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

FORM 10-Q

(Mark One)

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

For the quarterly period ended June 30, 2023

or

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

For the transition period from to

Commission File Number: 001-39619

Kiromic BioPharma, Inc.

(Exact name of registrant as specified in its charter)

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

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

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

Title of Each Class	**Trading symbol**	**Name of Exchange on which registered**
Common Stock, par value $0.001 per share	KRBP	The Nasdaq Stock Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes ☒ No ☐

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

Large Accelerated Filer ☐	Accelerated Filer ☐
Non-accelerated Filer ☒	Smaller Reporting Company ☒
	Emerging Growth Company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of August 11, 2023, there were 1,176,260 shares of the registrant's common stock outstanding.

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Note Regarding 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; and
- 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; and
- 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 and our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, 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)

	June 30, 2023	December 31, 2022
Assets		
Current Assets:		
Cash and cash equivalents	$ 2,704,200	$ 645,200
Prepaid expenses and other current assets	2,009,000	1,043,700
Total current assets	4,713,200	1,688,900
Property and equipment, net	7,061,800	8,136,900
Operating lease right-of-use asset, net	1,840,400	2,117,300
Other assets	21,400	24,400
Total Assets	$ 13,636,800	$ 11,967,500
Liabilities and Stockholders' Deficit:		
Current Liabilities:		
Senior secured convertible promissory note, net	$ 8,035,300	$ 3,809,900
Accounts payable	6,621,500	7,308,100
Accrued expenses and other current liabilities	2,314,800	881,600
Interest payable	891,900	142,100
Note payable	227,600	557,200
Operating lease liability - short term	608,800	584,400
Total current liabilities	18,699,900	13,283,300
Subordinated convertible promissory note	—	2,914,000
Operating lease liability - long term	1,231,700	1,544,900
Total Liabilities	19,931,600	17,742,200
Commitments and contingencies (Note 7)		
Stockholders' Deficit:		
Preferred Stock, $0.0001 par value: 60,000,000 shares authorized, 8,000 and 0, issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	1	—
Common stock, $0.001 par value: 300,000,000 shares authorized as of June 30, 2023 and December 31, 2022; 1,176,260 and 648,384 shares issued and outstanding as of June 30, 2023 and December 31, 2022, respectively	1,176	648
Additional paid-in capital	107,716,223	96,172,152
Accumulated deficit	(114,012,200)	(101,947,500)
Total Stockholders' Deficit	(6,294,800)	(5,774,700)
Total Liabilities and Stockholders' Deficit	$ 13,636,800	$ 11,967,500

See accompanying notes to the condensed consolidated financial statements

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 1,966,600	$ 3,880,700	$ 4,041,600	$ 6,806,500
General and administrative	2,325,900	4,551,700	5,028,300	8,990,800
Total operating expenses	4,292,500	8,432,400	9,069,900	15,797,300
Loss from operations	(4,292,500)	(8,432,400)	(9,069,900)	(15,797,300)
Other expense:				
Interest expense	(335,400)	(2,700)	(779,400)	(5,500)
Debt issuance amortization	(366,500)	—	(445,400)	—
Litigation settlement	(1,770,000)	—	(1,770,000)	—
Total other expense	(2,471,900)	(2,700)	(2,994,800)	(5,500)
Net loss	$ (6,764,400)	$ (8,435,100)	$ (12,064,700)	$ (15,802,800)
Net loss per preferred share, basic and diluted	$ (495.89)	$ —	$ (1,235.17)	$ —
Net loss per common share, basic and diluted	$ (3.22)	$ (16.25)	$ (8.07)	$ (30.64)
Weighted average preferred shares outstanding, basic and diluted	8,000	—	4,022	—
Weighted average common shares outstanding, basic and diluted	1,054,277	524,402	964,049	521,259

See accompanying notes to the condensed consolidated financial statements

KIROMIC BIOPHARMA, INC.
Condensed Consolidated Statements of Stockholders' Deficit
(Unaudited)

	Preferred Stock		Common Stock				
	Number of Shares	Amount	Number of Shares	Amount	Additional Paid-In Capital	Accumulated Deficit	Total
Balance at December 31, 2022	—	$ —	648,384	$ 648	$ 96,172,152	$(101,947,500)	$ (5,774,700)
Common stock discount amortization	—	—	—	—	85,000	—	85,000
Warrants underlying common stock issuance	—	—	—	—	(85,000)	—	(85,000)
Released restricted stock units	—	—	1,773	2	(2)	—	—
Conversion of subordinated convertible notes into shares of common stock	—	—	329,086	329	2,913,671	—	2,914,000
Stock compensation expense	—	—	—	—	20,700	—	20,700
Net loss	—	—	—	—	—	(5,300,300)	(5,300,300)
Balance at March 31, 2023	—	$ —	979,243	$ 979	$ 99,106,521	$(107,247,800)	$ (8,140,300)
Common stock discount amortization	—	—	—	—	85,900	—	85,900
Warrants underlying common stock issuance	—	—	—	—	(85,900)	—	(85,900)
Issuance of preferred stock	8,000	1	—	—	7,999,999	—	8,000,000
Commitments shares issuance from standby equity purchase agreement	—	—	197,017	197	658,903	—	659,100
Stock issuance costs	—	—	—	—	(84,600)	—	(84,600)
Stock compensation expense	—	—	—	—	35,400	—	35,400
Net loss	—	—	—	—	—	(6,764,400)	(6,764,400)
Balance at June 30, 2023	8,000	$ 1	1,176,260	$ 1,176	$ 107,716,223	$(114,012,200)	$ (6,294,800)

See accompanying notes to the condensed consolidated financial statements

KIROMIC BIOPHARMA, INC.
Condensed Consolidated Statements of Stockholders' Equity
(Unaudited)

	Common Stock		Additional	Accumulated	
	Shares	Amount	Paid-In Capital	Deficit	Total
Balance at December 31, 2021	516,284	$ 516	$ 94,535,784	$ (67,216,500)	$ 27,319,800
Common stock discount amortization	—	—	85,100	—	85,100
Warrants underlying common stock issuance	—	—	(85,100)	—	(85,100)
Released restricted stock units	3,236	4	(4)	—	—
Stock compensation expense	—	—	80,100	—	80,100
Net loss	—	—	—	(7,367,700)	(7,367,700)
Balance at March 31, 2022	519,520	$ 520	$ 94,615,880	$ (74,584,200)	$ 20,032,200
Common stock discount amortization	—	—	85,900	—	85,900
Warrants underlying common stock issuance	—	—	(85,900)	—	(85,900)
Released restricted stock units	8,451	8	(8)	—	—
Stock compensation expense	—	—	184,200	—	184,200
Net loss	—	—	—	(8,435,100)	(8,435,100)
Balance at June 30, 2022	527,971	$ 528	$ 94,800,072	$ (83,019,300)	$ 11,781,300

See accompanying notes to the condensed consolidated financial statements

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

	Six Months Ended June 30,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (12,064,700)	$ (15,802,800)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation	1,105,400	581,900
Operating lease non-cash expense	276,900	139,200
Stock compensation expense	56,100	264,300
Amortization of debt issuance costs	445,400	—
Changes in operating assets and liabilities:		
Accounts receivable	—	16,200
Prepaid expenses and other current assets	(962,300)	176,800
Accounts payable	(1,339,900)	794,500
Interest payable	749,800	—
Accrued expenses and other current liabilities	1,433,300	413,600
Operating lease liability	(288,800)	(131,700)
Net cash used for operating activities	(10,588,800)	(13,548,000)
Cash flows from investing activities:		
Purchases of property and equipment	—	(4,955,700)
Net cash used for investing activities	—	(4,955,700)
Cash flows from financing activities:		
Proceeds from senior secured convertible note payable	12,400,000	—
Proceeds from issuance of common stock	659,100	—
Stock issuance costs	(81,700)	—
Repayments of note payable	(329,600)	(339,600)
Net cash provided by (used for) financing activities	12,647,800	(339,600)
Net change in cash and cash equivalents	2,059,000	(18,843,300)
Cash and cash equivalents:		
Beginning of year	645,200	25,353,900
End of period	$ 2,704,200	$ 6,510,600
Supplemental disclosures of cash flow information:		
Right-of-use asset/liability recognized from ASC 842 implementation	$ —	$ 2,232,700
Conversion of 25% senior convertible promissory notes into preferred stock	$ 8,000,000	$ —
Conversion of subordinated convertible promissory notes into common stock	$ 2,914,000	$ —
Accruals for property and equipment purchases	$ —	$ 1,154,900
Stock issuance costs in accounts payable	$ 2,900	$ —
Cash paid for interest on note payable	$ 34,900	$ 5,500
Right-of-use asset/liability acquired through lease liability	$ —	$ 204,800
Construction in progress in accounts payable	$ 30,400	$ —
New debt issuance costs in accounts payable	$ 620,000	$ —

See accompanying notes to the condensed consolidated financial statements

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

1. ORGANIZATION

Nature of Business

Kiromic BioPharma, Inc. and subsidiaries (the "Company") is a clinical stage fully integrated biotherapeutics company formed under the Texas Business Organizations Code in December 2012. The Company maintains offices in Houston, Texas. The Company has not generated any revenues to date.

The Company is an Artificial Intelligence (“AI”) driven, end-to-end allogeneic cell therapy company, currently developing multi-indication allogeneic T cell therapies that exploit the natural potency of Gamma Delta T cells (“GDTs”) to target solid tumors. Our end-to-end approach consists of target discovery and validation, product development, and current good manufacturing practices (“cGMP”), which we believe will allow us to leverage a new framework for the next generation of cell therapies. We also have new technologies in development to support our end-to-end approach.

From a development standpoint, we utilize innovative engineered and non-engineered GDT manufacturing 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. Deltacel is our first allogeneic off-the-shelf GDT cell-based product in Phase 1 clinical stage. Our ProcelÔ (“Procel”) and IsocelÔ (“Isocel”) product candidates consist of allogeneic, cryopreserved, and engineered GDT cells and they are currently in the preclinical development stage. Our Deltacel product candidate consists of non-engineered GDTs that have been expanded, enriched, and activated ex-vivo through a proprietary process, and are intended to treat solid tumors regardless of the specific tumor antigen expression. Our Procel product candidate consists of engineered GDTs and is intended to be used to target PD-L1. Our Isocel product candidate consists of engineered GDTs and is intended to be used to target Mesothelin Isoform 2 positive tumors (“Iso-Meso”).

We currently have three product candidates: 1) Deltacel: not-engineered GDTs, expanded and activated with proprietary technology; 2) Procel: GDTs engineered with a PD-1 switch receptor; and 3) Isocel: GDTs engineered with an anti-Mesothelin isoform 2 Chimeric Antigen Receptor.

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

1) Deltacel-01: This phase 1 clinical trial will evaluate Deltacel in combination with low-dose radiation for patients with non-small cell lung cancer (NSCLC)

2) 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.

3) Alexis-PRO-1: This phase 1 clinical trial is expected to evaluate Procel in patients with PD-L1 positive solid malignancies.

4) 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.

5) Alexis-ISO-1: This phase 1 clinical trial is expected to evaluate Isocel in patients with Mesothelin Isoform 2 positive solid malignancies.

In June 2021, the FDA noted deficiencies in the chemistry, manufacturing, and control (CMC) sections of Alexis-PRO-1 (clinical trial evaluating Procel) and Alexis-ISO-1 (clinical trial evaluating Isocel) IND applications, consequently placing them on clinical hold.

On July 13, 2021, the Company received the FDA’s formal clinical hold letters, which asked the Company to address key components regarding the chemical, manufacturing, and control components of the IND applications. The basis for the hold was mainly rooted in the use of a non-suitable retroviral vector to engineer the gamma delta T cells. The Company is developing a novel and virus-independent engineering method, which will result in the submission of new IND applications (numbers 2 to 5 above). These applications are expected to be ready for submission to the FDA in the first

half of 2025, subject to sufficient financing to support the progression of the developments of those additional clinical trial candidates.

IND #1 (number 1 above) will evaluate Deltacel GDTs in combination with low-dose radiation. We submitted the IND for the Deltacel trial on March 31, 2023. On April 28, 2023, the FDA authorized us to proceed with the first-in-human clinical trial of Deltacel (IND #1). We began the clinical trial activation process during the three months ended June 30, 2023.

Reverse Stock Split — On March 10, 2023, the Company's Board of Directors approved a one-for-thirty reverse split of the Company's issued and outstanding shares of common stock ("the Reverse Stock Split"). In addition, a proportionate adjustment was made to the per share exercise price and the number of shares issuable upon the exercise of all outstanding stock options, restricted stock units and warrants to purchase shares of common stock and the number of shares reserved for issuance pursuant to the Company's equity incentive compensation plans. Any fraction of a share of common stock that would be created as a result of the Reverse Stock Split was rounded up to the next whole share. Unless noted otherwise, all common shares and per share amounts contained in the consolidated financial statements have been retroactively adjusted for the Reverse Stock Split.

Going Concern— These condensed 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 $10,588,800 for the six months ended June 30, 2023, and an accumulated deficit of $114,012,200 as of June 30, 2023. 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 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 of future operations. These plans may include, but are not limited to, obtaining funding from current or new investors, including through private placements or public offering. However, there can be no assurance that the Company will be able to secure 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 that 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 sufficient financing 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, 2022. The results of operations for the period ended June 30, 2023 are not necessarily indicative of the operating results that may be expected for a full year. The condensed consolidated balance sheet as of December 31, 2022 contains financial information taken from the audited Company consolidated financial statements as of that date.

All intercompany balances were eliminated upon consolidation.

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

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

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

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 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, 2023 or 2022.

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 clinical development activities including costs of outside consultants and contractors, the submission and maintenance of regulatory filings, equipment and supplies used in developing products prior to market approval and an allocation of certain overhead costs such as facility and related expenses.

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

Net Loss per Share Attributable to Common Stockholders—The Company follows the two-class method when computing net loss per share as the Company has issued shares that meet the definition of participating securities. The two-class method determines net loss per share for each class of common and participating securities according to dividends declared or accumulated and participation rights in undistributed earnings. The two-class method requires income available to common stockholders for the period to be allocated between common and participating securities based upon their respective rights to receive dividends as if all income for the period had been distributed.

Basic net loss per share attributable to common stockholders is computed by dividing the net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period. Diluted net loss attributable to common stockholders is computed by adjusting net loss attributable to common stockholders to reallocate undistributed earnings based on the potential impact of dilutive securities.

Diluted net loss per share attributable to common stockholders is computed by dividing the diluted net loss attributable to common stockholders by the weighted average number of common shares outstanding for the period, including potential dilutive common shares. For purpose of this calculation, outstanding stock options, convertible preferred stock and warrants to purchase shares of convertible preferred stock are considered potential dilutive common shares.

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

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

Expected Term. The expected term represents the period that the Company's stock options are expected to be outstanding. Due to limitations on the sale or transfer of the Company's common stock under the lock-up agreements and market standoff components of the stock option agreements, the Company does not believe its historical exercise pattern is indicative of the pattern it will experience after restricted periods expire. The Company uses the Staff Accounting Bulletin ("SAB") No. 110, 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 US 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. We use our listed Nasdaq Capital Market closing price on the grant date to determine 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, new accounting pronouncements 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. Unless otherwise discussed, the impact of recently issued standards that are not yet effective will not have a material impact on the Company's financial position, results of operations, or cash flows upon adoption.

In June 2016, FASB issued ASU 2016-13, *Financial Instruments—Credit Losses (Topic 326)*. The amendments in ASU 2016-13 affect entities holding financial assets and net investment in leases that are not accounted for at fair value through net income. The amendments affect loans, debt securities, trade receivables, net investments in leases, off-balance-sheet credit exposures, reinsurance receivables, and any other financial assets not excluded from the scope that have the contractual right to receive cash. The amendments in ASU 2016-13 require a financial asset (or a group of financial assets) measured at amortized cost basis to be presented at the net amount expected to be collected. The allowance for credit losses is a valuation account that is deducted from the amortized cost basis of the financial asset(s) to present the net carrying value at the amount expected to be collected on the financial asset. On October 16, 2019, the FASB has changed the effective date of this standard applicable to the Company as an emerging growth company to January 1, 2023. The Company has evaluated the potential impact of this standard on its financial position, results of operations, and cash flows, and determined that it is immaterial to the financial statements as of June 30, 2023.

3. NET LOSS PER SHARE OF COMMON STOCK

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 are the same. The following table illustrates the computation of basic and diluted loss per share:

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Net loss	$ (6,764,400)	$ (8,435,100)	$ (12,064,700)	$ (15,802,800)
Less: Initial Public Offering Common Stock discount amortization	(24,900)	(24,900)	(49,500)	(49,600)
Less: Public Offering Common Stock discount amortization	(61,000)	(61,000)	(121,400)	(121,400)
Less: Dividends attributable to preferred stock	(515,100)	—	(515,100)	—
Net loss attributable to common shareholders	$ (7,365,400)	$ (8,521,000)	$ (12,750,700)	$ (15,973,800)

	Three Months Ended June 30, 2023		Three Months Ended June 30, 2022	
	Common Stock	Preferred Stock	Common Stock	Preferred Stock
Net loss per share, basic and diluted				
Allocation of undistributed net loss	$ (3,398,256)	$ (3,967,144)	$ (8,521,000)	$ —
Weighted average shares outstanding, basic and diluted	1,054,277	8,000	524,402	—
Basic and diluted net loss per share	$ (3.22)	$ (495.89)	$ (16.25)	$ —

	Six Months Ended June 30, 2023		Six Months Ended June 30, 2022	
	Common Stock	Preferred Stock	Common Stock	Preferred Stock
Net loss per share, basic and diluted				
Allocation of undistributed net loss	$ (7,782,723)	$ (4,967,977)	$ (15,973,800)	$ —
Weighted average shares outstanding, basic and diluted	964,049	4,022	521,259	—
Basic and diluted net loss per share	$ (8.07)	$ (1,235.17)	$ (30.64)	$ —

For the three months ended June 30, 2023, there were 23,936 restricted stock units and 15,416 warrants, that were potentially dilutive securities excluded from the computations of diluted weighted-average shares of common stock.

During the six months ended June 30, 2023, the Company entered into an Exchange Agreement whereby outstanding promissory notes totaling $8,000,000 were exchanged for 8,000 shares of Series C Convertible Voting Preferred Stock (the "Series C Stock"). The Series C Stock accrues an annual 25% dividend, whether or not declared, which if unpaid is added to the aggregate liquidation preference. During the six months ended June 30, 2023, the preferred shareholders earned $515,100 of preferred dividends, which were not declared.

4. PROPERTY AND EQUIPMENT

Property and equipment consisted of the following as of June 30, 2023 and December 31, 2022:

	June 30, 2023	December 31, 2022
Equipment	$ 3,041,900	$ 3,041,900
Leasehold improvements	7,298,500	7,298,500
Office furniture, fixtures, and equipment	137,300	137,300
Software	359,500	359,500
Construction in progress	30,400	—
	10,867,600	10,837,200
Less: Accumulated depreciation	(3,805,800)	(2,700,300)
Total	$ 7,061,800	$ 8,136,900

Depreciation expense was $549,600 and $399,100 for the three months ended June 30, 2023 and 2022, respectively, and $1,105,400 and $581,900 for the six months ended June 30, 2023 and 2022, 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 June 30, 2023 and December 31, 2022.

	June 30, 2023	December 31, 2022
Accrued litigation *	$ 1,770,000	$ —
Accrued compensation	323,500	668,700
Accrued consulting and outside services	221,300	212,900
Total	$ 2,314,800	$ 881,600

* See Note 13 Subsequent Events for more information.

6. NOTE PAYABLE

In November 2022, the Company entered into a financing arrangement for its Director and Officer Insurance policy. The total amount financed was approximately $610,700 with an annual interest rate of 8.49%, to be paid over a period of eleven months. As of June 30, 2023 and December 31, 2022, the remaining payable balance on the financed amount was $227,600 and $557,200, respectively.

7. 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, 2023 and December 31, 2022, the Company has not incurred any milestone or royalty liabilities related to these license agreements.

Legal Proceedings— On March 22, 2021, Jason Terrell ("Terrell"), a former consultant and former 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 the Company is obligated to issue him (i) options to purchase 16,667 shares of common stock at a price of $5.10 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 the 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.

The Company disputes Terrell's claims and allegations in the Action and intends 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 on June 21, 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 parties are awaiting guidance from the Chancery Court regarding further briefing and/or argument on our motion to dismiss.

In a separate matter, 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, submitted substantially identical reports (the "Complaints") through the Company's complaint hotline. These Complaints, alleged, among other topics, risks associated with the Company's public disclosures in securities filings and in statements made to the public, investors, and potential investors regarding (i) the anticipated timing of the FDA authorization of the 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.

On February 2, 2022, following the conclusion of the Internal Review, the Company's Special Committee reported the results of its Internal Review to the Board. The Board approved certain actions to address the fact that the Company had received communications from the FDA on June 16 and June 17, 2021 that the FDA was placing the IND applications that the Company submitted to the FDA on May 14 and May 17, 2021 for the ALEXIS-PRO-1 and ALEXIS-ISO-1 product candidates, respectively, on clinical hold (the "June 16 and 17 FDA Communications"). The Company did not disclose the June 16 and 17, 2021 FDA Communications in the Registration Statement on Form S-1 (Registration No. 333-257427) that was filed on June 25, 2021 and declared effective on June 29, 2021, nor the final prospectus contained therein dated June 29, 2021 (collectively, the "Registration Statement"). The Company then consummated a public offering of $40 million of its common stock pursuant to the Registration Statement on July 2, 2021. On July 13, 2021, the Company received the FDA's formal clinical hold letters, which asked the Company to address key components regarding the chemical, manufacturing, and control components of the IND applications. On July 16, 2021, the Company issued a press release disclosing that it had received comments from the FDA on the two INDs, but did not use the term "clinical hold." The Company did not disclose the clinical hold in its Form 10-Q for the fiscal quarter ended June 30, 2021 that was filed with the Securities and Exchange Commission on August 13, 2021. On August 13, 2021, the Company issued a press release announcing that these INDs were placed on clinical hold.

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

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

As a result of the disclosure omission of the June 16 and 17 FDA Communications, on March 7, 2022, entities related to Sabby Management LLC (the "Sabby Entities") and Empery Asset Management, LP (the "Empery Entities") filed a complaint in the United States District Court for the Southern District of New York 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. On July 1, 2022, the defendants filed motions to dismiss the complaint. In response, on July 22, 2022, the plaintiffs amended their complaint to, among other things, include the Company's underwriters on the July 2, 2021 public offering, ThinkEquity LLC, as a defendant. The plaintiffs seek unspecified damages; rescission to the extent they still hold the Company's securities, or if sold, rescissory damages; reasonable costs and expenses, including attorneys' and experts' fees; and other unspecified equitable and injunctive relief. The two parties reached a settlement agreement in principle on September 26, 2022, which the Company's board of directors approved on September 27, 2022. The settlement contained a cash component of $75,000 payable to Sabby Entities and $75,000 to Empery Entities.

As part of the settlement, the Company also agreed to issue convertible notes (the "Settlement Notes") in the aggregate principal amount of $1,656,720 to each of the Empery Entities and the Sabby Entities. The Settlement Notes are convertible into shares (the "Conversion Shares") of the Company's common stock at an initial conversion price per share of $9.20 and can be convertible into a maximum of 180,000 shares of the Company's common stock to each of the Empery Entities and Sabby Entities, subject to the adjustment of the conversion price and a beneficial ownership limitation equivalent to 9.99%. The United States District Court for the Southern District of New York granted a motion jointly filed by the plaintiffs and defendants, pursuant to which the Settlement Notes will be unrestricted and exempt from the registration requirements of the Securities Act of 1933, as amended (the "Securities Act"), and the Conversion Shares, when issued upon conversion of the Settlement Notes in accordance with the terms set forth therein, will also be unrestricted and exempt from the registration requirements of the Securities Act.

There was also a related subordinated convertible promissory note totaling $2,914,000 on the balance sheet at December 31, 2022, which Empery held $1,502,700 and Sabby held $1,411,300. During the three months ended March 31, 2023, Empery and Sabby converted the totality of their notes into shares of common stock of 163,268 and 153,333, respectively, at a share price of $9.20.

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") covering the same subject matter as the Sabby Entities' and Empery Entities' claim discussed above asserting claims against the Company and certain current and former officers and directors for alleged violations of Sections 11, 12, and 15 of the Securities Act of 1933 in connection with the purchase of common stock through the Company's public offering that closed on July 2, 2021 and Section 10(b) of the Exchange Act of 1934 and Rule 10b-5 promulgated thereunder in connection with the certain statements and acts made by the defendants between June 25, 2021 and August 13, 2021.

On October 3, 2022, Joseph Podmore filed a class action complaint in the United States District Court for the Southern District of New York (the "Podmore Class Action") covering the same subject matter as the Sabby Entities' and Empery Entities' claim discussed above asserting claims against the Company and certain current and former officers and directors 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.

The Karp Class Action and the Podmore Class Action are collectively referred to as the "Class Action." See Note 13 – Subsequent Events for further discussion.

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 or cash flows.

8. LEASES

The Company adopted FASB ASU No. 2016-02, Leases (Topic 842) on January 1, 2022, using the modified retrospective method, in which it did not restate prior periods. Upon adoption, the Company elected the package of practical expedients permitted under the transition guidance within Topic 842 which, among other things, allowed the Company to carry forward the historical lease classification.

In our implementation of ASU No. 2016-02 the Company elected to discount lease obligations using our incremental borrowing rate, which is derived from information available at the lease commencement date, in determining the present value of lease payments. The Company's incremental borrowing rate represents the rate of interest that it would have to pay to borrow over a similar term an amount equal to the lease payments in a similar economic environment. The Company considers publicly available data for instruments with similar terms and characteristics when determining its incremental borrowing rates. In addition, we elected the practical expedient to account for the lease and non-lease components on a combined basis. The Company intends to use the full lease term under the existing lease agreement as the lease term,

which is currently set to expire on April 30, 2026. As of June 30, 2023, the Company is not able to determine if any renewal options will be exercised.

The Company leases its premises in Houston, Texas under an operating lease which was renewed on November 19, 2020. This renewed lease agreement will commence under an operating lease agreement that is noncancelable from commencement until May 1, 2024.

On March 22, 2021, the Company's Board of Directors approved a lease expansion within its premises in Houston, Texas. The amended lease agreement commenced on August 1, 2021 under an operating lease agreement that is noncancelable from commencement until May 1, 2024. The amended lease agreement adds approximately 15,385 square feet. The Company has the option to cancel the lease thereafter until the agreement expires on May 1, 2026. The termination date is effective after a 90-day notice of cancellation.

Two further amendments were executed in 2021. The agreements commenced on November 1, 2021, and December 1, 2021 under an operating lease agreement that is noncancelable from commencement until May 1, 2024. The amended lease agreement adds approximately 3,684 square feet. The Company has the option to cancel the lease thereafter until the agreement expires on May 1, 2026. The termination date is effective after a 90-day notice of cancellation.

An amendment to the lease agreement was executed in January 2022 and commenced May 1, 2022. The amendment added approximately 9,352 square feet. The Company has the option to cancel the lease thereafter until the agreement expires on May 1, 2026. The termination date is effective after a 90-day notice of cancellation. In year one and two monthly rent is $4,800 per month, in year three and four monthly rent is $4,896 per month, and in year five monthly rent is $5,000 per month.

If the Company exercises the cancellation option, the Company must also pay the lessor a termination payment equal to three months of base rent.

The Company entered into a sublease of three suites for the use of certain fixture, fixtures and equipment on June 2, 2023. The lease commenced on June 5, 2023 under an operating lease agreement that is noncancelable until April 29, 2026. The monthly rent is $6,444 and remains flat during the period of the lease. The rent income received for this sublease is recorded in other income.

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

	June 30, 2023	December 31, 2022
	Operating lease	Operating lease
Right-of-Use Asset		
Operating lease	$ 1,840,400	$ 2,117,300
Total right-of use asset	$ 1,840,400	$ 2,117,300
Lease Liabilities		
Operating lease - short term	$ (608,800)	$ (584,400)
Operating lease - long term	(1,231,700)	(1,544,900)
Total lease liabilities	$ (1,840,500)	$ (2,129,300)

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

	Three Months Ended June 30, 2023	Three Months Ended June 30, 2022	Six Months Ended June 30, 2023	Six Months Ended June 30, 2022
Operating lease cost allocated to research and development expense	$ 89,500	$ 131,300	$ 179,000	$ 213,700
Operating lease cost allocated to general and administrative expense	89,500	38,200	179,000	106,300
Total lease expense	$ 179,000	$ 169,500	$ 358,000	$ 320,000
Weighted-average remaining lease term	2.84	3.84	2.84	3.84
Weighted-average discount rate	7.12 %	7.12 %	7.12 %	7.12 %

As of June 30, 2023, the maturities of the Company's operating lease liabilities were as follows:

Maturity of Lease Liabilities	Operating lease
2023 (remaining)	$ 358,800
2024	717,600
2025	724,700
2026	242,800
Total lease payments	2,043,900
Less: imputed interest	(203,400)
Present value of lease payments	1,840,500

The Company maintained a month-to-month lease in Arlington, VA, until October 1, 2022, which was considered a short-term lease. The Company elected to exclude this lease from the determination of the right-of-use asset and lease liability, as permitted under ASC 842. The Company recognized the lease payments in profit or loss in the statement of operations on a straight-line basis over the term of the lease. The monthly rent expense prior to termination of the lease was $2,500 per month. For the six months ended June 30, 2022, short-term lease expense was $15,000.

9. CONVERTIBLE DEBT

The Company began issuing senior secured promissory notes (each a "CPN" and together the "Notes") notes payable to a private accredited investor (the "Investor") during 2022. The Company has continued to issue notes to the Investor during 2023. Through June 30, 2023, the Company has issued to the Investor eight notes totaling $16,400,000, of which $12,400,000 were issued during the six months ended June 30, 2023. The notes are each 25% Senior Secured Convertible Promissory Notes with largely consistent terms including a stated interest rate of 25% per year, a stated conversion price subject to a beneficial ownership limitation and share cap representing a certain percentage of the outstanding shares of Common Stock at the time of conversion, and a one year maturity. 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, the Company executed an exchange agreement to convert $8,000,000 of convertible promissory notes principal into shares of preferred stock. See Note 10 – Stockholder's Equity for further discussion..

	June 30, 2023	December 31, 2022
Senior Secured Convertible Promissory Note, maturing December 12, 2023	$ —	$ 4,000,000
Senior Secured Convertible Promissory Note, maturing March 28, 2024	2,000,000	—
Senior Secured Convertible Promissory Note, maturing April 25, 2024	2,000,000	—
Senior Secured Convertible Promissory Note, maturing May 24, 2024	2,000,000	—
Senior Secured Convertible Promissory Note, maturing June 26, 2024	2,400,000	—
Total Convertible Promissory Note	$ 8,400,000	$ 4,000,000
Less: unamortized debt issuance costs	(364,700)	(190,100)
Convertible Promissory Note, net	$ 8,035,300	$ 3,809,900

10. STOCKHOLDERS' EQUITY

Stock— As of June 30, 2023 and December 31, 2022, 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) and 300,000,000 shares of common stock (1,176,260 and 648,384 shares issued and outstanding, respectively). Additionally, for the six months ended June 30, 2023, the Company authorized the issuance of 8,000 shares of Series C Convertible Voting Preferred Stock (the "Series C Stock"). The Company issued 8,000 shares of Series C Stock on April 2, 2023 as part of the Exchange agreement discussed below, of which 8,000 shares remain outstanding as of June 30, 2023.

The Series C Stock is convertible into shares of the Company's common stock, par value $0.001 per share. The Series C Preferred Stock is voting stock and holders of the Series C Preferred Stock are entitled to vote together with the Common Stock on an as-if-converted-to-Common-Stock basis as determined by dividing the Liquidation Preference with respect to such shares of Series C Preferred Stock by the 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 Series C Preferred Stock will be entitled to one vote for each whole share of Common Stock into which their Series C Preferred Stock is then-convertible on all matters submitted to a vote of stockholders.

Cumulative Rights of Series C Stock Shareholders— The Series C Stock accumulates undeclared dividends at an annual rate of 25%. Unpaid dividends and undeclared dividends are added to the aggregate Liquidation Preference, which also includes the face value of the Series C Stock outstanding. In the event of any liquidation of the Company, holders of shares of Series C Stock 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. As of June 30, 2023 and December 31, 2022, the outstanding Liquidation Preference of the Series C Stock is $8,515,100 and zero, respectively.

Participating Rights of Series C Stock Shareholders— In the event the Company declares a dividend, and all cumulative dividends have been distributed, the Series C stock participates in any remaing 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.

Exchange Agreement

In April 2023, the Company entered into an Exchange Agreement with the holder of promissory notes to exchange an aggregate principal amount of $8 million of the Company's 25% Senior Secured Convertible Promissory Notes for 8,000 shares of Series C Stock. The $8 million Senior Secured Convertible Promissory Notes is the aggregate of four promissory notes that were issued in the previous months, for $2 million each.

Representative's Warrants—In connection with a public offering on October 15, 2020, the Company granted the underwriters warrants (the "Underwriters' Warrants") to purchase an aggregate of 2,083 shares of common stock at an exercise price of $450.00 per share. The Underwriters' Warrants have a five-year term and were not exercisable prior to April 13, 2021. All of the Underwriters' Warrants were outstanding and exercisable at June 30, 2023 and December 31, 2022. The warrants related to the IPO stock discount will be fully amortized in July 2024.

In connection with a public offering on July 2, 2021, the Company granted the underwriters warrants to purchase an aggregate of 13,333 shares of common stock at an exercise price of $187.50 per share, The Underwriters' Warrants have a five-year term. All of the Underwriters' Warrants were outstanding as of June 30, 2023 and December 31, 2022. The warrants related to the Public Offering stock discount will be fully amortized in April 2025.

Standby Equity Purchase Agreement

On May 24, 2023, we exercised the Commitment increase under the SEPA and issued to YA II PN, Ltd. 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 exercised an additional Commitment increase under the SEPA and issued to YA II PN, Ltd. 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 at:

	2023		2022	
	Shares	Weighted Average Grant Date Fair Value Per Share	Shares	Weighted Average Grant Date Fair Value Per Share
Nonvested RSUs at beginning of period	650	$ 259.50	17,028	$ 374.40
Granted	—	—	—	—
Vested	(251)	255.85	(356)	259.20
Cancelled and forfeited	(11)	260.10	(11,191)	383.70
Nonvested RSUs at June 30	388	$ 285.36	5,481	$ 362.70

Total stock compensation expense recognized from stock-based compensation awards classified as restricted stock units were recognized in the condensed consolidated statements of operations for the three and six months ended June 30, 2023 and 2022, as follows:

	Three Months Ended		Six Months Ended	
	2023	2022	2023	2022
Research and development	$ 15,100	$ 1,900	$ 15,100	$ 13,900
General and administrative	14,500	2,400	14,500	(4,700)
Total	$ 29,600	$ 4,300	$ 29,600	$ 9,200

2017 Stock Incentive Plan— Stock Options

The following table summarizes the activity for all stock options outstanding at June 30, 2023 under the 2017 Plan:

	2023		2022	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Options outstanding at beginning of period	11,286	$ 254.40	12,697	$ 257.10
Granted	—	—	—	—
Exercised	—	—	—	—
Cancelled and forfeited	(5,433)	215.35	(1,401)	275.70
Balance at June 30	5,853	$ 285.36	11,296	$ 254.70
Options exercisable at June 30:	5,853	$ 285.36	11,165	$ 255.00

In addition, the weighted average remaining contractual life for the options is 4.43 years and 4.93 years as of June 30, 2023 and December 31, 2022, respectively. The options have no intrinsic value as of June 30, 2023 or December 31, 2022, respectively.

Total stock compensation expense recognized from stock-based compensation awards classified as stock options were recognized in the condensed consolidated statements of operations for the three and six months ended June 30, 2023 and 2022 as follows:

	Three Months Ended		Six Months Ended	
	2023	2022	2023	2022
Research and development	$ —	$ 3,000	$ —	$ 52,000
General and administrative	—	7,000	—	15,000
Total	$ —	$ 10,000	$ —	$ 67,000

As of June 30, 2023, there was no unrecognized stock compensation expense related to unvested stock options.
As of June 30, 2023, there was $96,600 unrecognized stock compensation expense related to unvested restricted stock units.

2021 Stock Incentive Plan—Restricted Stock Units

The following table summarizes the activity for all RSUs outstanding at June 30, 2023 and 2022 under the 2021 Plan:

	2023		2022	
	Shares	Weighted Average Grant Date Fair Value Per Share	Shares	Weighted Average Grant Date Fair Value Per Share
Nonvested RSUs at beginning of period	684	$ 133.20	2,068	$ 165.60
Granted	36,910	0.62	—	—
Vested	(13,425)	0.62	—	—
Cancelled and forfeited	(668)	126.60	(131)	126.60
Nonvested RSUs at June 30	23,501	$ 20.41	1,937	$ 168.30

Total stock compensation expense recognized from stock-based compensation awards classified as restricted stock units were recognized in the condensed consolidated statements of operations for the three and six months ended June 30, 2023 and 2022, as follows:

	Three Months Ended		Six Months Ended	
	2023	2022	2023	2022
Research and development	$ 3,900	$ 17,400	$ 11,800	$ 25,700
General and administrative	1,900	19,900	14,700	29,800
Total	$ 5,800	$ 37,300	$ 26,500	$ 55,500

The vested outstanding restricted stock units have not been released to grantees as of June 30, 2023, but they were included in calculation of weighted average common shares outstanding, basic and diluted (See Note 3, Net Loss Per Share of Common Stock). The Company plans to release these shares to the grantees before the end of the year. Since there is a possibility that any portion of those shares could be sold as part of the release, the shares will be released in compliance with the Company's insider trading policy when there is an open trading window and grantees are not in possession of any material non-public information.

2021 Stock Incentive Plan — Stock Options

The following table summarizes the activity for all stock options outstanding at June 30, 2023 under the 2021 Plan:

	2023		2022	
	Shares	Weighted Average Exercise Price	Shares	Weighted Average Exercise Price
Options outstanding at beginning of period	21,420	$ 12.90	—	$ —
Granted	—	—	24,480	12.90
Exercised	—	—	—	—
Cancelled and forfeited	(9,180)	12.90	—	—
Balance at June 30	12,240	$ 12.90	24,480	$ 12.90
Options exercisable at June 30:	12,240	$ 12.90	12,240	$ 12.90
Weighted average grant date fair value for options granted during the year:		$ —		$ 10.80

In addition, the stock options had weighted average remaining contractual life of 4.93 years. There was no stock compensation expense during the six months ended June 30, 2023 and June 30, 2022, respectively.

12. INCOME TAXES

The Company's effective tax rate from continuing operations was 0% for the three and six months ended June 30, 2023 and 2022. The Company recorded no income tax provision for the three or six months ended June 30, 2023.

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

Exchange Agreement

On July 18, 2023, the Company entered into an Exchange Agreement (the "July 18 Exchange Agreement") with the holder of promissory notes of the Company (the "Holder") pursuant to which the Holder agreed to exchange aggregate principal amount of $6 million of the Company's 25% Senior Secured Convertible Promissory Notes (the "July 18 Exchange Notes") for 6,000 shares of Series C Stock. The $6 million Senior Secured Convertible Promissory Notes is the aggregate of three promissory notes that were issued in the previous months, for $2 million each, as discussed in Note 9 above.

Board of Directors Appointment

On July 20, 2023, the Board of Directors appointed Pam Misajon and Mike Catlin as members of the Board of Directors. Ms. Misajon has been appointed chair of the Nominating and Corporate Governance Committee and member of the Compensation Committee, Mr. Catlin has been appointed chair of the Audit Committee and member of the Nominating and Corporate Governance Committee. After these nominations, the Company regained the audit committee requirements under Listing Rule 5605 (c)(4), meeting the expectations of the Nasdaq which gave the Company until November 16, 2023 for compliance.

Issuance of Senior Secured Convertible Promissory Note

On July 25, 2023, the Company issued a 25% Senior Secured Convertible Promissory Note (the "July 25 Note") to the investor. The Note has a principal amount of $2,400,000, bears interest at a rate of 25% per annum (the "Stated Rate") and matures on July 25, 2024 (the "July 25 Maturity Date"), on which the principal balance and accrued but unpaid interest under the Note shall be due and payable. The Stated Rate will increase to 27% per annum or the highest rate then allowed under applicable law (whichever is lower) 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 July 25 Note is convertible into shares of the Company's common stock, par value $0.001 per share, at an initial conversion price of $6.50 per share, subject to a beneficial ownership limitation equivalent to 9.99%.

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 Actions. In the Class Action, the plaintiffs have made allegations and asserted claims against the Company and certain current and former directors and officers, as well as the Company's former underwriter, including for alleged violations of Sections 11, 12(a)(2), and 15 of the Securities Act of 1933 as well as Section 10(b) (and Rule 10b-5 promulgated thereunder) and Section 20(a) of the Securities Exchange Act of 1934 in connection with a public offering by the Company that closed on or about July 2, 2021. The Term Sheet provides, among other things, that it is subject to approval by the U.S. District Court for the Southern District of New York (the "Court"); that plaintiffs and the Company will prepare settlement materials consistent with the Term Sheet; that the settlement will globally resolve all claims and allegations; that no defendant admits any liability or any allegation; that the Company shall make cash consideration payments totaling $2,300,000 into an escrow account, of which $530,000 we expect to be paid by our insurance carrier directly to the plaintiffs, resulting in recognition of a $1.77 million expense in our income statement for the three and six months ended June 30, 2023. Such amounts shall be distributed as set forth in the Term Sheet, including that amounts shall be distributed upon approval of the settlement by the Court. The plaintiffs subsequently sent a letter to the Court on August 7, 2023, informing the Court of the settlement in principle and requesting that the Court stay all proceedings pending approval of the settlement.

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

The following management's discussion and analysis of financial condition and results of operations provides information that management believes is relevant to an assessment and understanding of our plans and financial condition. The following financial information is derived from our financial statements and should be read in conjunction with such financial statements and notes thereto set forth elsewhere herein.

Our Business

Overview

Kiromic BioPharma, Inc. and subsidiaries (the "Company") is a clinical stage fully integrated biotherapeutics company formed under the Texas Business Organizations Code in December 2012. The Company maintains offices in Houston, Texas. The Company has not generated any revenues to date.

The Company is an Artificial Intelligence ("AI") driven, end-to-end allogeneic cell therapy company, currently developing multi-indication allogeneic T cell therapies that exploit the natural potency of Gamma Delta T cells ("GDTs") to target solid tumors. Our end-to-end approach consists of target discovery and validation, product development, and current good manufacturing practices ("cGMP"), which we believe will allow us to leverage a new framework for the next generation of cell therapies. We also have new technologies in development to support our end-to-end approach.

From a development standpoint, we utilize innovative engineered and non-engineered GDT manufacturing 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. Deltacel is our first allogeneic off-the-shelf gamma delta T cell-based product in Phase 1 clinical stage. Our ProcelÔ ("Procel") and IsocelÔ ("Isocel") product candidates consist of allogeneic, cryopreserved, and engineered gamma delta T cells and they are currently in the preclinical development stage. Our Deltacel product candidate consists of non-engineered GDTs that have been expanded, enriched, and activated ex-vivo through a proprietary process, and are intended to treat solid tumors regardless of the specific tumor antigen expression. Our Procel product candidate consists of engineered GDTs and is intended to target PD-L1. Our Isocel product candidate consists of engineered GDTs and is intended to target Mesothelin Isoform 2 positive tumors ("Iso-Meso").

We currently have three product candidates: 1) Deltacel: not-engineered GDTs, expanded and activated with proprietary technology; 2) Procel: GDTs engineered with a PD-1 switch receptor; and 3) Isocel: GDTs engineered with an anti-Mesothelin isoform 2 Chimeric Antigen Receptor.

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

1) Deltacel-01: This phase 1 clinical trial will evaluate Deltacel in combination with low-dose radiation for patients with non-small cell lung cancer (NSCLC).

2) 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.

3) Alexis-PRO-1: This phase 1 clinical trial is expected to evaluate Procel in patients with PD-L1 positive solid malignancies.

4) 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.

5) Alexis-ISO-1: This phase 1 clinical trial is expected to evaluate Isocel in patients with Mesothelin Isoform 2 positive solid malignancies..

Since the second half of 2022, we have been developing a novel, non-engineered GDT cell therapy based on a proprietary methodology of expanding and activating GDT cells from healthy donors. The product candidate, Deltacel, is intended to be used in combination with low-dose radiation.

Accordingly, we have entered into a Sponsored Research Agreement (the "SRA") with Principal Investigator James W. Welsh, M.D. of The University of Texas MD Anderson Cancer Center, to facilitate the development of our Deltacel,

Procel, and Isocel product candidates. We believe this SRA will generate sufficient in-vivo, pre-clinical data to enhance our GDT product platform, supporting three new IND submissions: (1) Deltacel in combination with low-dose radiation; (2) Procel in combination with a low-dose radiation; and (3) Isocel in combination with a low-dose radiation. The first IND submitted to the FDA was IND #1, as explained in further detail below. The clinical trial activation process begins after the following two events: (1) the IND receives FDA authorization to begin the clinical trial (which would take place 30 days after receipt by the FDA, unless the FDA raises concerns or questions regarding the proposed clinical trials and places the trial on a clinical hold within that 30-day time period); and (2) the review and approval process commences by an independent institutional review board ("IRB") or ethics committee at the selected clinical trial site(s).

IND #1 (number 1 above) will evaluate Deltacel GDTs in combination with low-dose radiation. We submitted the IND for the Deltacel trial on March 31, 2023, and on April 28, 2023, the FDA authorized the Deltacel-01 IND application. We began the clinical trial activation process in Q2 2023 and expect to begin the clinical trial in Q4 of 2023. The Procel combination IND will evaluate a combination of low-dose radiation and our genetically engineered product candidate targeting PD-L1, which is the target associated with the ALEXIS-PRO-1 clinical trial candidate on the Procel product candidate platform. The Isocel combination IND will evaluate a combination of low-dose radiation in combination of our genetically engineered product candidate targeting Iso-Meso, the target associated with the ALEXIS-ISO-1 clinical trial candidate on the Isocel product candidate platform. Since the Company has aligned its operations with the Deltacel product candidate and IND #1, we are planning to submit the other IND applications once we obtain sufficient financing to support the progression of the development of these additional clinical trial candidates.

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 combined with verbal, non-contractual commitments for additional financing will not be sufficient to meet operating and liquidity needs beyond the beginning of October 2023.

Recent Developments

Settlement Update

On October 10, 2022, we and certain current and former officers and directors (together with us, the "Defendants") entered into a Stipulation of Settlement and Mutual Release (the "Initial Settlement Agreements") with the Empery Entities and with the Sabby Entities (collectively, the "Plaintiffs"), respectively, in connection with a case filed by the Plaintiffs against the Defendants for alleged violations of Sections 11, 12, and 15 of the Securities Act in connection with the purchase of Company's common stock through the Company's public offering that closed on July 2, 2021. Pursuant to the Initial Settlement Agreements, the Plaintiffs and the Defendants agreed to dismiss the case with prejudice against all Defendants (including ThinkEquity, LLC) with no admission of liability. As part of the Settlement, the Company agreed to (a) make a $75,000 cash payment to each of the Empery Entities and Sabby Entities and (b) issue the Settlement Notes in the aggregate principal amount of $1,656,720 to each of the Empery Entities and Sabby Entities. The Settlement Notes are convertible into shares of the Company's common stock at an initial conversion price per share of $9.20 (the "Conversion Price"), subject to a beneficial ownership limitation equivalent to 9.99% ("Beneficial Ownership Limitation").

On November 2, 2022, the Court granted a joint motion, pursuant to which the Settlement Notes will be unrestricted and exempt from the registration requirements of the Securities Act, and the Conversion Shares, when issued upon conversion of the Settlement Notes in accordance with the terms set forth therein, will also be unrestricted and exempt from the registration requirements of the Securities Act.

All the subordinated convertible promissory notes totaling $2,914,000 on the balance sheet at December 31, 2022 held by Empery and Sabby for $1,502,700 and $1,411,300, respectively, were converted into shares of common stock of 163,268 and 153,333, respectively, at a share price of $9.20 during the six months ended June 30, 2023.

On August 7, 2023, the Company entered into a term sheet with the plaintiffs in *re Kiromic BioPharma, Inc. Securities Litigation*, Case No. 1:22-cv-06690 (S.D.N.Y.) ("Class Action"), to settle in principle (and globally resolve) the Class Action. In the Class Action, the plaintiffs have made allegations and asserted claims against the Company and certain current and former directors and officers, as well as the Company's former underwriter, for alleged violations of Sections

11, 12(a)(2), and 15 of the Securities Act of 1933 as well as Section 10(b) (and Rule 10b-5 promulgated thereunder) and Section 20(a) of the Securities Exchange Act of 1934 in connection with a public offering by the Company that closed on or about July 2, 2021. The Term Sheet provides, among other things, that it is subject to approval by the U.S. District Court for the Southern District of New York (the "Court"); that plaintiffs and the Company will prepare settlement materials consistent with the Term Sheet; that the settlement will globally resolve all claims and allegations; that no defendant admits any liability or any allegation; that the Company shall make cash consideration payments totaling $2,300,000 into an escrow account, of which $530,000 we expect to be paid by our insurance carrier directly to the plaintiffs, resulting in recognition of a $1.77 million expense in our income statement for the three and six months ended June 30, 2023. Such amounts shall be distributed as set forth in the Term Sheet, including that amounts shall be distributed upon approval of the settlement by the Court. The plaintiffs subsequently sent a letter to the Court on August 7, 2023 informing the Court of the settlement in principle and requesting that the Court stay all proceedings pending approval of the settlement.

Subsequent to June 30, 2023, the Company has:

- Issued $2.4 million of convertible promissory notes;
- Converted $6 million of convertible promissory notes into 6,000 shares of Series C Stock;
- Appointed two new independent members to the Board of Directors; and
- Entered into a settlement agreement with plaintiffs with respect to the Class Action suit for a net $1.77 million on August 7, 2023 as disclosed above.

See Note 13 – Subsequent Events for more information.

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 of future operations. These plans may include, but are not limited to, additional funding from current or new investors; 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 cash and cash equivalents were $2,704,200 as of June 30, 2023. 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. The Company has begun working with a financial advisor to assist it with its efforts to obtain financing. In the absence of such 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 the beginning of October 2023. 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 pending securities litigation and 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

For the six months ended June 30, 2023, the Company has issued 197,000 shares under the SEPA for $659,100, and $12,400,000 of principal of senior secured convertible notes. The Company converted $8 million of outstanding senior secured convertible notes to Series C preferred shares.

NASDAQ Letter

On March 14, 2023, the Company received written notice (the "**Notice**") from The Nasdaq Stock Market LLC ("**Nasdaq**") stating that the Company did not maintain a minimum bid price of at least $1.00 for a minimum of ten (10) consecutive business days before the end of the Nasdaq grace period and, therefore, did not regain compliance with Listing Rule 5550(a)(2) by March 13, 2023, as required.

As a result of the foregoing, the Staff informed the Company that its common stock would be subject to delisting from The Nasdaq Capital Market, unless the Company timely requested a hearing before the Nasdaq Hearings Panel (the "Panel"). Accordingly, the Company timely requested and attended a hearing before the Panel, at which the Company presented its plan to evidence compliance with the minimum bid price requirement as well as its plan to comply with Nasdaq's $2,500,000 minimum stockholders' equity requirement for continued listing as set forth in Listing Rule 5550(b)(1).

On March 28, 2023, the Company was notified by Nasdaq that compliance with the bid price deficiency has been cured and now the Company complies with Listing Rule 5550(a)(2). However, the Company remains out of compliance with respect to the stockholders' equity requirement set forth in Listing Rule 5550(b)(1).

As previously disclosed, on April 20, 2023, the Company presented its plan to comply with the minimum stockholders' equity requirement for continued listing on The Nasdaq Capital Market (the "Stockholders' Equity Requirement") to the Nasdaq Hearings Panel. On May 11, 2023, the Nasdaq Hearings Panel granted the Company's request to provide an extension until September 11, 2023 for the Company to comply with the stockholders' equity requirement.

Based on the information regarding the appointment of Michael Catlin to the Company's Board of Directors and Audit Committee, the Company was notified by Nasdaq on July 26, 2023 that it complies with the rule 5605(c)(2), and the matter is now closed.

Clinical Update

IND #1 will evaluate Deltacel GDTs in combination with low-dose radiation. We submitted the IND for the Deltacel trial on March 31, 2023 and on May 1, 2023, we announced that the FDA authorized our IND. We began the activation of the clinical trial process during the three months ended June 30, 2023. We expect to have the first clinical data by end of 2023 and to complete the Phase 1 of the trial by the second half of 2024.

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.

On February 2, 2022, following the conclusion of the Internal Review, the Special Committee reported the results of its Internal Review to the Board. The Board approved certain actions to address the fact that we had received communications

from the FDA on June 16 and June 17, 2021 that the FDA was placing our IND applications that we submitted to the FDA on May 14 and May 17, 2021 for the ALEXIS-PRO-1 and ALEXIS-ISO-1 product candidates, respectively, on clinical hold (the "June 16 and 17, 2021 FDA Communications"). On July 13, 2021, we received the FDA's formal clinical hold letters, which asked us to address key components regarding the chemical, manufacturing, and control components of the IND applications. On July 16, 2021, we issued a press release disclosing that it had received comments from the FDA on our two INDs, but did not use the term "clinical hold." On August 13, 2021, we issued a press release announcing that these INDs were placed on clinical hold. We did not disclose the June 16 and 17, 2021 FDA Communications in (i) our Registration Statement on Form S-1 (Registration No. 333-257427) that was filed on June 25, 2021 and declared effective on June 29, 2021, nor the final prospectus contained therein dated June 29, 2021 (collectively, the "Registration Statement"); or (ii) our Form 10-Q for the fiscal quarter ended June 30, 2021 that was filed with the Securities and Exchange Commission on August 13, 2021. We consummated a public offering of $40 million of our common stock pursuant to the Registration Statement on July 2, 2021.

In the course of the Internal Review, the Special Committee also identified that Mr. Tontat submitted incorrect information regarding his educational background to us. Specifically, although Mr. Tontat represented to us that he held a BA in Economics from Harvard University, it was determined that he had actually received an ALB, a degree conferred by the Harvard Extension School. We have implemented changes to our vetting process for prospective director and officer candidates including the implementation of thorough background checks to verify background information provided by such candidates.

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

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

Remediation Actions resulting from the Internal Review

1. The Board approved the inclusion of certain Risk Factors for inclusion in its periodic reports. See Part II, Item 1A. Risk Factors for further information. Such risk factors have been included in our Form 10-K for the year ended December 31, 2022.

2. On January 10, 2022, the Board approved the formation of a Disclosure Committee comprised of certain members of the management including (i) its Chief Executive Officer; (ii) the executive in charge of overseeing submissions of any nature to the FDA; (iii) its Chief Financial Officer, if any; (iv) its General Counsel, if any; (v) its Controller, if any; (vi) any other finance executive overseeing financial disclosures; (vii) the executive in charge of investor relations, if any; and (viii) such other employees as the Chief Financial Officer, who serves as chairman of the Disclosure Committee, may invite from time to time. The Disclosure Committee shall be responsible for preparing and reviewing all corporate disclosures made by us to our security holders, the Securities and Exchange Commission and/or the broader investment community to ensure that such disclosures (i) shall be accurate and complete; (ii) shall fairly present, in all material respects, our financial condition, results of operations and cash flows; and (iii) shall be made on a timely basis in accordance with all applicable requirements of (A) the Securities Exchange Act of 1934, as amended and the rules and regulations promulgated thereunder, (B) the Securities Act of 1933, as amended and the rules and regulations promulgated thereunder (C) the Nasdaq Stock Market or such other stock exchange on which the our securities may be traded and (D) any other applicable laws or legal requirements. The Board adopted and approved the Disclosure Committee Charter.

3. The Board terminated Maurizio Chiriva-Internati as Chief Executive Officer for cause on January 27, 2022, after the Special Committee's Internal Review found evidence of conduct that the Board believed was inconsistent with the Company's policies. Under the terms of the Executive Employment Agreement between Dr. Chiriva and the Company effective as of July 1, 2020, as amended October 21, 2021, as the result of the termination of his employment, Dr. Chiriva also is deemed to have resigned as a Director on the Board effective as of January 27, 2022.

4. The Board named Pietro Bersani as Interim Chief Executive Officer, effective as of January 27, 2022. Mr. Bersani has resigned from all Committees of the Board. Subsequently on May 10, 2022, Mr. Bersani was named Chief Executive Officer.

5. The Board named independent Director Michael Nagel as Chairperson of the Board, effective as of January 27, 2022.

6. The Board approved the appointment of Frank Tirelli as a member of the Board to fill a vacancy, effective as of January 28, 2022. The Board has determined that Mr. Tirelli is "independent" as that term is defined under Nasdaq Listing Rule 5605(a)(2). Mr. Tirelli has been named Chairperson of the Audit Committee effective January 28, 2022. He was also nominated and appointed as a member of the Nominating and Corporate Governance Committee effective March 1, 2022. Mr. Tirelli was nominated by our Nominating and Corporate Governance Committee of the Board after a thorough review of all his background, relevant experience, and professional and personal reputations.

7. On November 16, 2022, Frank Tirelli informed the Board of Directors (the "Board") of Kiromic BioPharma, Inc. (the "Company") that he was resigning his position as a director of the Company, effective immediately. Mr. Tirelli also ceased to be a member of the Audit Committee, and the Nominating and Corporate Governance Committee of the Board, effective immediately. Mr. Tirelli's resignation did not involve a disagreement with the Company on any matter relating to the Company's operations, policies or practices.

8. On February 10, 2022, we and Dr. Scott Dahlbeck ("Dr. Dahlbeck") entered into a Modification to Employment Agreement dated as of February 9, 2022 (the "Dahlbeck Agreement"). The Dahlbeck Agreement amends and supersedes certain terms of the Employment Agreement dated as of January 1, 2020, between the Company and Dr. Dahlbeck. Pursuant to the Dahlbeck Agreement, effective as of February 9, 2022, Dr. Dahlbeck's title was changed to Chief of Staff, and he ceased to be our Chief Medical Officer and Head of Clinical.

9. On February 10, 2022, we and Mr. Gianluca Rotino ("Mr. Rotino") entered into a Transition and Consulting Agreement dated as of February 9, 2022 (the "Rotino Agreement"). Pursuant to the terms of the Rotino Agreement, effective as of February 9, 2022, Mr. Rotino's employment as our Chief Strategy and Innovation Officer terminated and the Company retained Mr. Rotino to provide consulting services to the Company for a period of nine months (until November 9, 2022). Notwithstanding the foregoing, the Rotino Agreement may be terminated by either us or Mr. Rotino upon 30 days' prior written notice, except no such prior notice shall be required in the event we terminate the Rotino Agreement for cause.

10. Under the terms of the Executive Employment Agreement between Mr. Rotino and the Company effective as of July 1, 2020, as amended October 21, 2020, as the result of the termination of Mr. Rotino's employment, Mr. Rotino is deemed to have resigned as a member of the Board effective as of February 9, 2022.

11. The Board approved the appointment of Karen Reeves as a member of the Board to fill a vacancy, effective as of February 14, 2022. The Board has determined that Dr. Reeves is "independent" as that term is defined under Nasdaq Listing Rule 5605(a)(2). Dr. Reeves was nominated and appointed to be the Nominating and Corporate Governance Committee Chairperson and a member of the Compensation Committee effective March 1, 2022. Dr. Reeves was nominated by our Nominating and Corporate Governance Committee of the Board after a thorough review of all her background, relevant experience, and professional and personal reputations.

12. On December 6, 2022, Dr. Karen Reeves informed the Board of Directors (the "Board") of Kiromic BioPharma, Inc. (the "Registrant") that she was resigning her position as a director of the Registrant, effective immediately. Dr. Reeves also ceased to be a member of the Nominating and Corporate Governance Committee, and the Compensation Committee of the Board. Dr. Reeves' resignation did not involve a disagreement with the Registrant on any matter relating to the Registrant's operations, policies or practices.

13. On June 12, 2023, Kiromic BioPharma, Inc. (the "Company") appointed Brian Hungerford as Interim Chief Financial Officer of the Company. Mr. Hungerford was retained by the Company through an agreement with Element 78 Partners, LLC.

14. On July 20, 2023, the Board of Directors of Kiromic BioPharma, Inc. (the "Company") appointed Pam Misajon and Mike Catlin as members of the Board of Directors. Ms. Misajon has been appointed chair of the Nominating and Corporate Governance Committee and member of the Compensation Committee and Mr. Catlin has been appointed chair of the Audit Committee and member of the Nominating and Corporate Governance Committee. After these nominations, the Company regained the audit committee requirements under Listing Rule 5605 (c)(4), meeting the expectations of the Nasdaq which gave us until November 16, 2023 for compliance.

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; and
- changes in laws or the regulatory environment affecting our company.

Emerging Growth Company

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

- have an auditor report on our internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act;
- comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (i.e., an auditor discussion and analysis);
- submit certain executive compensation matters to stockholder advisory votes, such as "say-on-pay" and "say-on-frequency;" and
- disclose certain executive compensation related items such as the correlation between executive compensation and performance and comparisons of the chief executive officer's compensation to median employee compensation.

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

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

Components of Results of Operations

Revenue

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from product sales in the foreseeable future. We will record revenue from collaboration agreements, including amounts related to upfront payments, annual fees for licenses of our intellectual property and research and development funding. However, none of those agreements have been executed as of the issuance date of this report.

Research and Development Expenses

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

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

Research and development activities are central to our business model. We expect that our research and development expenses will comprise a larger percentage of our total expenses as we initiate Phase 1 clinical trials for our Deltacel, Isocel and Procel, and continue to discover and develop additional candidates. However, management may further evaluate various cost reduction actions, including delay of research and development expenditures on one or more product candidates to focus on Deltacel, in order to reduce the Company's current expenditures and preserve cash. As of the date of this quarterly report, we are not able to predict on what product candidates and how much expenditures 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 of Deltacel, and of preclinical and clinical development of Isocel and Procel (and any other trial candidate we may develop) will depend on a variety of factors, including:

- the scope, rate of progress, expense and results of clinical trialsDeltacel 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 Nasdaq 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, 2023 and 2022

The following table sets forth key components of our results of operations for the three months ended June 30, 2023 and 2022.

	Three Months Ended June 30,		Increase (Decrease)	
	2023	2022	$	%
Operating expenses:				
Research and development	$ 1,966,600	$ 3,880,700	$ (1,914,100)	(49)%
General and administrative	2,325,900	4,551,700	(2,225,800)	(49)%
Total operating expenses	4,292,500	8,432,400	(4,139,900)	(49)%
Loss from operations	(4,292,500)	(8,432,400)	(4,139,900)	(49)%
Other expense				
Interest expense	(335,400)	(2,700)	332,700	NM
Debt issuance amortization	(366,500)	—	366,500	NM
Litigation settlement	(1,770,000)	—	(1,770,000)	NM
Total other expense	(2,471,900)	(2,700)	2,469,200	NM
Net loss	$ (6,764,400)	$ (8,435,100)	$ (1,670,700)	(20)%

NM – Not meaningful

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 (Decrease)	
	2023	2022	$	%
Direct research and development expenses by product candidate:				
AIDT-1 development costs	$ 161,900	$ —	$ 161,900	NM
ALEXIS-PRO-1	—	426,900	(426,900)	(100)%
ALEXIS-ISO-1	—	738,100	(738,100)	(100)%
Platform development, early-stage research and unallocated expenses:				
Employee-related costs	614,500	1,456,200	(841,700)	(58)%
Laboratory supplies and services	43,100	428,800	(385,700)	(90)%
Outsourced research and development (net of reimbursements)	140,500	18,000	122,500	681 %
Laboratory equipment and maintenance	788,400	493,900	294,500	60 %
Facility-related costs	158,300	238,100	(79,800)	(34)%
Intellectual property	45,800	58,300	(12,500)	(21)%
Other research and development costs	14,100	22,400	(8,300)	(37)%
Total research and development expenses	$ 1,966,600	$ 3,880,700	$ (1,914,100)	(49)%

NM – Not meaningful

The primary drivers for the reduction in cost are as follows:

1- AIDT-1 development cost increased by $161,900, related to the prioritization of the Deltacel-01 development.

2- Direct research and development costs for ALEXIS-PRO-1 and ALEXIS-ISO-1 decreased by $426,900 and $738,100, respectively, related to the prioritization of Deltacel-01 and the temporary suspension of the development of these two product lines.

3- Employee related costs decreased by $841,700, mainly related to a decrease in employee headcount.

4- Laboratory supplies and services decreased by $385,700, primarily due to the temporary suspension of the development of ALEXIS-PRO-1 and ALEXIS-ISO-1.

5- Outsourced research and development increased by $122,500 primarily due to the focus on Deltacel, and the related expense attributable to preparation for our clinical trials.

6- Laboratory equipment and maintenance increased by $294,500, primarily due to increased depreciation expense related to purchases of equipment for the development of ALEXIS-PRO that occurred in June of 2022.

7- Facilities related costs decreased by $79,800, due to the lab expansion attributable to GDT manufacturing during the three months ended June 30, 2022.

General and administrative expenses. The decrease in general and administrative expenses by $2,225,800, or 49%, for the three months ended June 30, 2023, compared to June 30, 2022 were primarily due to:

1- A decrease in legal services of $999,200 driven by a significant decline in expenses related to the Internal Review and related matters.

2- A decrease in employee-related expenses of $1,088,700 driven by a decline in the average headcount.

Comparison of the Six Months Ended June 30, 2023 and 2022

The following table sets forth key components of our results of operations for the six months ended June 30, 2023 and 2022.

	Six Months Ended June 30,		Increase (Decrease)	
	2023	2022	$	%
Operating expenses:				
Research and development	$ 4,041,600	$ 6,806,500	$ (2,764,900)	(41)%
General and administrative	5,028,300	8,990,800	(3,962,500)	(44)%
Total operating expenses	9,069,900	15,797,300	(6,727,400)	(43)%
Loss from operations	(9,069,900)	(15,797,300)	(6,727,400)	(43)%
Other expense				
Interest expense	(779,400)	(5,500)	773,900	NM
Debt issuance amortization	(445,400)	—	445,400	NM
Litigation settlement	(1,770,000)	—	1,770,000	NM
Total other expense	(2,994,800)	(5,500)	2,989,300	NM
Net loss	$ (12,064,700)	$ (15,802,800)	$ (3,738,100)	(24)%

NM: Not meaningful

Research and development expenses.

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

	Six Months Ended June 30,		Increase (Decrease)	
	2023	2022	$	%
Direct research and development expenses by product candidate:				
AIDT-1 development costs	$ 683,100	$ —	$ 683,100	NM
ALEXIS-PRO-1	—	892,000	(892,000)	(100)%
ALEXIS-ISO-1	—	843,200	(843,200)	(100)%
Platform development, early-stage research and unallocated expenses:				
Employee-related costs	1,190,700	2,798,700	(1,608,000)	(57)%
Laboratory supplies and services	153,300	594,100	(440,800)	(74)%
Outsourced research and development (net of reimbursements)	247,700	190,700	57,000	30 %
Laboratory equipment and maintenance	1,399,200	864,400	534,800	62 %
Facility-related costs	278,100	432,300	(154,200)	(36)%
Intellectual property	43,400	154,800	(111,400)	(72)%
Other research and development costs	46,100	36,300	9,800	27 %
Total research and development expenses	$ 4,041,600	$ 6,806,500	$ (2,764,900)	(41)%

NM – Not meaningful

The primary drivers for the reduction in cost are as follows:

1- AIDT-1 development cost increased by $683,100, related to the prioritization of the Deltacel-01 development.

2- Direct research and development costs for ALEXIS-PRO-1 and ALEXIS-ISO-1 decreased by $892,000 and $843,200, respectively, related to the prioritization of Deltacel-01 and the temporary suspension of the development of these two product lines.

3- Employee related costs decreased by $1,608,000 mainly related to a decrease in employee headcount, in addition to corresponding decrease to a retention bonus for those employees.

4- Laboratory supplies and services decreased by $440,800 mainly related to the tempoarary suspension of the development of ALEXIS-PRO-1 and ALEXIS-ISO-1.

5- Outsourced research and development increased by $57,000, primarily due to the focus on Deltacel, and the related expense attributable to preparation for our clinical trials.

6- Laboratory equipment and maintenance increased by $534,800, primarily due to increased depreciation expense related purchases of equipment due for the development of ALEXIS-PRO that occurred in June of 2022.

7- Facilities related costs decreased by $154,800, due to the lab expansion attributable to GDT manufacturing during the six months ended June 30, 2022.

8- Intellectual Property expenses decreased by $111,400, related to the Company's alignment towards maintaining our key product candidates (Deltacel, Procel, and Isocel) while certain non-key and legacy technologies had patent applications which either expired or were abandoned

General and administrative expenses. The decrease in general and administrative expenses by $3,962,600, or 44%, for the six months ended June 30, 2023, compared to June 30, 2022 were primarily due to:

1- A decrease in legal services of $1,800,500 driven by a significant decline in expenses related to the Internal Review and related matters.

2- A decrease in employee-related expenses of $1,752,800 driven by a decrease in the average headcount.

Liquidity and Capital Resources

As of June 30, 2023, we had cash and cash equivalents of $2,704,200. As of July 31, 2023, we had cash and cash equivalents of $3,109,900. 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.

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 the beginning of October 2023. 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 expenses and operating losses for the foreseeable future as we advance the preclinical and clinical development of our product candidates. We expect that our research and development and general and administrative costs will increase over the long-term, even if we are able to successfully reduce our costs in the short-term in order to preserve cash in light of 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.

As described above, our recent planned underwritten public offering was not successful, and we are currently seeking short-term financing to be able to continue our operations past the beginning of October 2023. 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, the results of our Internal Review demonstrated that we had ineffective disclosure controls and procedures during the first quarter of 2022 and earlier periods, which resulted in our failure to disclose certain information, which has resulted in litigation which has adversely affected our ability to raise capital. 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 the Internal Review and securities litigation, and other risk factors listed in Item 1A. of Part I of our Annual Report on Form 10-K for the year ended December 31, 2022. 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 30,	
	2023	2022
Net cash used in operating activities	$ (10,588,800)	$ (13,548,000)
Net cash used in investing activities	—	(4,955,700)
Net cash provided by financing activities	12,647,800	(339,600)
Net increase (decrease) in cash and cash equivalents	2,059,000	(18,843,300)
Cash and cash equivalents at beginning of the period	645,200	25,353,900
Cash and cash equivalents at end of the period	$ 2,704,200	$ 6,510,600

Cash flows from operating activities

Net cash used in operating activities decreased by approximately $3 million dollars. This decrease is driven primarily by the reduction in overall spending in research and development due to the deferral of expenditures on the Procel and Isocel lines combined with an overall reduction 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 zero for the six months ended June 30, 2023, as compared to $4,955,700 for the six months ended June 30, 2022. Our net cash used in investing activities for the six months ended June 30, 2022 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

The change in cash flows from financing activities for the periods shown are driven by the issuance of approximately $578 thousand of equity and $12.4 million of convertible notes for the six months ended June 30, 2023.

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, 2023. The term “disclosure controls and procedures,” as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”), means controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC’s rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company’s management, including its principal executive and principal financial officers, as appropriate to allow

timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Under the supervision, and with the participation, of our current management, including our CEO and Principal Financial Officer, we evaluated the effectiveness of our disclosure controls and procedures as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, as of June 30, 2023. 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 not effective as of June 30, 2023 because of the material weaknesses in our internal control over financial reporting described below.

Material Weaknesses

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our financial statements will not be prevented or detected on a timely basis. The material weaknesses were identified during the quarter ended June 30, 2023 because we do not have a formal process for period end financial closing and reporting, and also because we have insufficient resources to conduct an effective monitoring and oversight function independent from our operations. These material weaknesses result in an increased risk of material misstatement in the financial statements. In addition, during the year ended December 31, 2021, we identified a material weakness in our internal control over financial reporting related to a lack of effective disclosure controls. Such material weakness has not been fully remediated during the quarter ended June 30, 2023.

Remediation Activities

We believe that we are addressing the material weaknesses identified in connection with the quarter ended June 30, 2023, through measures including:

- Implementation of additional internal control processes and procedures regarding the financial close and reporting process, procure to pay process, and human resources and payroll process.
- Designing those controls with the appropriate segregation of duties.
- The recruitment of full-time accounting and finance personnel, including, but not limited to, personnel focused upon enhanced scrutiny of accounting entries in the areas where we have observed material weaknesses in our internal control over financial reporting.

Management concluded that these material weaknesses still existed as of June 30, 2023. In order to consider these material weaknesses to be fully remediated, we believe additional time is needed to demonstrate effectiveness of the remediation.

As a remedial measure to address the Company's material weakness in internal control over financial reporting identified as a result of the Internal Review, on January 10, 2022, and as amended on April 10, 2023, the Board approved the formation of a Disclosure Committee comprised of certain members of the Company's management including (i) its Chief Executive Officer; (ii) the executive in charge of overseeing submissions of any nature to the FDA; (iii) its Chief Financial Officer, if any; (iv) its General Counsel, if any; (v) its Controller, if any; (vi) any other finance executive overseeing financial disclosures; (vii) the executive in charge of investor relations, if any; and (viii) such other employees as the Chief Executive Officer, who serves as chairman of the Disclosure Committee, may invite from time to time. The Disclosure Committee shall be responsible for preparing and reviewing all corporate disclosures made by the Company to its security holders, the SEC and/or the broader investment community to ensure that such disclosures (i) shall be accurate and complete; (ii) shall fairly present, in all material respects, the Company's financial condition, results of operations and cash flows; and (iii) shall be made on a timely basis in accordance with all applicable requirements of (A) the Exchange Act and the rules and regulations promulgated thereunder, (B) the Securities Act of 1933, as amended and the rules and regulations promulgated thereunder (C) the Nasdaq Stock Market or such other stock exchange on which the Company's securities may be traded and (D) any other applicable laws or legal requirements.

Our management believes that these material weaknesses were not remediated as of June 30, 2023 because the Company continues to be cash constrained and could not fully remediate. In order to consider these material weaknesses to be fully remediated, we believe additional time is needed to demonstrate effectiveness of the remediation.

Changes in Internal Control over Financial Reporting

There have been no other changes in our internal control over financial reporting for the quarter ended June 30, 2023.

PART II — OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS.

From time to time in the future, we may become involved in litigation or other legal proceedings that arise in the ordinary course of business.

Dr. Terrell Claim

On March 22, 2021, Jason Terrell ("Terrell"), a former consultant for 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 500,000 shares of our common stock at a price of $0.50 per share pursuant to an alleged 2014 consulting agreement, and (ii) options to purchase an additional 500,005 shares of our common stock at a price of $0.17 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, we 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 on June 21, 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 our 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 our 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. No further proceedings are taking place.

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 parties have stipulated to and the Chancery Court has so ordered a schedule for supplemental briefing on our motion to dismiss to address the import of the Delaware Supreme Court's Opinion. Under that schedule, supplemental briefing will conclude by August 18, 2023. The Chancery Court has not yet indicated whether it wishes to hold further oral argument on the motion to dismiss.

Karp Class Action

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") covering the same subject matter as the Sabby Entities' and Empery Entities' claims discussed above 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.

Podmore Class Action

On October 3, 2022, Joseph Podmore filed a class action complaint in the United States District Court for the Southern District of New York (the "Podmore Class Action") covering the same subject matter as the Sabby Entities' and Empery Entities' claim discussed above asserting claims against the Company and certain current and former officers and directors 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.

The Karp Class Action and the Podmore Class Action 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 Actions. In the Class Action, the plaintiffs have made allegations and asserted claims against the Company and certain current and former directors and officers, as well as the Company's former underwriter, including for alleged violations of Sections 11, 12(a)(2), and 15 of the Securities Act of 1933 as well as Section 10(b) (and Rule 10b-5 promulgated thereunder) and Section 20(a) of the Securities Exchange Act of 1934 in connection with a public offering by the Company that closed on or about July 2, 2021. The Term Sheet provides, among other things, that it is subject to approval by the U.S. District Court for the Southern District of New York (the "Court"); that plaintiffs and the Company will prepare settlement materials consistent with the Term Sheet; that the settlement will globally resolve all claims and allegations; that no defendant admits any liability or any allegation; that the Company shall make cash consideration payments totaling $2,300,000 into an escrow account, of which $530,000 we expect to be paid by our insurance carrier directly to the plaintiffs, resulting in recognition of a $1.77 million expense in our income statement for the three and six months ended June 30, 2023. Such amounts shall be distributed as set forth in the Term Sheet, including that amounts shall be distributed upon approval of the settlement by the Court. The plaintiffs subsequently sent a letter to the Court on August 7, 2023 informing the Court of the settlement in principle and requesting that the Court stay all proceedings pending approval of the settlement.

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.

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, 2022.

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

None.

ITEM 6. EXHIBITS.

Exhibit No.	Description of Exhibit
3.1	Amendment to Bylaws of Kiromic BioPharma, Inc. (incorporated by reference to Exhibit 3.1 to Form 8-K filed on July 18, 2023)
3.2	Amendment to Certificate of Designation of Preferences, Rights and Limitation of the Series C Convertible Voting Preferred Stock dated July 18, 2023 (incorporated by reference to Exhibit 3.1 to Form 8-K filed on July 19, 2023)
10.1	Form of the 25% Senior Secured Convertible Promissory Note (incorporated by reference to Exhibit 10.1 to Form 8-K filed on April 28, 2023)
10.2	Form of the 25% Senior Secured Convertible Promissory Note (incorporated by reference to Exhibit 10.1 to Form 8-K filed on May 30, 2023)
10.3	Form of the 25% Senior Secured Convertible Promissory Note (incorporated by reference to Exhibit 10.1 to Form 8-K filed on June 27, 2023)
10.4	Form of Exchange Agreement dated as of July 18, 2023 between the Company and the holder of the Exchange Securities (incorporated by reference to Exhibit 10.1 to Form 8-K filed on July 19, 2023)
10.5	Form of the 25% Senior Secured Convertible Promissory Note (incorporated by reference to Exhibit 10.1 to Form 8-K filed on July 27, 2023)
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 14, 2023

KIROMIC BIOPHARMA, INC.

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

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

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER

I, Pietro Bersani, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 14, 2023

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

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER

I, Brian Hungerford, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: August 14, 2023

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

Exhibit 32.1

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

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

1. The Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2023 (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

IN WITNESS WHEREOF, the undersigned has executed this statement on August 14, 2023.

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

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

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

Exhibit 32.2

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

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

1. The Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2023 (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and

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

IN WITNESS WHEREOF, the undersigned has executed this statement on August 14, 2023.

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

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

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