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

FORM 10-Q

(Mark One)		
☑ QUARTERLY REPORT PURSUANT TO S	ECTION 13 OR 15(d) OF THE	SECURITIES EXCHANGE ACT OF 1934
For th	e quarterly period ended June 30,	2024
	or	
☐ TRANSITION REPORT PURSUANT TO SE	ECTION 13 OR 15(d) OF THE	SECURITIES EXCHANGE ACT OF 1934
For th	e transition period from	to
Co	mmission File Number: 001-396	19
K	iromic BioPharma, In	с.
(Exact na	me of registrant as specified in its	charter)
Delaware		46-4762913
(State or other jurisdiction of incorporation or o	rganization) (I.F	S.S. Employer Identification Number)
7707 Fannin Street, Suite 200, Houston		77054
(Address of Principal Executive Office	es)	Zip Code
	(832) 968-4888	
	(Registrant's telephone number)	
Securities registered pursuant to Section 12(b) of t	he 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) Exchange Act of 1934 during the preceding 12 mo and (2) has been subject to such filing requirement	nths (or for such shorter period th	
		Yes ⊠ No □
Indicate by check mark whether the registrant has s to Rule 405 of Regulation S-T (§232.405 of this chwas required to submit such files).		
,		Yes ⊠ No □
Indicate by check mark whether the registrant is a keep company, or an emerging growth company. See company," and "emerging growth company" in Ru	the definitions of "large-accelera	
Large Accelerated Filer [Acceler	ated Filer
Non-accelerated Filer ⊠		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 to 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 \square No \boxtimes										
As of August 7, 2024, there were 1,545,920 shares of the registrant's common stock outstanding.										

TABLE OF CONTENTS

PART I FINANCIAL INFORMATION

Item 1.	<u>Financial Statements</u>	5
	Condensed Consolidated Balance Sheets as of June 30, 2024 (Unaudited) and December 31, 2023	5
	Condensed Consolidated Statements of Operations for the three and six months ended June 30, 2024 and 2023	
	(Unaudited)	6
	Condensed Consolidated Statements of Stockholders' Deficit for the three and six months ended June 30, 2024 and	
	2023 (Unaudited)	7
	Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2024 and 2023 (Unaudited)	ç
	Notes to Condensed Consolidated Financial Statements	10
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	22
Item 3.	Quantitative and Qualitative Disclosures about Market Risk	32
Item 4.	Controls and Procedures	32
	<u>PART II</u>	
	OTHER INFORMATION	
Item 1.	<u>Legal Proceedings</u>	<u>32</u>
Item 1A.	Risk Factors	<u>32</u>
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	<u>32</u>
Item 5.	Other Information	<u>32</u>
Item 6.	<u>Exhibits</u>	<u>33</u>
Signatures		33

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; including those fluctuations caused by COVID-19.
- Our ability to raise capital when needed.
- Relevant government policies and regulations relating to our industry.
- The outcome of any pending or threatened litigation.

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)

	 June 30, 2024	De	cember 31, 2023
Assets:			
Current Assets:			
Cash and cash equivalents	\$ 4,048	\$	3,204
Restricted cash	131		_
Prepaid expenses and other current assets	1,848		1,226
Total current assets	6,027		4,430
Property and equipment, net	5,183		6,175
Operating lease right-of-use asset, net	1,233		1,543
Other assets	21		21
Total Assets	\$ 12,464	\$	12,169
Liabilities and Stockholders' Deficit:			
Current Liabilities:			
Senior secured convertible promissory notes	\$ 12,040	\$	14,000
Accounts payable	1,996		2,136
Accrued expenses and other current liabilities	1,161		1,673
Interest payable	1,108		1,938
Note payable	96		_
Operating lease liability - short term	656		631
Total current liabilities	17,057		20,378
Operating lease liability - long term	577		912
Total Liabilities	17,634		21,290
Commitments and contingencies (Note 8)			
Stockholders' Deficit:			
Preferred Stock, \$0.0001 par value: 60,000,000 shares authorized, 30,838 and 14,000 issued and outstanding, with a liquidation preference of \$35,364 and \$16,206, as of June 30, 2024			
and December 31, 2023, respectively	_		_
Common stock, \$0.001 par value: 300,000,000 shares authorized as of June 30, 2024 and December 31, 2023; 1,542,420 and 1,258,460 shares issued and outstanding as of June 30,			
2024 and December 31, 2023, respectively	1		1
Additional paid-in capital	130,699		113,775
Accumulated deficit	 (135,870)		(122,897)
Total Stockholders' Deficit	(5,170)		(9,121)
Total Liabilities and Stockholders' Deficit	\$ 12,464	\$	12,169

KIROMIC BIOPHARMA, INC. Condensed Consolidated Statements of Operations (Unaudited)

(In thousands, except share and per share amounts)

	Three Months Ended June 30,				Six Months Ended June 30,			
		2024		2023		2024		2023
Operating expenses:								
Research and development	\$	4,135	\$	1,967	\$	7,157	\$	4,042
General and administrative		2,218		2,326		4,309		5,028
Total operating expenses		6,353		4,293		11,466		9,070
Loss from operations		(6,353)		(4,293)		(11,466)		(9,070)
Other expense:				_		_		
Interest expense		(957)		(335)		(2,028)		(779)
Debt issuance amortization		_		(366)		_		(445)
Other income (expense)		485		(1,770)		521		(1,770)
Total other expense		(472)		(2,471)		(1,507)		(2,994)
Net loss	\$	(6,825)	\$	(6,764)	\$	(12,973)	\$	(12,064)
Net loss per preferred share, basic and diluted	\$	(314.47)	\$	(495.89)	\$	(695.77)	\$	(1,234.92)
Net loss per common share, basic and diluted	\$	(0.74)	\$	(3.22)	\$	(1.77)	\$	(8.07)
Weighted average preferred shares outstanding, basic and diluted	-	22,971		8,000		18,661		4,022
Weighted average common shares outstanding, basic and diluted		1,506,076		1,054,277		1,405,312		964,049

KIROMIC BIOPHARMA, INC.

Condensed Consolidated Statements of Stockholders' Deficit (Unaudited)

(In thousands, except share amounts)

	Preferre	ed Stock	Commo	n Stock			
	Number		Number		_		
	of		of		Additional	Accumulated	
					Paid-In		
	Shares	Amount	Shares	Amount	Capital	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						(6,148)	(6,148)
Balance at March 31, 2024	22,000	\$ —	1,288,235	\$ 1	\$ 121,832	\$ (129,045)	\$ (7,212)
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	\$ (135,870)	\$ (5,170)

KIROMIC BIOPHARMA, INC.

Condensed Consolidated Statements of Stockholders' Deficit (Unaudited)

(In thousands, except share amounts)

	Preferr	ed Stock	Common Stock		_		
	Number of		Number of		Additional Paid-In	Accumulated	
	Shares	Amount	Shares	Amount	Capital	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)
Released restricted stock units	_	_	_	_	_	_	_
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)

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

Six Months Ended
June 30.

		June			
		2024		2023	
Cash flows from operating activities:					
Net loss	\$	(12,973)	\$	(12,064)	
Adjustments to reconcile net loss to net cash used for operating activities:					
Depreciation		1,114		1,105	
Operating lease non-cash expense		310		277	
Stock compensation expense		86		56	
Amortization of debt issuance costs		_		445	
Changes in operating assets and liabilities:					
Prepaid expenses and other current assets		(621)		(962)	
Accounts payable		(143)		(1,340)	
Interest payable		(830)		750	
Accrued expenses and other current liabilities		(512)		1,433	
Operating lease liability		(310)		(289)	
Net cash used for operating activities		(13,879)		(10,589)	
Cash flows from investing activities:					
Purchases of property and equipment		(119)		_	
Net cash used for investing activities		(119)		_	
Cash flows from financing activities:					
Proceeds from senior secured convertible note payable		14,877		12,400	
Proceeds from issuance of common stock				659	
Stock issuance costs		_		(82)	
Borrowings from note payable		400			
Repayments of note payable		(304)		(329)	
Net cash provided by financing activities		14,973		12,648	
Net change in cash and cash equivalents and restricted cash		975		2,059	
Cash and cash equivalents and restricted cash:		-		,	
Beginning of period		3,204		645	
End of period	\$	4,179	\$	2,704	
		1,21,2	_		
Supplemental disclosures of cash flow information:					
Cash paid for interest on note payable	\$	9	\$	35	
Non-cash investing and financing activities:	·		•		
Exchange of 25% senior convertible promissory notes and accrued interest into preferred					
stock	\$	16,838	\$	8,000	
Conversion of subordinated convertible promissory notes into common stock	\$	_	\$	(2,914)	
Stock issuance costs in accounts payable	\$	_	\$	3	
Property and equipment in accounts payable	\$	3	\$	30	
Debt issuance costs in accounts payable	\$	_	\$	620	

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.

	June 30, 2024	June 30, 2023
Cash and cash equivalents	4,048	2,704
Restricted cash	131	_
Total cash and cash equivalents and restricted cash	\$ 4,179	\$ 2,704

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. DeltacelTM (Deltacel) is our first off-the-shelf, non-engineered GDT cell-based product currently in a Phase 1 clinical stage. Our IsocelTM ("Isocel") and ProcelTM ("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 DeltacelTM 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. IsocelTM consists of engineered GDTs targeting solid tumors expressing a tumor-specific variant (Isoform) of Mesothelin ("Iso-Meso"), while ProcelTM 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 phase 1 clinical trial is active, and it is evaluating Deltacel in combination with low-dose targeted radiation for patients with stage 4 non-small cell lung cancer (NSCLC).
- 2) Isocel combination: This phase 1 clinical trial is expected to evaluate Isocel in combination with low-dose radiation for patients with Mesothelin Isoform 2 positive solid malignancies.
- 3) Alexis-ISO-1: This phase 1 clinical trial is expected to evaluate Isocel in patients with Mesothelin Isoform 2 positive solid malignancies.
- 4) Procel combination: This phase 1 clinical trial is expected to evaluate Procel in combination with low-dose radiation for patients with PD-L1 positive solid malignancies.
- 5) Alexis-PRO-1: This phase 1 clinical trial is expected to 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 \$13.9 million for the six months ended June 30, 2024, and an accumulated deficit of \$13.5.9 million as of June 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 June 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 believe s 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 commercials uccess; and changes in the industry or customer requirements including the emergence of competitive products with new capabilities.

Restricted Cash— Restricted cash of \$131 thousand as of June 30, 2024, 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.

Internal Use Software Development Costs—The Company capitalizes certain costs incurred to develop internal use software. All costs incurred that relate to planning and post-implementation phases of development are expensed as incurred. Costs incurred in the development and implementation phases are capitalized and amortized over the estimated life of the software, generally five years. The Company capitalized software development costs of approximately \$23 thousand and \$0 for the three months ended June 30, 2024 and 2023, respectively, which are recorded in Property and equipment, net on the accompanying condensed consolidated balance sheets.

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.

Comprehensive Loss—Comprehensive loss includes net loss as well as other changes in stockholders' equity that result from transactions and economic events other than those with stockholders. For all periods presented, there was no difference between net loss and comprehensive loss.

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 six months ended June 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 licen sing 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, RSUs and RSAs include annual and monthly vesting. Annual vesting conditions are for four years. 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 RSUs include cliff vesting conditions. Certain RSUs vest with a range of 6 to 12 months following the expiration of employee lock-up agreements. Certain RSUs vest based on the later of achievement of key milestones or the expiration of employee lock-up agreements. When nonvested RSUs are vested, 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 a wards, 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 prospec tive 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 End June 30,				hs Ended e 30,	
(In thousands)		2024		2023	2024	2023
Net loss	\$	(6,825)	\$	(6,764)	(12,973)	(12,064)
Less: Initial Public Offering Common Stock discount amortization		(25)		(25)	(50)	(50)
Less: Public Offering Common Stock discount amortization		(61)		(61)	(122)	(121)
Less: Undeclared dividends attributable to preferred stock		(1,432)		(515)	(2,321)	(515)
Net loss attributable to common shareholders	\$	(8,343)	\$	(7,365)	(15,466)	(12,750)

		Three Months Ended June 30, 2024				Three Mon June 30		
(In thousands, except share and per share amounts)	Common Stock		Preferred Stock		Common Stock		I	Preferred Stock
Net loss per share, basic and diluted								
Allocation of undistributed net loss	\$	(1,119)	\$	(7,224)	\$	(3,398)	\$	(3,967)
Weighted average shares outstanding, basic and diluted		1,506,076		22,971		1,054,277		8,000
Basic and diluted net loss per share	\$	(0.74)	\$	(314.47)	\$	(3.22)	\$	(495.89)

	Six Months Ended June 30, 2024				Ended 023			
	Common Stock		Preferred Stock		Common Stock		F	Preferred Stock
Net loss per share, basic and diluted								
Allocation of undistributed net loss	\$	(2,481)	\$	(12,985)	\$	(7,783)	\$	(4,967)
Weighted average shares outstanding, basic and diluted		1,405,312		18,661		964,049		4,022
Basic and diluted net loss per share	\$	(1.77)	\$	(695.77)	\$	(8.07)	\$	(1,234.92)

For the three months ended June 30, 2024, there were 60,971 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 six months ended June 30, 2024, the Company entered into two exchange agreements (the "Exchange Agreements"). The first agreement reclassified convertible promissory notes with \$8,000,000 of principal for 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 \$8,837,580 for 8,837.58 shares of Series D Stock. See Note 10 - Stockholder's Equity for details concerning the Series D Stock.

4. PROPERTY AND EQUIPMENT, NET

Property and equipment, net consisted of the following:

(In thousands)	June	30, 2024	Dec	ember 31, 2023
Equipment	\$	3,136	\$	3,126
Leasehold improvements		7,372		7,372
Office furniture, fixtures, and equipment		137		137
Software		402		360
Construction in progress		171		101
		11,218		11,096
Less: Accumulated depreciation		(6,035)		(4,921)
Total	\$	5,183	\$	6,175

Depreciation expense was \$557 thousand and \$550 thousand for the three months ended June 30, 2024 and 2023, respectively. Depreciation expense was \$1,114 thousand and \$1,105 thousand for the six months ended June 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)	June 30, 2024	De	ecember 31, 2023
Accrued litigation	\$ —	\$	448
Accrued compensation	940		865
Accrued consulting and outside services	221		360
Total	\$ 1,161	\$	1,673

6. NOTE PAYABLE

In January 2024, the Company entered into a financing arrangement for its Director and Officer Insurance policy. The total am ount financed was approximately \$400 thousand with an annual interest rate of 4.93%, to be paid over a period of eleven months. As of June 30, 2024, the remaining payable balance on the financed amount was \$96 thousand.

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 June 30, 2024, the Company has issued twenty notes totaling \$41.2 million, of which \$13.2 million were issued during the six months ended June 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, and June 2024, the Company executed an exchange agreement to reclassify \$8,000,000, \$6,000,000, \$8,000,000 of the Notes' principal and \$8,837,580 of the Notes' principal and interest into shares of preferred stock, respectively. See Note 10—Stockholders' Equity for further discussion.

Senior secured convertible promissory notes consisted of the following:

(In thousands)

				Decei	mber 31,
Issue Date	Maturity Date	June 3	30, 2024	2	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		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		
Total senior secured convertible promissory notes		\$	12,040	\$	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 June 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. In his complaint, Terrell also claimed that, pursuant to our operative certificate of incorporation, he is entitled to indemnification from us for attorneys' fees and costs he incurs in connection with the Action because the Action arises in connection with his position as a former director.

We dispute Terrell's claims and allegations in the Action and intend to vigorously defend against them. On May 21,2021, the Company filed a motion to dismiss Terrell's claims in the actions with prejudice, arguing that (i) Terrell's options-related claims fail because his 2014 and January 2017 agreements were explicitly superseded by a later options agreement, under which Terrell relinquished his prior options; and (ii) Terrell is not entitled to indemnification because the Action relates to contracts between the Company and Terrell in his personal capacity, and not in connection with any activities or duties of Terrell in his official capacity as former director. In response to the motion filed in June 2021, Terrell withdrew his claim for indemnification, but opposed the portion seeking dismissal of his declaratory judgment claim. The motion was fully briefed with the filing of the Company's reply brief on July 7, 2021.

Oral argument was held before the Vice Chancellor on October 20, 2021. During oral argument, the Vice Chancellor invited the parties to submit supplemental letter briefs on the question of whether the Court of Chancery even had the authority to adjudicate the Action in light of the delegation of authority in Terrell's most recent stock option agreement with the Company (the "SOA") to the Company's Compensation Committee to resolve all disputes regarding the interpretation of the SOA. The parties submitted simultaneous supplemental letters briefs on this issue on November 15, 2021. On January 20, 2022, the Vice Chancellor issued her decision on our motion to dismiss, ruling that the Action is stayed until the Compensation Committee itself resolves whether it has sole authority to resolve the parties' contract interpretation dispute.

Subsequently, the parties agreed upon a process for coordinating submissions and/or presentations to the Compensation Committee. The parties made their respective written submissions to the Compensation Committee on March 31, 2022, and on July 21, 2022, the Compensation Committee determined that (i) the Compensation Committee has sole authority under the SOA to resolve the parties' contract interpretation dispute, and (ii) Terrell's most recent options agreement superseded and nullified any option rights Terrell may have had under his prior agreements. On August 2, 2022, the Vice Chancellor issued an order dismissing the Action for lack of subject matter jurisdiction.

On August 23, 2022, Terrell filed a notice of appeal of the Vice Chancellor's order of dismissal to the Delaware Supreme Court.

Oral argument on Terrell's appeal was held before the Delaware Supreme Court on February 8, 2023. On May 4, 2023, the Delaware Supreme Court issued a written opinion (the "Opinion") reversing the Vice Chancellor's order of dismissal and remanding to Chancery Court for further proceedings consistent with the Opinion. In its Opinion, the Delaware Supreme Court affirmed several of the Chancery Court's legal determinations on the motion to dismiss, but concluded that Chancery Court itself should independently review the Compensation Committee's determinations under Delaware law.

The Delaware Supreme Court also rejected Terrell's argument that the waiver clause in the third options agreement (which, according to the Company, superseded and extinguished unexercised options under the prior options agreements) was unconscionable.

Pursuant to a stipulated scheduling order, the parties submitted supplemental letter briefs to the Chancery Court in mid-August 2023, addressing the impact of the Opinion on the Company's motion to dismiss. Thereafter, the Chancery Court notified the parties that it had received the supplemental letter briefs and would take the matter under advisement without holding oral argument.

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 is not mandatory and will be scheduled only at the discretion of the Delaware Supreme Court. On appeal, the Company is vigorously arguing that the Chancery Court's dismissal should be affirmed.

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 Octo ber 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 June 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 June 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)		2 30, 2024	December 31, 2023			
	Opera	ating lease	Operating lease			
Right-of-Use Asset						
Operating lease, net	\$	1,233	\$	1,543		
Total right-of use asset, net	\$	1,233	\$	1,543		
Lease Liabilities						
Operating lease - short term	\$	(656)	\$	(631)		
Operating lease - long term		(577)		(912)		
Total lease liabilities	\$	(1,233)	\$	(1,543)		

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

	Three Months Ended					Six Mont	hs Ended												
σ 1	June 30,		,		,		,		/		,		,		une 30,	J	une 30,	J	une 30,
(In thousands)		2024		2023		2024		2023											
Operating lease cost allocated to research and development expense	\$	113	\$	90	\$	226	\$	179											
Operating lease cost allocated to general and administrative expense		66		90		132		179											
Total lease expense	\$	179	\$	180	\$	358	\$	358											
Weighted-average remaining lease term		1.84		2.84		1.84		2.84											
Weighted-average discount rate		7.12%)	7.12%		7.12%	ı	7.12%											

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

Maturity of Lease Liabilities (In thousands)	Opera	ting lease
2024 (remaining)	\$	359
2025		725
2026		242
Total lease payments		1,326
Less: imputed interest		(93)
Present value of lease payments	\$	1,233

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 June 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). Additionally, as of June 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, and 20,000 and 0 shares of Series D Convertible Preferred 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, and 8,837.58 shares of Series D Stock on June 21, 2024, as part of four agreements to reclassify convertible preferred notes for Preferred Shares.

As discussed in Note 3, the Company reclassified certain CPNs into preferred shares by executing the Exchange Agreements. This reclassification resulted in a new class of convertible preferred shares in 2024, the Series D Stock. The Company has two classes of preferred shares issued and outstanding for both balance sheet dates presented - Series C Stock and Series D 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 and \$2.50 for the Series D Stock., subject to a beneficial owners hip maximum of 19.99%. The Preferred Shares are voting stock and holders are entitled to vote together with the C ommon 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 and D 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 June 30, 2024 Liquidation Preference										
		Three									
	N	Months	Si	x Months	ths June 30,		Decemb				
(In thousands)]	Ended		Ended		2024		31, 2023			
Series C	\$	873	\$	1,745	\$	17,951	\$	16,206			
Series D	559			576		17,413		-			
Total	\$	1,432	\$	2,321	\$	35,364	\$	16,206			

<u>Participating Rights of Series C and D Stock Shareholders</u>—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 June 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 \$8,000,000 (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 June 30, 2024 and 2023:

	202	24	202	23
		Weighted		Weighted
		Average		Average
		Grant Date		Grant Date
		Fair Value		Fair Value
	Shares	Per Share	Shares	Per Share
Nonvested RSUs at beginning of period	605	\$ 285.36	650	\$ 259.50
Granted	_	_	_	_
Vested	_	255.85	(35)	252.60
Cancelled and forfeited	(161)	260.10		_
Outstanding RSUs as of June 30	444	\$ 355.01	615	\$ 258.88

In addition, the weighted average remaining recognition period for the 2017 RSUs is 0.85 years as of June 30, 2024

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

	Three Months Ended June 30,					Ended),		
(In thousands)	2	2024		2023		2024		2023
Research and development	\$	4	\$	15	\$	9	\$	15
General and administrative		7		15		15		15
Total	\$	11	\$	30	\$	24	\$	30

2017 Stock Incentive Plan—Stock Options

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

20	24		202	23	
	Average		A	Veighted Average Exercise	
Shares		Price Shares			Price
5,853	\$	285.36	11,286	\$	254.40
		_	_		_
_		_	_		_
		_	(5,433)		215.35
5,853	\$	285.36	5,853	\$	285.36
5,853	\$	285.36	5,853	\$	285.36
	Shares 5,853 — — — 5,853	Shares 5,853 \$ 5,853 \$	Weighted Average Exercise Price	Weighted Average Exercise Shares Price Shares 5,853 \$ 285.36 11,286 — — — — — — — — (5,433) 5,853 \$ 285.36 5,853	Weighted Average Exercise Weighted Average Exercise Meighted Average Exercise Me

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

There were no stock compensation expenses recognized from stock-based compensation awards classified as stock options in the condensed consolidated statements of operations for the three and six months ended June 30, 2024 and 2023.

As of June 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 June 30, 2024 and 2023 under the 2021 Plan:

	202	24	20	23
		Weighted Average Grant Date Fair Value		Weighted Average Grant Date Fair Value
	Shares	Per Share	Shares	Per Share
Outstanding RSUs at beginning of period	89,206	\$ 1.56	684	\$ 133.20
Granted	76,996	2.48	_	_
Vested	(29,775)	4.95	_	_
Cancelled and forfeited	(75,900)	1.78	(667)	126.60
Outstanding RSUs as of June 30	60,527	\$ 4.62	17	\$ 126.60

In addition, the weighted average remaining recognition period for the 2021 RSUs is 3.01 years as of June 30, 2024.

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

	Three Months Ended June 30,									Six Mont June	
(In thousands)	2	024	2	023		2024	2023				
Research and development	\$	13	\$	4	\$	24	\$ 12				
General and administrative		5		2		38	15				
Total	\$	18	\$	6	\$	62	\$ 27				

As of June 30, 2024, there was \$211,800 unrecognized stock compensation expense related to unvested restricted stock units.

2021 Stock Incentive Plan — Stock Options

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

	2024			202		
		1	Veighted Average Exercise		A	Veighted Average Exercise
	Shares		Price	Shares		Price
Options outstanding at beginning of period	12,240	\$	12.90	21,420	\$	12.90
Granted	_		_	_		_
Exercised	_		_	_		_
Cancelled and forfeited			_	(9,180)		12.90
Balance as of June 30	12,240	\$	12.90	12,240	\$	12.90
Options exercisable as of June 30:	12,240	\$	12.90	12,240	\$	12.90

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

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 June 30, 2024.

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

	20	24	2023			
	Shares	Weighted Average Grant Date Fair Value Per Share	Shares	Weighted Average Grant Date Fair Value Per Share		
Outstanding RSAs at beginning of period	_	\$ —	_	\$ —		
Granted	254,185	2.42	_	_		
Non-vested	254,185	2.42	_	_		
Released	(254,185)	2.42	_	_		
Cancelled and forfeited	_	_	_	_		
Outstanding RSAs as of June 30	254,185	\$ 2.42		\$ —		

In addition, the weighted average remaining recognition period for the RSAs is 0.67 years as of June 30, 2024. As of June 30, 2024, there was \$614,800 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 six months ended June 30, 2024 and 2023. The Company recorded no income tax provision for the three or six months ended June 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

Issuance of Senior Secured Convertible Promissory Note

On each of July 3, 2024 and August 1, 2024, the Company issued a 25% Senior Secured Convertible Promissory Note (the "Subsequent Notes"). The Subsequent Notes each have a principal amount of \$2,000,000, bear interest at a rate of 25% per annum (the "Stated Rate") and mature 365 days from their issuance (the "Maturity Date"), on which the principal balance and accrued but unpaid interest under each note shall be due and payable. The Stated Rate will increase to the lower of (i) 27% per annum or (ii) the high est rate then allowed under applicable law, upon occurrence of an event of default, including the failure by the Company to make payment of principal or interest due under the Note on the Maturity Date and any commencement by the Company of a case under any applicable bankruptcy or insolvency laws.

The Subsequent Notes are convertible into shares of the Company's common stock, par value \$0.001 per share, at a floating conversion price equal to 90% of the 5-day VWAP for the Company's common stock beginning on the fifth day preceding the notice by the Investor of the intent to convert, subject to a beneficial ownership limitation equivalent to 19.99%.

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 b elieves 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 include d 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.

From a development standpoint, we utilize innovative non-engineered and engineered GDT cell technologies and are developing proprietary, virus-free cell engineering tools to develop novel therapies for solid tumors that we believe will be effective and cost-efficient. DeltacelTM (Deltacel) is our first off-the-shelf non-engineered GDT cell-based product in Phase 1 clinical stage. Our IsocelTM ("Isocel") and ProcelTM ("Procel") product candidates consist of allogeneic, engineered, off-the-shelf GDT cells and they are currently in the preclinical development stage. 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 currently have three product candidates: 1) DeltacelTM, non-engineered GDTs, expanded and activated with proprietary technology; 2) IsocelTM, GDTs engineered with an anti-Mesothelin isoform Chimeric Antigen Receptor; and 3) ProcelTM, GDTs engineered with a PD-1 switch receptor.

The Company is 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, the Company is 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 November 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 the Company's 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 in vestors, 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. Therefore, this condition raises substantial doubt about the Company's ability to continue as a going concern. See Note 1 to the Company's Condensed Consolidated Financial Statements, "Going Concern" for further details.

The Company's unrestricted cash and cash equivalents were \$4.05 million as of June 30, 2024. The Company is 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. The Company is working with a financial advisor to assist it with its efforts to obtain financing. In the absence of such financing, management anticipates that existing c ash resources as of June 30,

2024, combined with the Subsequent Notes (see Note 13 - Subsequent Events for more information), and verbal, non-contractual commitments for additional financing will not be sufficient to meet operating and liquidity needs beyond November 2024. However, management may further evaluate additional cost reduction actions, including additional reductions in the Company's workforce and delay of research and development expenditures on one or more product candidates, in order to reduce the Company's current expenditures and preserve cash. We are not able to predict whether any such cost reduction actions will be successful.

As a result of the Company's current liquidity position, management can provide no assurance that the Company 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, the Company executed monthly CPNs to finance its operations and executed two Exchange Agreements to strengthen its 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, we have enrolled six patients in our clinical trial, five of which have entered the long-term follow-up phase, while the sixth has started treatment on August 6, 2024.

None of the enrolled patients developed a dose-limiting toxicity. One elderly patient developed a serious adverse event, which was caused by a series of pre-existing co-morbidities. The patient did not complete the two infusions and was replaced with a new patient. All patients are being treated at the BHCC. Based on data from the five patients evaluated for Progression-Free Survival (PFS), we have registered an average PFS of 4.8 months so far, with one patient achieving a PFS of 8 months.

On February 28, 2024, we activated a second clinical trial site with Virginia Oncology Associates, PC. in our Deltacel-01 Phase 1 Study. On April 8, 2024, we activated the third site in the Deltacel-01 trial, Texas Oncology, at Tyler, TX. On May 8, 2024, we activated our fourth clinical trial site, UPMC Hillman Cancer Center located in Pittsburgh, PA. We expect to have one additional clinical trial site by the end of August 2024.

The Deltacel-01 study, encompassing long-term follow-up, spans up to 24 months. By the mid-term follow-up, expected by the conclusion of 2024, we anticipate gathering substantial evidence of clinical benefit from approximately 15 patients. This trial consists of two parts: Part 1 is designed to identify the optimal dose of DeltacelTM. Following approval by the Safety Monitoring Committee, Part 2 (the Expansion Phase) will further assess the therapy's effectiveness at the optimal dose identified in Part 1. We expect to begin enrolling patients in the Expansion Phase in September, expanding the size of the trial by nine patients. In the first half of 2025, we may consider petitioning for early termination of the Deltacel-01 Phase 1 study, contingent upon demonstrated clinical benefits and the absence of toxicities.

On June 18, 2024, we submitted a Fast-Track Designation (FTD) Application to the FDA. We expect to receive a response from the Agency within two months of the submission. 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. We believe that receiving an FTD for our DeltacelTM 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 and 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

Depending on the response rates registered during our Deltacel-01 Phase 1 clinical trial, in 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 Sou them District of Texas. The Company is 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:

- 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 emergin g 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 stan dards 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 no n-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 the Company's expenditures and preserve cash. As of the date of this quarterly report, we are notable 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 the Company's 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 June 30, 2024 and 2023

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

		Three Mon		Ended			
		June	30,		Increase (Decrease)		
(In thousands)		2024		2023		\$	%
Operating expenses:							
Research and development	\$	4,135	\$	1,967	\$	2,168	110%
General and administrative		2,218		2,326		(108)	(5)%
Total operating expenses		6,353		4,293		2,060	48%
Loss from operations		(6,353)		(4,293)		2,060	48%
Other expense:							
Interest expense	h	(957)		(335)		622	186%
Debt issuance amortization		_		(366)		(366)	(100)%
Other income (expense)	g	485	_	(1,770)		(2,255)	(127)%
Total other expense		(472)	·	(2,471)		(1,999)	(81)%
Net loss	\$	(6,825)	\$	(6,764)	\$	61	1 %

Research and development expenses.

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

		Three Months Ended June 30,			Increase (D	ecrease)
(In thousands)		2024		2023	 \$	%
Direct research and development expenses by product candidate:	_					
AIDT-1 development costs	a \$	41	\$	162	\$ (121)	(75)%
Platform development, early-stage research and unallocated						
expenses:						
Employee-related costs	b	1,214		615	599	97%
Laboratory supplies and services	c	638		43	595	1,384%
Outsourced research and development (net of reimbursements)	d	1,399		141	1,258	892%
Laboratory equipment and maintenance	e	531		788	(257)	(33)%
Facility-related costs	f	283		158	125	79%
Intellectual property		5		46	(41)	(89)%
Other research and development costs		24		14	10	71%
Total research and development expenses	\$	4,135	\$	1,967	\$ 2,168	110%

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

- a- AIDT-1 development cost decreased due to the leverage of employee manpower rather than consulting services.
- b- Employee related costs increased mainly related to an increase in employee headcount, and executive bonuses.
- c- Laboratory supplies and services increased primarily due to the prioritization of the Deltacel-01 development.
- d- Outsourced research and development increased primarily due to the prioritization of the Deltacel-01 development.
- e- Laboratory equipment and maintenance decreased primarily due to a decrease in purchase of supplies and other lab related materials.
- f- Facility-related costs increased due to more repairs and maintenance expenses during the three months ended June 30, 2024.

General and administrative expenses.

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

		Three Months Ended June 30,				Increase (Decrease)			
		2024		2023		\$	%		
Operating expenses:									
Employee Expenses	c \$	986	\$	586	\$	400	68%		
Facilities Expenses	b	330		460		(130)	(28)%		
Legal Expenses	d	528		233		295	126%		
Professional Fees	a	374		1,047		(673)	(64)%		
Total general and administrative expenses	\$	2,218	\$	2,326	\$	(108)	(5)%		

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

- a- Professional fees decreased driven by the decrease in the use of consultants to the benefit of full-time employees.
- b- Facilities expenses decreased due to less repairs and maintenance expenses; offset by:
- c- Employee expenses increased driven by the hiring of full-time employees.
- d- Legal services increased driven by the S-1 review services.

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

- g- The payment of the settlement in principle of the class action of 1,770,000 in 2023. See Item 1 Legal Proceedings for more discussion; and other income increased primarily related to an engagement with a vendor to facilitate the payment of the balance due; offset by:
- h- Interest expense increased driven by the issuance of \$24,839,700 convertible promissory notes subsequent to the three months ended June 30, 2023. See Note 7— Senior Secured Convertible Promissory Note for more discussion, which was partially offset by an increase in other income.

Comparison of the Six Months Ended June 30, 2024 and 2023

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

	June	30,		Increase (Decrease)			
	2024	2023		\$	%		
\$	7,157	\$ 4,04	12 5	\$ 3,115	77%		
	4,309	5,02	28	(719)	(14)%		
	11,466	9,0′	70	2,396	26%		
	(11,466)	(9,0'	70)	2,396	26%		
h	(2,028)	(7'	79)	1,249	160%		
	_	(44	45)	(445)	(100)%		
g	521	(1,7	70)	(2,291)	(129)%		
	(1,507)	(2,99	94)	(1,487)	(50)%		
\$	(12,973)	\$ (12,00	54)	\$ 909	8%		
	h	\$ 7,157 4,309 11,466 (11,466) h (2,028) g 521 (1,507)	\$ 7,157 \$ 4,04 4,309 5,02 11,466 9,07 (11,466) (9,07 h (2,028) (77 — (44 g 521 (1,77) (1,507) (2,99	June 30, 2024 2023 \$ 7,157 \$ 4,042 4,309 5,028 11,466 9,070 (11,466) (9,070) h (2,028) (779) — (445) g 521 (1,770) (1,507) (2,994)	June 30, Increase (I 2024 2023 \$ \$ 7,157 \$ 4,042 \$ 3,115 4,309 5,028 (719) 11,466 9,070 2,396 (11,466) (9,070) 2,396 h (2,028) (779) 1,249 — (445) (445) g 521 (1,770) (2,291) (1,507) (2,994) (1,487)		

Research and development expenses.

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

	Six Months Ended June 30,			Increase (D	ecrease)	
(In thousands)		2024		2023	\$	%
Direct research and development expenses by product candidate:						
AIDT-1 development costs	a \$	61	\$	683	\$ (622)	(91)%
Platform development, early-stage research and unallocated						
expenses:						
Employee-related costs	b	2,310		1,191	1,119	94%
Laboratory supplies and services	c	954		153	801	524%
Outsourced research and development (net of reimbursements)	d	2,209		248	1,961	791%
Laboratory equipment and maintenance	e	1,089		1,399	(310)	(22)%
Facility-related costs	f	473		278	195	70%
Intellectual property		9		43	(34)	(79)%
Other research and development costs		52		47	5	11%
Total research and development expenses	\$	7,157	\$	4,042	\$ 3,115	77%

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

- a- AIDT-1 development cost decreased due to the leverage of employee manpower rather than consulting services.
- b- Employee related costs increased mainly related to an increase in employee headcount, and executive bonuses.
- c- Laboratory supplies and services increased primarily due to the prioritization of the Deltacel-01 development.
- d- Outsourced research and development increased primarily due to the prioritization of the Deltacel-01 development.
- e- Laboratory equipment and maintenance decreased primarily due to a decrease in purchase of supplies and other lab related materials.
- f- Facilities related costs increased due to more repairs and maintenance expenses.

General and administrative expenses.

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

		Six Months Ended June 30,				Increase (Decrease)			
		2024		2023		\$	%		
Operating expenses:						_			
Employee Expenses	d \$	1,843	\$	1,227	\$	616	50%		
Facilities Expenses	c	728		862		(134)	(16)%		
Legal Expenses	b	803		982		(179)	(18)%		
Professional Fees	a	935		1,957		(1,022)	(52)%		
Total general and administrative expenses	\$	4,309	\$	5,028	\$	(719)	(14)%		

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

- a- Professional fees decreased driven by a decrease in the use of consultants to the benefit of full-time employees.
- b- Legal services and other services decreased driven by a significant decline in expenses related to the Settlement in Principle of the Class Action.
- c- Facilities expenses decreased due to less repairs and maintenance expenses; offset by:
- d- Employee expenses increased driven by the hiring of full-time employees.

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

- g- The payment of the settlement in principle of the class action of 1,770,000 in 2023. See Item 1— Legal Proceedings for more discussion; and other income increased primarily related to an engagement with a vendor to facilitate the payment of the balance due; offset by:
- h- Interest expense increased driven by the issuance of \$24,839,700 convertible promissory notes subsequent to the six months ended June 30, 2023. See Note 7— Senior Secured Convertible Promissory Note for more discussion, which was partially offset by an increase in other income.

Liquidity and Capital Resources

As of June 30, 2024, we had cash and cash equivalents of \$4.18 million, which included \$131 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, preferred stock, common stock from the initial public offering and follow-on offering.

As of July 31, 2024, we had cash and cash equivalents of \$3.96 million, which included \$131 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 November 2024. Management may further evaluate various cost reduction actions, including possible reductions in the Company's workforce and suspending research and development expenditures on one or more product candidates, in order to reduce the Company's 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 the Company to continue to operate without financing.

As previously disclosed, we have incurred significant operating losses since inception, and we expect to incur significant ex penses and operating losses for the foreseeable future as we advance the preclinical and clinical development of our product candid ates. 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 the Company's 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:

	Six Months Ended June						
(In thousands)		2024		2023			
Net cash used in operating activities	\$	(13,879)	\$	(10,589)			
Net cash used in investing activities		(119)		_			
Net cash provided by financing activities		14,973		12,648			
Net change in cash and cash equivalents and restricted cash		975		2,059			
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	\$	4,179	\$	2,704			

Cash flows from operating activities

Net cash used in operating activities was \$13.9 million for the six months ended June 30, 2024, as compared to \$10.6 million for the six months ended June 30, 2023. The increase by approximately \$3.3 million dollars 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 \$119 thousand for the six months ended June 30, 2024, as compared to none for the six months ended June 30, 2023. Our net cash used in investing activities for the six months ended June 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.

Cash flows from financing activities

Net cash provided by financing activities was \$15.0 million for the six months ended June 30, 2024, as compared to net cash used of \$12.6 million for the six months ended June 30, 2023. The change in cash flows from financing activities for the periods sho wn are driven by the issuance of approximately \$0.4 million of note payable and \$14.9 million of convertible notes, offset by \$0.3 million repayment of the note payable, for the six months ended June 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 June 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 judg ment 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 June 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 June 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 June 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 and Series D 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.

On August 7, 2024, the Company entered into an employment contract amendment with Brian Hungerford, our Chief Financial Officer.

ITEM 6. EXHIBITS.

Exhibit No.	Description of Exhibit
10.1	Exchange Agreement dated as of June 21, 2024 between the Company and the holder of the Exchange Securities
	(incorporated by reference to Exhibit 10.1 to Form 8-K filed on June 27, 2024)
10.2	Form of the 25% Senior Secured Convertible Promissory Note (incorporated by reference to Exhibit 10.2 to Form 8-K
	<u>filed on June 27, 2024)</u>
10.3	Form of the 25% Senior Secured Convertible Promissory Note (incorporated by reference to Exhibit 10.1 to Form 8-K
	<u>filed on July 10, 2024)</u>
10.4	First Amendment to the 25% Senior Secured Convertible Promissory Note (incorporated by reference to Exhibit 10.2 to
	Form 8-K filed on July 10, 2024)
10.5	Executive Employment Agreement Amendment dated as of August 7, 2024 by and between Kiromic Biopharma, Inc.
	and Brian Hungerford
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: August 9, 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)