, in the second half of 2025 we may be able to initiate a registrational Phase 2 trial to support a Biologics License Application (BLA) to accelerate the clinical development of Deltacel.

We plan to continue the development of Isocel and Procel once we gather sufficient financial support. We expect to be able to submit the Isocel IND in the second half of 2025, and the Procel IND in the second quarter of 2026.

Results from our Internal Review

On or about August 17 and 23, 2021, Tony Tontat, who at the time was the Chief Financial Officer and a member of the Board of Directors ("the Board"), submitted substantially identical reports (the "Complaints") through our complaint hotline. These Complaints, alleged, among other topics, risks associated with our public disclosures in our securities filings and in statements made to the public, investors, and potential investors regarding (i) the anticipated timing of the U.S. Food and Drug Administration's ("FDA") authorization of our investigational new drug ("IND") applications and (ii) the anticipated timing of human clinical trials. These Complaints were subsequently submitted to the Audit Committee of the Board.

After receiving the Complaints, the Audit Committee recommended that the Board form, and the Board did in turn form, a Special Committee comprised of three independent directors (the "Special Committee") to review the Complaints and other related issues (the "Internal Review"). The Special Committee retained an independent counsel to assist it in conducting the Internal Review. As previously disclosed in the Company's Form 10-K for the year ended December 31, 2023, the Internal Review concluded on February 2, 2022, and the remedial actions taken by the Company in response to the Internal Review are set forth in the Form 10-K.

Upon completion of the Internal Review, we voluntarily contacted the SEC to report certain information about the Internal Review. Since that time, we have been voluntarily cooperating with requests for information from the SEC and intend to fully cooperate with any further requests from the SEC.

In November 2022, we received a Grand Jury Subpoena (the "Subpoena") from the U.S. Department of Justice requesting certain information from the company in connection with an ongoing investigation being conducted by the Federal Grand Jury in the Southern District of Texas. We are not a target of this investigation at this time.

Principal Factors Affecting Our Financial Performance

Our operating results are primarily affected by the following factors:

- Clinical trials discontinuation for any or a combination of the following reasons: commercial or strategic decision, lack of efficacy, poor recruitment.
- Slow or delayed IND applications.
- Slow or delayed clinical trial enrollment.
- Patent reinforcement and prosecution.
- Changes in laws or the regulatory environment affecting our company.

Emerging Growth Company

We qualify as an "emerging growth company" under the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). As a result, we are permitted to, and intend to, rely on exemptions from certain disclosure requirements. For so long as we are an emerging growth company, we will not be required to:

- Have an auditor report on our internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act;
- 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 (i.e., an auditor discussion and analysis);
- Submit certain executive compensation matters to stockholder advisory votes, such as "say-on-pay" and "say-on-frequency;" and
- 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.

In addition, Section 107 of the JOBS Act also provides that an emerging growth company can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, for complying with new or revised accounting standards. In other words, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to take advantage of the benefits of this extended transition period. Our financial statements may therefore not be comparable to those of companies that comply with such new or revised accounting standards.

We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year (a) following the fifth anniversary of our initial public offering, which was October 15, 2020, (b) the date in which our total annual gross revenues exceed $1.07 billion, or (c) the date in which we become a "large accelerated filer" as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which would occur if the market value of our common stock that is held by non-affiliates exceeds $700 million as of the last business day of our most recently completed second fiscal quarter, or (ii) the date on which we have issued more than $1 billion in non-convertible debt during the preceding three year period.

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 product sales in the foreseeable future. We will record revenue from collaboration agreements, including amounts related to upfront payments, annual fees for licenses of our intellectual property and research and development funding. However, none of those agreements have been executed as of the issuance date of this report.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred for our research activities, including our discovery efforts and the development of our product candidates. These include the following:

- Salaries, benefits and other related costs, including stock-based compensation expense, for personnel engaged in research and development functions;
- Expenses incurred under agreements with third parties, including contract research organizations and other third parties that conduct preclinical research and development activities and clinical trials on our behalf;
- Costs of developing and scaling our manufacturing process and manufacturing drug products for use in our preclinical studies and future clinical trials, including the costs of contract manufacturing organizations, that will manufacture our clinical trial material for use in our preclinical studies and potential future clinical trials;
- Costs of outside consultants, including their fees and related travel expenses;
- Costs of laboratory supplies and acquiring, developing and manufacturing preclinical study and clinical trial materials;
- License payments made for intellectual property used in research and development activities; and
- Facility-related expenses, which include direct depreciation costs and expenses for rent and maintenance of facilities and other operating costs if specifically, identifiable to research activities.

Research and development activities are central to our business model. We expect that our research and development expenses will comprise a larger percentage of our total expenses as we initiate Phase 1 clinical trials for our Isocel and Procel product candidates and continue to discover and develop additional candidates. However, management is currently evaluating various cost reduction actions, including suspending research and development expenditures on one or more product candidates, in order to reduce our expenditures and preserve cash. As of the date of this quarterly report, we are not able to predict on what product candidates and how much expenditure we plan to reduce. However, we expect that our research and development and general and administrative costs will increase over the long-term, even if we are able to successfully reduce our costs in the short-term in order to preserve cash in light of our current liquidity situation.

We cannot determine with certainty the duration and costs of future clinical trials of our Deltacel, Procel, and Isocel product candidates, or any other product candidate we may develop or if, when or to what extent we will generate revenue from the commercialization and sale of any product candidate for which we obtain marketing approval. We may never succeed in obtaining marketing approval for any product candidate. The duration, costs and timing of clinical trials and development of our Isocel and Procel product candidates and any other our trial candidate we may develop will depend on a variety of factors, including:

- The scope, rate of progress, expense and results of clinical trials of our Isocel and Procel trial candidates, as well as of any future clinical trials of other product candidates and other research and development activities that we may conduct;
- Uncertainties in clinical trial design and patient enrollment rates;
- The actual probability of success for our product candidates, including their safety and efficacy, early clinical data, competition, manufacturing capability and commercial viability;
- Significant and changing government regulation and regulatory guidance;
- the timing and receipt of any marketing approvals;
- The expense of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights; and
- Our ability to effectively address the deficiencies elucidated in the FDA's clinical hold letters for our IND applications related to key chemical manufacturing and control components.

A change in the outcome of any of these variables with respect to the development of a product candidate could mean a significant change in the costs and timing associated with the development of that product candidate. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we anticipate will be required for the completion of clinical development of a product candidate, or if we experience significant delays in our clinical trials due to slower than expected patient enrollment or other reasons, we would be required to expend significant additional financial resources and time on the completion of clinical development.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs, including stock-based compensation for personnel in our executive, finance, business development, operations and administrative functions. General and administrative expenses also include legal fees relating to intellectual property and corporate matters; professional fees for accounting, auditing, tax and consulting services; insurance costs; travel expenses; and facility-related expenses, which include direct depreciation costs and expenses for rent and maintenance of facilities and other operating costs that are not specifically attributable to research activities.

We expect that our general and administrative expenses will increase in the future as we increase our personnel headcount to support our continued research activities, development, and manufacturing of product candidates. We also have incurred and expect to continue to incur increased expenses associated with being a public company, including costs of accounting, audit, legal, regulatory and tax-related services associated with maintaining compliance with OTCQB and SEC requirements; director and officer insurance costs; and investor and public relations costs.

Results of Operations

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

The following table sets forth key components of our results of operations for the three months ended September 30, 2024 and 2023.

(In thousands)		Three Months Ended September 30, 2024	Three Months Ended September 30, 2023	Increase (Decrease) $	Increase (Decrease) %
Operating expenses:					
Research and development		$ 4,228	$ 2,677	$ 1,551	58%
General and administrative		2,375	2,875	(500)	(17)%
Total operating expenses		6,603	5,552	1,051	19%
Loss from operations		(6,603)	(5,552)	1,051	19%
Other expense:					
Interest expense	g	(935)	(440)	495	113%
Litigation settlement		—	40	40	(100)%
Other income (expense)	h	103	1,758	1,655	(94)%
Total other expense		(832)	1,358	2,190	(161)%
Net loss		$ (7,435)	$ (4,194)	$ 3,241	77%

Research and development expenses.

The following table summarizes our change in research and development expenses by product candidate or development program:

(In thousands)		Three Months Ended September 30, 2024	Three Months Ended September 30, 2023	Increase (Decrease) $	Increase (Decrease) %
Direct research and development expenses by product candidate:					
Isocel development costs	a	$ 38	$ 258	$ (220)	(85)%
Platform development, early-stage research and unallocated expenses:					
Employee-related costs	b	1,325	881	444	50%
Laboratory supplies and services	c	519	441	78	18%
Outsourced research and development (net of reimbursements)	d	1,501	219	1,282	585%
Laboratory equipment and maintenance	e	562	611	(49)	(8)%
Facility-related costs	f	239	224	15	7%
Intellectual property		16	29	(13)	(45)%
Other research and development costs		28	14	14	100%
Total research and development expenses		$ 4,228	$ 2,677	$ 1,551	58%

The primary drivers for the increase in research and development expenses are as follow:

a- Isocel development cost decreased due to the leverage of full-time employees rather than outside consulting services.

b- Employee related costs increased due to an increase in employee headcount, and executive bonuses.

c- Laboratory supplies and services increased due to the prioritization of the Deltacel-01 development to support preclinical studies and clinical trials.

d- Outsourced research and development also increased due to the prioritization of the Deltacel-01 development to support preclinical studies and clinical trials.

e- Laboratory equipment and maintenance decreased due to a decline in purchase of supplies and other lab related materials during the quarter.

f- Facility-related costs increased due to repairs and maintenance expenses during the three months ended September 30, 2024.

General and administrative expenses.

The following table summarizes our change in general and administrative expenses:

		Three Months Ended September 30,		Increase (Decrease)	
		2024	2023	$	%
Operating expenses:					
Employee Expenses	a	$ 1,017	$ 784	$ 233	30%
Facilities Expenses	b	314	378	(64)	(17)%
Legal Expenses	c	717	675	42	6%
Professional Fees	d	327	1,038	(711)	(69)%
Total general and administrative expenses		$ 2,375	$ 2,875	$ (500)	(17)%

The primary drivers for the decrease in general and administrative expenses are as follow:

a- Employee expenses increased due to the hiring of additional full-time employees, and executive bonuses.

b- Facilities expenses decreased due to less repairs and maintenance expenses.

c- Legal services increased due to ongoing legal proceedings. See Note 8— Commitment and Contingencies for more discussion.

d- Professional fees decreased due to the decline in outside consulting fees as a result of the addition of full-time employees.

Other expenses. The primary drivers of the decrease in other expenses are as follow:

g- Interest expense increased due to the issuance of additional convertible promissory notes subsequent to September 30, 2023. See Note 7— Senior Secured Convertible Promissory Note for more discussion.

h- Other income decreased mainly due to a credit memo resulting from an engagement letter with a major vendor to facilitate the payment of the balance due for the three months ended September 30, 2023.

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

The following table sets forth key components of our results of operations for the nine months ended September 30, 2024 and 2023.

(In thousands)		Nine Months Ended September 30, 2024	Nine Months Ended September 30, 2023	Increase (Decrease) $	Increase (Decrease) %
Operating expenses:					
Research and development		$ 11,385	$ 6,719	$ 4,666	69%
General and administrative		6,684	7,903	(1,219)	(15)%
Total operating expenses		18,069	14,622	3,447	24%
Loss from operations		(18,069)	(14,622)	3,447	24%
Other expense:					
Interest expense	g	(2,957)	(1,219)	1,738	143%
Litigation settlement	h	—	(1,730)	(1,730)	(100)%
Other income (expense)	i	619	1,313	694	(53)%
Total other expense		(2,338)	(1,636)	702	43%
Net loss		$ (20,407)	$ (16,258)	$ 4,149	26%

Research and development expenses.

The following table summarizes our change in research and development expenses by product candidate or development program:

(In thousands)		Nine Months Ended September 30, 2024	Nine Months Ended September 30, 2023	Increase (Decrease) $	Increase (Decrease) %
Direct research and development expenses by product candidate:					
Isocel development costs	a	$ 99	$ 942	$ (843)	(89)%
Platform development, early-stage research and unallocated expenses:					
Employee-related costs	b	3,635	2,071	1,564	76%
Laboratory supplies and services	c	1,473	835	638	76%
Outsourced research and development (net of reimbursements)	d	3,710	466	3,244	696%
Laboratory equipment and maintenance	e	1,651	1,770	(119)	(7)%
Facility-related costs	f	711	502	209	42%
Intellectual property		25	72	(47)	(65)%
Other research and development costs		81	61	20	33%
Total research and development expenses		$ 11,385	$ 6,719	$ 4,666	69%

The primary drivers for the increase in research and development expenses are as follow:

a- Isocel development cost decreased due to the leverage of full-time employees rather than outside consulting services.

b- Employee related costs increased due to an increase in employee headcount, and executive bonuses.

c- Laboratory supplies and services increased due to the prioritization of the Deltacel-01 development to support preclinical studies and clinical trials.

d- Outsourced research and development increased due to the prioritization of the Deltacel-01 development to support preclinical studies and clinical trials.

e- Laboratory equipment and maintenance decreased due to a decline in purchase of supplies and other lab related materials during the quarter.

f- Facilities related costs increased due to repairs and maintenance expenses during the nine months ended September 30, 2024.

General and administrative expenses.

The following table summarizes our change in general and administrative expenses:

		Nine Months Ended September 30,		Increase (Decrease)	
		2024	2023	$	%
Operating expenses:					
Employee Expenses	a	$ 2,860	$ 2,011	$ 849	42%
Facilities Expenses	b	1,042	1,241	(199)	(16)%
Legal Expenses	c	1,520	1,657	(137)	(8)%
Professional Fees	d	1,262	2,994	(1,732)	(58)%
Total general and administrative expenses		$ 6,684	$ 7,903	$ (1,219)	(15)%

The primary drivers for the decrease in general and administrative expenses are as follow:

a- Employee expenses increased due to the hiring of additional full-time employees, and executive bonuses.

b- Facilities expenses decreased due to less repairs and maintenance expenses.

c- Legal services and other services decreased due to a significant decline in expenses related to the Settlement in Principle of the Class Action.

d- Professional fees decreased due to the decline in outside consulting fees as a result of the addition of full-time employees.

Other expenses. The primary drivers of the decrease in other expenses are as follow:

g- Interest expense increased due to the issuance of additional convertible promissory notes subsequent to September 30, 2023. See Note 7— Senior Secured Convertible Promissory Note for more discussion.

h- Litigation settlement decreased due to the settlement in principle of the class action of 1,730,000 in 2023. See Item 1— Legal Proceedings for more discussion.

i- Other income decreased mainly due to a credit memo resulting from an engagement letter with a major vendor to facilitate the payment of the balance due for the nine months ended September 30, 2023.

Liquidity and Capital Resources

As of September 30, 2024, we had cash and cash equivalents of $3.06 million, which included $132 thousand of restricted cash. We do not currently have any approved products and have never generated any revenue from product sales. To date, we have financed our operations primarily with proceeds from the sale of our convertible promissory notes, convertible preferred stock, common stock from the initial public offering and follow-on offering.

As of October 31, 2024, we had cash and cash equivalents of $2.15 million, which included $132 thousand of restricted cash. We have material contractual obligations which will require cash to meet their requirements. These applicable obligations include our facility lease agreement, our employment contracts, and our financing arrangement for our Director and Officer Insurance Policy. We also plan to deploy cash for other research and development and general and administrative operating expenses. Our ability to continue meeting these contractual obligations will be reliant upon our ability to secure significant additional capital funding.

As described above under “Going Concern and Liquidity,” in the absence of financing, management anticipates that existing cash resources combined with verbal, non-contractual commitments for additional financing will not be sufficient to meet operating and liquidity needs beyond December 2024. Management may further evaluate various cost reduction actions, including possible reductions in our workforce and suspending research and development expenditures on one or more product candidates, in order to reduce our expenditures and preserve cash. We are limited in our ability to reduce expenditures for known contractual obligations. As a result, we are not able to predict whether any cost reduction actions will be successful or how much longer any such actions will allow us to continue to operate without financing.

As previously disclosed, we have incurred significant operating losses since inception, and we expect to incur significant expenses and operating losses for the foreseeable future as we advance the preclinical and clinical development of our product candidates. We expect that our research and development and general and administrative costs will increase over the long-term, even if we are able to successfully reduce our costs in the short-term in order to preserve cash in light of our current liquidity situation. These costs include conducting preclinical studies and clinical trials for our product candidates, contracting with clinical research organizations and building out internal capacity to have product candidates manufactured to support preclinical studies and clinical trials, expanding our intellectual property portfolio and providing general and administrative support for our operations. As a result, substantial doubt exists regarding the going concern assumption on our condensed consolidated financial statements. Therefore, these condition raises substantial doubt about our ability to continue as a going concern.

We are currently seeking short-term financing to be able to continue our operations. If we are successful in obtaining short-term financing to fund our operations beyond the end of the year, we intend to seek significant additional capital funding to develop our platform, hire scientific professionals and other general and administrative employees, and for clinical trials. However, there can be no assurance that such efforts will be successful or that, in the event that they are successful, the terms and conditions of any such financings will be favorable. Further, there are other factors which may make financing our operations more difficult, including potential governmental investigation, continued elevated legal and accounting professional fees associated with litigation, and other risk factors listed in Item 1A. of Part II of our Annual Report on Form 10-K for the year ended December 31, 2023. In consideration of our plans, substantial doubt is not alleviated.

Summary of Cash Flow

The following table sets forth a summary of our cash flows for the periods presented:

	Nine Months Ended September 30,	
(In thousands)	**2024**	**2023**
Net cash used in operating activities	$ (15,810)	$ (15,816)
Net cash used in investing activities	(338)	(98)
Net cash provided by financing activities	16,000	19,649
Net change in cash and cash equivalents and restricted cash	(148)	3,735
Cash and cash equivalents and restricted cash at beginning of the period	3,204	645
Cash and cash equivalents and restricted cash at end of the period	$ 3,056	$ 4,380

Cash flows from operating activities

Net cash used in operating activities was $15.8 million for the nine months ended September 30, 2024, as compared to $15.8 million for the nine months ended September 30, 2023. The increase is driven primarily by the increase in overall spending in research and development due to the development of Deltacel combined with an overall increase in headcount. See our discussion in Results of Operations and our Statement of Cash Flows for more information.

Cash flows from investing activities

Net cash used in investing activities was $338 thousand for the nine months ended September 30, 2024, as compared to $98.0 thousand for the nine months ended September 30, 2023. Our net cash used in investing activities for the nine months ended September 30, 2024 primarily consisted of cash flows for purchases of property and equipment for our cGMP facilities located in our leased facility in Houston, Texas, and for the purchases of internal use software.

Cash flows from financing activities

Net cash provided by financing activities was $16.0 million for the nine months ended September 30, 2024, as compared to $19.6 million for the nine months ended September 30, 2023. The change in cash flows from financing activities for the periods shown are driven by the issuance of $19.5 million of convertible notes for the nine months ended September 30, 2024.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements for any of the periods presented.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

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

ITEM 4. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer ("CEO") and Principal Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of September 30, 2024. The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Under the supervision, and with the participation, of our current management, including our CEO and Principal Financial Officer, we evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of September 30, 2024. Based on this evaluation of our disclosure controls and procedures, our management, including our CEO and Principal Financial Officer, have concluded that our disclosure controls and procedures were effective as of September 30, 2024.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting for the quarter ended September 30, 2024.

PART II — OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

Information related to Item 1. Legal Proceedings is included in Note 8 – Commitments and Contingencies.

ITEM 1A. RISK FACTORS.

There have been no material changes from the risk factors disclosed in our Form 10-K for the year ended December 31, 2023 except as indicated below.

Our principal stockholder has significant influence over the election of our board of directors and approval of any significant corporate actions, including any sale of the company.

We have a principal stockholder who beneficially owns a substantial amount of our outstanding stock through securities convertible into our outstanding stock, consisting of certain convertible promissory notes and shares of our Series C Convertible Voting Preferred Stock, Series D Convertible Voting Preferred Stock and Series E Convertible Voting Preferred Stock. Each of these convertible securities contains beneficial ownership limitations equivalent to 19.99%. However, upon 61 days' notice to the company, the principal stockholder can increase or remove the beneficial ownership limitations. If the principal stockholder were to remove the beneficial ownership limitations, the principal stockholder would beneficially own over 90% of our outstanding stock. This stockholder currently has, and likely will continue to have, significant influence with respect to the election of our board of directors and approval or disapproval of all significant corporate actions, including a potential merger or sale of the company or its assets, which may occur at times or on terms that are undesirable to other stockholders. The concentrated voting power of this stockholder could also have the effect of delaying or preventing an acquisition of the company or another significant corporate transaction. The interests of the principal stockholder may not always coincide with your interests or the interests of other stockholders, and the principal stockholder may act in a manner that advances its best interests and not necessarily those of other stockholders.

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS.

None.

ITEM 5. OTHER INFORMATION.

None.

ITEM 6. EXHIBITS.

Exhibit No.	Description of Exhibit
3.1	Certificate of Designation of Preferences, Rights and Limitations of the Series E Convertible Voting Preferred Stock dated September 27, 2024 (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on September 30, 2024)
10.1	Exchange Agreement dated as of September 27, 2024 between the Company and the holder of the Exchange Securities (incorporated by reference to Exhibit 10.1 to Form 8-K filed on September 30, 2024)
31.1	Certifications of Principal Executive Officer filed pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certifications of Principal Financial Officer filed pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certifications of Principal Executive Officer furnished pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certifications of Principal Financial Officer furnished 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
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File – the cover page interactive data file does not appear in the Interactive Data File because its XBRL tags are embedded within the Inline XBRL document

SIGNATURES

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

Date: November 8, 2024

KIROMIC BIOPHARMA, INC.

/s/ Pietro Bersani
Name: Pietro Bersani
Title: Chief Executive Officer (Principal Executive Officer)

/s/ Brian Hungerford
Name: Brian Hungerford
Title: Chief Financial Officer (Principal Financial and Accounting Officer)

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

I, Pietro Bersani, certify that:

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

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

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

4. The registrant's other certifying officer(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 8, 2024

/s/ Pietro Bersani
Pietro Bersani
Chief Executive Officer (Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

I, Brian Hungerford, certify that:

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

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

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

4. The registrant's other certifying officer(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 8, 2024

/s/ Brian Hungerford
Brian Hungerford
Chief Financial Officer (Principal Financial and Accounting Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

The undersigned Chief Executive Officer of KIROMIC BIOPHARMA, INC. (the "Company"), DOES HEREBY CERTIFY that:

1. The Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2024 (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. Information contained in the Report fairly presents, in all material respects, the financial condition and results of operation of the Company.

IN WITNESS WHEREOF, the undersigned has executed this statement on November 8, 2024.

/s/ Pietro Bersani
Pietro Bersani
Chief Executive Officer (Principal Executive Officer)

A signed original of this written statement required by Section 906 has been provided to Kiromic BioPharma, Inc. and will be retained by Kiromic BioPharma, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

The forgoing certification is being furnished to the Securities and Exchange Commission pursuant to § 18 U.S.C. Section 1350. It is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906
OF THE SARBANES-OXLEY ACT OF 2002

The undersigned Chief Financial Officer of KIROMIC BIOPHARMA, INC. (the "Company"), DOES HEREBY CERTIFY that:

1. The Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2024 (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

2. Information contained in the Report fairly presents, in all material respects, the financial condition and results of operation of the Company.

IN WITNESS WHEREOF, the undersigned has executed this statement on November 8, 2024.

/s/ Brian Hungerford
Brian Hungerford
Chief Financial Officer (Principal Financial and Accounting Officer)

A signed original of this written statement required by Section 906 has been provided to Kiromic BioPharma, Inc. and will be retained by Kiromic BioPharma, Inc. and furnished to the Securities and Exchange Commission or its staff upon request.

The forgoing certification is being furnished to the Securities and Exchange Commission pursuant to § 18 U.S.C. Section 1350. It is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.