UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 13, 2022

KIROMIC BIOPHARMA, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-39619**	**46-4762913**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

7707 Fannin, Suite 140
Houston, TX, 77054
(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code **(832) 968-4888**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of Each Class	**Trading Symbol(s)**	**Name of Each Exchange on Which Registered**
Common Stock, $0.001 par value	KRBP	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

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. ☐

Item 2.02. Results of Operations and Financial Condition

On May 13, 2022, Kiromic BioPharma, Inc. issued a press release announcing its financial results for the three months ended March 31, 2022. A copy of the press release is furnished as Exhibit 99.1 to this report.

In accordance with General Instruction B.2 of Form 8-K, the information contained in this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), or otherwise subject to the liability of that section, and shall not be deemed incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits:

The following exhibit is furnished as part of this Report on Form 8-K:

Exhibit No.	**Description**
99.1	Press Release of Kiromic BioPharma, Inc., dated May 13, 2022, reporting three months ended March 31, 2022 financial results and continued corporate progress.
104	Cover Page Interactive Data File (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 hereunto duly authorized.

Kiromic BioPharma, Inc.

Date: May 13, 2022

By: */s/ Daniel Clark*
Daniel Clark
Chief Financial Officer

Kiromic BioPharma Reports First Quarter 2022 Financial Results and Recent Corporate Highlights

Recent Corporate Highlights Include:

- *New Leadership Appointed at the Company, Board of Director Level*
- *Completed Studies to Further Optimize Potency and Validity of the ALEXIS Gamma Delta T (GDT) Cell Platform*
- *Progressed a Master Cell Bank Strategy for Retro-viral Vector (RVV) Production*
- *Enhanced Kiromic's Diamond AI™ Mediated Pooled Donor Gamma Delta T Cell Banking Technology*
- *Expansion and Redesign of In-house cGMP Manufacturing Facility*
- *DIAMOND®AI 2.0 New Component NOEMI (**N**eur**O** **E**volutive) **M**achine Learning Enabled Antibody Design) Designed to Dramatically Reduce Time and Cost of CAR-T Cell Therapy Development*
- *Cash Position $15,123,100 as of March 31, 2022*

HOUSTON, May 13, 2022 – Kiromic BioPharma, Inc. (NASDAQ: KRBP) ("Kiromic" or the "Company"), a clinical-stage fully integrated biotherapeutics company using its proprietary DIAMOND® artificial intelligence (AI) and data mining platform to discover and develop cell and gene therapies with a therapeutic focus on immuno-oncology, today announces financial results for the first quarter ended March 31, 2022.

"This past quarter has seen tremendous progress inside the Company, particularly within the research, development, and manufacturing functions. As an organization, we have achieved important goals, from optimizing and validating our ALEXIS Gamma Delta T (GDT) cell platform, enhancing our GDT cell banking technology, to expanding and redesigning our cGMP manufacturing facility and deploying a master cell bank strategy. These are all critical activities for achieving our milestone of beginning the activation of the clinical trial for our first oncology cell therapy candidate Procel™ by the end of the fourth quarter later this year," stated Pietro Bersani, Kiromic BioPharma's Chief Executive Officer. "We have been intensely preparing for this

milestone, and we believe that we now have the right team, the right capabilities, and the right processes in place to achieve this objective. We have a tremendous opportunity ahead of us, with incredible science that we are looking forward to ultimately making available to patients."

Quarter 1 Fiscal Year 2022 Financial Highlights:

- **Cash Position:** Cash and cash equivalents were $15,123,100 as of March 31, 2022, compared to $25,353,900 as of December 31, 2021. The difference is attributable to cash outflows of $7,520,200, $2,541,800, and $168,800 for operating, investing, and financing activities, respectively.

- **R&D Expenses:** Our research and development expenses increased by $1,040,200, or 55.17%, to $2,925,800 for the three months ended March 31, 2022, from $1,885,600 for the three months ended March 31, 2021. The increase was attributable to increased headcount, manufacturing, and experimentation costs for the development of our ALEXIS clinical platform.

- **G&A Expenses:** Our general and administrative expenses increased by $2,368,200, or 114.35%, to $4,439,200 for the three months ended March 31, 2022, from $2,071,000 for the three months ended March 31, 2021. This increase was primarily due to increases in professional services fees, personnel, and recruiting costs.

- **Net Loss:** Our net loss increased to $7,019,400 during the three months ended March 31, 2022, compared to $3,854,500 during the three months ended March 31, 2021.

Recent Business Highlights:

New Company Leadership:

- As previously announced, we appointed our Chief Executive Officer, a new Chair of our Board, and two new independent Board members.

ALEXIS (Gamma Delta CAR-T cell Platform) Research & Development:

- Continued to improve and enhance the manufacturing efficiencies of the ALEXIS platform, optimizing both cellular function and cost containment

- Progressed a Master Cell Bank strategy for retro-viral vector (RVV) production

- Performed additional studies on supplementary target tumor cell lines, thereby providing additional pre-clinical validation of the potency and specificity of the ALEXIS platform of products.

- Further optimized Kiromic's Diamond AI™ mediated pooled donor Gamma Delta T cell banking technology. The method of manufacturing GDT cells from pooled allogenic donors

has been validated and confirmed with post-freezing, thawing, recovery, stability, and potency. As a next step, the pooled donor GDT cell banks will be tested in vivo for tolerability and efficacy.

- Confirmed a quantitative methodology to determine the residual helper plasmid DNA in RVV preparations, which is an important RVV release test used in manufacturing Procel™ and Isocel™.

cGMP Manufacturing:

- We have expanded and redesigned our in-house current Good Manufacturing Practices (cGMP) facility.

DIAMOND®AI 2.0 Platform for Drug Discovery and Development: NOEMI (NeurO Evolutive) Machine Learning Enabled Antibody Design)

- Kiromic's DIAMOND®AI 2.0 identifies and validates cancer-specific proteins on the surface of cancer cells that can be targeted by engineered T-cells. Typically, a year of laboratory work in animal models and significant expense is then required to develop a chimeric antigen receptor (CAR) for our GDT cells so they will attack that cancer target.

- Consistent with Kiromic's mission to apply cutting edge techniques to improve immunotherapy, we believe we have created a groundbreaking system, NOEMI, to dramatically accelerate CAR development.

- NOEMI is a machine learning and genetic algorithm trained to provide the sequence of a chimeric antigen receptor (CAR) receptor that will bind a Diamond AI target. This software can do in hours what would normally take a year.

About Kiromic BioPharma

Kiromic BioPharma, Inc. is a clinical-stage, fully integrated biotherapeutics company using its proprietary DIAMOND® artificial intelligence (AI) platform to discover and develop cell and gene therapies with a therapeutic focus on immuno-oncology and other diseases. Kiromic is in the process of developing ALEXIS, a multi-indication allogeneic CAR-T cell therapy platform that exploits the natural potency of Gamma Delta T-cells to target solid cancers. From its heritage as a cancer vaccine development company, Kiromic is focused on discovering, developing, and commercializing novel immuno-oncology applications through its robust product pipeline. The pipeline development is leveraged through the Company's proprietary target discovery engine called "DIAMOND." Kiromic's DIAMOND is where data science meets target identification to dramatically compress the years and billions of drug development dollars required to develop a live drug. The Company maintains offices in Houston, Texas. To learn more, visit www.kiromic.com and connect with us on Twitter and LinkedIn.

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Note Regarding Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. Kiromic makes such forward-looking statements pursuant to the safe harbor provisions of the United States Private Securities Litigation Reform Act, Section 21E of the Securities Exchange Act of 1934, as amended, and other federal securities laws. All statements other than statements of historical facts are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as: “will,” “potential,” “could,” “can,” “believe,” “intends,” “continue,” “plans,” “expects,” “anticipates,” “estimates,” “may,” or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements regarding: Kiromic’s future financial performance, Kiromic’s ability to achieve its objectives, including the activation of its clinical trials; timing of the Company’s clinical trials; and the timing for the initiation and successful completion of Kiromic’s clinical trials of its product candidates. These forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, the risks and uncertainties discussed in our Annual Report on Form 10-K for the year ended December 31, 2021 and as detailed from time to time in our SEC filings. You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance, or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. Such forward-looking statements relate only to events as of the date of this press release. We undertake no obligation to update any forward-looking statements except to the extent required by law.

KIROMIC BIOPHARMA, INC.
Condensed Consolidated Balance Sheets
(Unaudited)

	March 31, 2022	December 31, 2021
Assets		
Current Assets:		
Cash and cash equivalents	$ 15,123,100	$ 25,353,900
Accounts receivable	—	16,200
Prepaid expenses and other current assets	1,607,900	1,699,400
Total current assets	16,731,000	27,069,500
Property and equipment, net	6,900,400	3,629,000
Operating lease right-of-use asset	2,227,300	—
Other assets	31,100	31,100
Total Assets	$ 25,889,800	$ 30,729,600
Liabilities and Stockholders' Equity:		
Current Liabilities:		
Accounts payable	$ 1,995,600	$ 2,214,300
Accrued expenses and other current liabilities	1,343,600	741,000
Note payable	285,700	454,500
Operating lease liability - short term	480,300	—
Total current liabilities	4,105,200	3,409,800
Deferred rent	5,500	—
Operating lease liability - long term	1,747,000	—
Total Liabilities	5,857,700	3,409,800
Commitments and contingencies (Note 8)		
Stockholders' Equity:		
Common stock, $0.001 par value: 300,000,000 shares authorized as of March 31, 2022 and December 31, 2021; 15,585,587 shares and 15,488,516 shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively	9,300	9,300
Additional paid-in capital	94,607,100	94,527,000
Accumulated deficit	(74,584,300)	(67,216,500)
Total Stockholders' Equity	20,032,100	27,319,800
Total Liabilities and Stockholders' Equity	$ 25,889,800	$ 30,729,600

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

	Three Months Ended March 31,	
	2022	**2021**
Operating expenses:		
Research and development	$ 2,925,800	$ 1,885,600
General and administrative	4,439,200	2,071,000
Total operating expenses	7,365,000	3,956,600
Loss from operations	(7,365,000)	(3,956,600)
Other income (expense)		
Gain on loan extinguishment	—	105,800
Interest expense	(2,800)	(3,700)
Total other income (expense)	(2,800)	102,100
Net loss	$ (7,367,800)	$ (3,854,500)
Net loss per share, basic and diluted	$ (0.48)	$ (0.53)
Weighted average common shares outstanding, basic and diluted	15,542,444	7,332,999

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

	Three Months Ended March 31,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	$ (7,367,800)	$ (3,854,500)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation	182,800	95,600
Stock compensation expense	80,100	945,200
Gain on loan extinguishment	—	(105,800)
Changes in operating assets and liabilities		
Accounts receivable	16,200	—
Prepaid expenses and other current assets	91,500	75,400
Operating lease right-of-use asset	(2,227,300)	—
Accounts payable	(1,189,800)	273,600
Accrued expenses and other current liabilities	602,600	(65,400)
Deferred rent	5,500	—
Operating lease liability	2,227,300	—
Net cash used for operating activities	(7,578,900)	(2,635,900)
Cash flows from investing activities:		
Purchases of property and equipment	(2,483,100)	(44,700)
Net cash used for investing activities	(2,483,100)	(44,700)
Cash flows from financing activities:		
Repayments of note payable	(168,800)	(134,600)
Net cash used for financing activities	(168,800)	(134,600)
Net change in cash and cash equivalents	(10,230,800)	(2,815,200)
Cash and cash equivalents:		
Beginning of year	25,353,900	10,150,500
End of period	$ 15,123,100	$ 7,335,300
Supplemental disclosures of non-cash investing and financing activities:		
Accruals for property and equipment	$ 971,100	$ 264,400
Cash paid for interest on note payable	$ 2,800	$ 3,700