
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): April 8, 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 April 8, 2022, Kiromic BioPharma, Inc. issued a press release announcing its financial results for the fiscal year ended December 31, 2021. 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 April 8, 2022, reporting year ended December 31, 2021 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: April 8, 2022

By: /s/ Daniel Clark

Daniel Clark

Interim Chief Financial Officer

Kiromic BioPharma Reports Fourth Quarter and Full-Year 2021 Financial Results and Recent Corporate Highlights

Highlights Include Company's Progress in the Following Areas:

- *Advances in the Research, Development, and Manufacturing Processes of the ALEXIS Gamma Delta T cell Platform*
- *Key Hires in Research & Development, Clinical Translational Medicine and Clinical Trial Preparation*
- *Completion of Approximately 90% of In-house cGMP Facility Expansion and Redesign*
- *Launch of DIAMOND® Artificial Intelligence (AI) 2.0 Platform for Identification and Selection of Immunotherapy Targets, which Now Includes Nearly Two Billion Data Points*

HOUSTON, April 8, 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 big data mining platform to discover and develop cell and gene therapies with a therapeutic focus on immuno-oncology, today announces financial results for the fourth quarter and fiscal year ended December 31, 2021.

“We are extremely encouraged by the progress the Company demonstrated in the fourth quarter. Our team’s unified efforts are strictly focused on achieving our goal of beginning the activation of the clinical trial for our first oncology cell therapy candidate by the end of the fourth quarter of 2022,” stated Pietro Bersani, Kiromic BioPharma’s Interim Chief Executive Officer. “We have been intensely preparing for this milestone, ensuring we have the right team, the right capabilities, and the right processes in place to achieve this objective. Our team has been executing critical advancements - occurring simultaneously - across our research and development, clinical trial preparation, facility expansion, and manufacturing operations, among other functions. We look forward to more opportunities to communicate with our shareholders as we demonstrate the Company’s overall progress.”

Fiscal Year Ended 2021 Financial Highlights:

- **Cash Position:** Cash and cash equivalents were \$25,353,900 as of December 31, 2021, compared to \$10,150,500 as of December 31, 2020. The difference is attributable to cash outflows of \$20,321,500, and \$1,810,800 for operating activities, and investing activities, respectively. There were cash inflows of \$37,335,700 from financing activities.
 - **R&D Expenses:** Our research and development expenses increased by \$6,314,900, or 124.98%, to \$11,367,800 for the year ended December 31, 2021 from \$5,052,900 for the year
-

ended December 31, 2020. 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 decreased by \$206,100, or 1.46%, to \$13,937,900 for the year ended December 31, 2021 from \$14,144,000 for the year ended December 31, 2020. This decrease was primarily due to reduced stock compensation expenses, offset by increases in professional services fees, personnel, and recruiting costs.
- **Net Loss:** Our net loss increased to \$25,588,700 during the year ended December 31, 2021 compared to \$19,200,200 during the year ended December 31, 2020.

Recent Business Highlights:

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

- Developed an innovative and highly efficient process that improves the manufacturing of our cell therapy candidates, making it more space-efficient and cost-effective. We believe that this will significantly reduce the costs of CAR-T cell manufacturing, providing a competitive market advantage.
- Successfully tested a prototype variant of the ALEXIS manufacturing process that leverages the potential of pooled donors' cells. This is a necessary step to building a proprietary bank of precursor cells for the manufacturing of our ALEXIS product line. A donor cell bank is expected to ensure a high degree of homogeneity and consistency of our drug products, and at the same time to improve the resilience of our supply chain.
- Continued progress towards a scalable and retrovirus-free process for the delivery of recombinant genes into T cells. This is an important step towards the deployment of our proprietary non-viral cell engineering system.

Key Hires in Research & Development, Clinical Translational Medicine and Clinical Trial Preparation:

- The Company added new hires across the organization, specifically augmenting research & development, clinical translational medicine and clinical trial preparation capabilities. This represents a headcount total of nearly 60 employees, which is an increase from 19 as of December 31, 2020.

cGMP Manufacturing:

- We have completed approximately 90% of our in-house current Good Manufacturing Practices (cGMP) facility expansion and redesign.

DIAMOND® AI 2.0 Platform for Drug Discovery and Development is Completed:

- The Company developed and made operational a completely revised version of its proprietary platform for identification and vetting of immunotherapy targets. Diamond AI 2.0 was developed by Kiromic's in-house bioinformatics team and includes:
 - Enhanced and updated existing models to provide more accurate predictions of therapy target efficacy;
-

- A modular, containerized architecture to support rapid addition of new algorithms, scientific methods, and therapy designs;
- Integrated data mining components to provide a seamless workflow from identification of cancer-specific surface protein regions through to vetted immunotherapy targets;
- Proteomic validation of transcript targets;
- An additional 300+ million data points were added to the DIAMOND database in Q4 2021, which included proteomic data covering and extending the range of cancer types; and
- Approximately 600 million data points were added in 2021, representing a 50% data point increase from 2020.

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 big data science meets target identification to dramatically compress the man-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](#).

Contact:

Linda Phelan Dyson, MPH
Global Head, Corporate Communications
ldyson@kiromic.com
M: 281-468-7683

Forward-Looking Statements

This press release contains forward-looking statements that involve substantial risks and uncertainties. We make such forward-looking statements pursuant to the safe harbor provisions of the U.S. 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. These statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of

activity, performance or achievements expressed or implied by these forward-looking statements. Forward-looking statements include, but are not limited to, statements about:

- our goals and strategies;
- our future business development, financial condition and results of operations;
- expected changes in our revenue, costs or expenditures;
- our expected timing of human clinical trials and other related milestones;
- 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;
- protection for our patents and other intellectual property or trade secrets;
- our expectations regarding our relationships with investors, institutional funding partners, strategic partners and other parties we collaborate with;
- adverse side effects or inadequate therapeutic efficacy of our products that could slow or prevent product development or commercialization;
- dependence on third party suppliers;
- 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.

In some cases, you can identify forward-looking statements by terms such as “may,” “could,” “will,” “should,” “would,” “expect,” “plan,” “intend,” “anticipate,” “believe,” “estimate,” “predict,” “potential,” “project” or “continue” or the negative of these terms or other comparable terminology. These statements are only predictions. You should not place undue reliance on forward-looking statements because they involve known and unknown risks,

uncertainties and other factors, which are, in some cases, beyond our control and which could materially affect results. Factors that may cause actual results to differ materially from current expectations include, among other things, those listed under the heading “Risk Factors” included in our Annual Report on Form 10-K for our fiscal year ended December 31, 2021 filed with the SEC on April 8, 2022 and elsewhere in this press release. If one or more of these risks or uncertainties occur, or if our underlying assumptions prove to be incorrect, actual events or results may vary significantly from those implied or projected by the forward-looking statements. No forward-looking statement is a guarantee of future performance.

The forward-looking statements made in this press release relate only to events or information as of the date on which the statements are made in this press release. Except as expressly required by the federal securities laws, there is no undertaking to publicly update or revise any forward-looking statements, whether as a result of new information, future events, changed circumstances or any other reason.

KIROMIC BIOPHARMA, INC.
Consolidated Balance Sheets

	December 31, 2021	December 31, 2020
Assets		
Current Assets:		
Cash and cash equivalents	\$ 25,353,900	\$ 10,150,500
Accounts receivable	16,200	—
Prepaid expenses and other current assets	1,699,400	588,800
Total current assets	27,069,500	10,739,300
Property and equipment, net	3,629,000	2,066,000
Other assets	31,100	24,400
Total Assets	\$ 30,729,600	\$ 12,829,700
Liabilities and Stockholders' Equity:		
Current Liabilities:		
Accounts payable	\$ 2,214,300	\$ 665,200
Accrued expenses and other current liabilities	741,000	334,200
Interest payable	—	200
Loan payable	—	105,600
Note payable	454,500	362,400
Total current liabilities	3,409,800	1,467,600
Total Liabilities	3,409,800	1,467,600
Commitments and contingencies (Note 9)		
Stockholders' Equity:		
Common stock, \$0.001 par value: 300,000,000 shares authorized as of December 31, 2021 and 2020; 15,488,516 shares and 7,332,999 shares issued and outstanding as of December 31, 2021 and 2020, respectively	9,300	1,200
Additional paid-in capital	94,527,000	52,988,700
Accumulated deficit	(67,216,500)	(41,627,800)
Total Stockholders' Equity	27,319,800	11,362,100
Total Liabilities and Stockholders' Equity	\$ 30,729,600	\$ 12,829,700

KIROMIC BIOPHARMA, INC.
Consolidated Statements of Operations

	Year Ended December 31,	
	2021	2020
Operating expenses:		
Research and development	\$ 11,367,800	\$ 5,052,900
General and administrative	13,937,900	14,144,000
Impairment expense	430,000	—
Total operating expenses	<u>25,735,700</u>	<u>19,196,900</u>
Loss from operations	<u>(25,735,700)</u>	<u>(19,196,900)</u>
Other income (expense)		
Gain on loan extinguishment	105,800	—
Other income	53,400	—
Interest expense	<u>(12,200)</u>	<u>(3,300)</u>
Total other income (expense)	<u>147,000</u>	<u>(3,300)</u>
Net loss	<u>\$ (25,588,700)</u>	<u>\$ (19,200,200)</u>
Net loss per share, basic and diluted	<u>\$ (2.26)</u>	<u>\$ (4.42)</u>
Weighted average common shares outstanding, basic and diluted	11,417,083	4,505,867

KIROMIC BIOPHARMA, INC.
Consolidated Statements of Cash Flows

	Year Ended December 31,	
	2021	2020
Cash flows from operating activities:		
Net loss	\$ (25,588,700)	\$ (19,200,200)
Adjustments to reconcile net loss to net cash used for operating activities:		
Depreciation	469,800	200,000
Stock compensation expense	3,762,900	13,245,700
Gain on loan extinguishment	(105,800)	—
Impairment expense	430,000	—
Non-cash interest	—	200
Inventory obsolescence impairment	—	22,200
Changes in operating assets and liabilities, net of effects from acquisition:		
Accounts receivable	9,800	—
Prepaid expenses and other current assets	(1,117,400)	(499,700)
Accounts payable	1,411,100	(7,700)
Accrued expenses and other current liabilities	406,800	112,900
Net cash used for operating activities	(20,321,500)	(6,126,600)
Cash flows from investing activities:		
Purchases of property and equipment, net of effects from acquisition	(1,894,800)	(1,457,600)
Cash received from acquisition	84,000	—
Net cash used for investing activities	(1,810,800)	(1,457,600)
Cash flows from financing activities:		
Proceeds from issuance of common stock	40,000,000	15,000,000
Issuance cost	(2,881,900)	(2,667,300)
Borrowings from note payable	665,900	540,500
Repayments of note payable	(573,700)	(178,100)
Exercise of stock options	125,400	—
Proceeds from warrant exercise	—	4,900
Proceeds from loan payable	—	115,600
Loan repayments	—	(10,000)
Proceeds from Series B Preferred Stock issuance	—	3,000,000
Net cash provided by financing activities	37,335,700	15,805,600
Net change in cash and cash equivalents	15,203,400	8,221,400
Cash and cash equivalents:		
Beginning of year	10,150,500	1,929,100
End of period	<u>\$ 25,353,900</u>	<u>\$ 10,150,500</u>
Supplemental disclosures of non-cash investing and financing activities:		
Accruals for property and equipment	\$ 138,000	\$ 220,500
Cash paid for interest on note payable	\$ 12,200	\$ 3,100
Common stock issuance for acquisition	\$ 400,000	\$ —
Restricted stock units granted for acquisition	\$ 140,000	\$ —
Acquisitions net of cash acquired	\$ 456,000	\$ —