# 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): **August 13, 2021**

# 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 August 13, 2021, Kiromic Biopharma, Inc. issued a press release announcing financial and corporate results for the three months ended June 30, 2021. A copy of the press release is furnished as Exhibit 99.1 to this Form 8-K.

The information disclosed under this Item 2.02, including Exhibit 99.1 hereto, is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be incorporated by reference into any registration statement or other document pursuant to the Securities Act of 1933, as amended, except as expressly set forth in such filing.

**Item 9.01 Financial Statements and Exhibit**

(d) Exhibits.

The following exhibit is filed with this Current Report on Form 8-K:

| Exhibit Number | Description |
|---|---|
| **99.1** | Press Release dated August 13, 2021 |
| **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 hereunto duly authorized.

**Kiromic BioPharma, Inc.**

Date: August 13, 2021

By: */s/ Maurizio Chiriva Internati*
Maurizio Chiriva Internati
Chief Executive Officer

**Exhibit 99.1**

***Kiromic BioPharma Reports***
***Second Quarter 2021 Financial Results and Operating Highlights***

***Kiromic Operating Highlights of 2Q-2021***

**Clinical Trials Updates**

| | |
|---|---|
| ***IND Applications*** | *Re-Submissions of two IND applications for ALEXIS product candidates:*<br><br>*-- ALEXIS-PRO-1: Off-the-Shelf, Allogenic CAR-T expressing chPD1 for Solid Tumors (IV admin.)*<br><br>*-- ALEXIS-ISO-1: Off-the-Shelf, Allogenic CAR-T expressing Iso-Mesothelin for Solid Tumors (IV admin.)* |
| ***Manufacturing GMP / CMC Validation*** | *Appointed IQVIA, leading cell therapy and gene therapy, for clinical and regulatory support as part of Kiromic FDA Response Task Force.* |
| ***Clinical Sites (CRO)*** | *IQVIA, leading cell therapy and gene therapy CRO, is working to identify and onboard clinical sites across the USA and Europe.* |

**Research and Development Updates**

| | |
|---|---|
| ***Research Grant Agreement for target validation in pancreatic cancer*** | *MD Anderson: Dr. Robert Bresalier of MD Anderson is conducting a biomarker validation study for our AI Target Iso-Mesothelin in pancreatic cancer.* |
| ***IP Filing*** | *2 composition of matter patents were filed:*<br><br>*-- Mesothelin isoform binding molecules and chimeric PD1 receptor molecules, cells containing the same and uses thereof*<br><br>*-- Peptide compositions for the treatment of pathogenic infections* |

**Key Management Updates**

| | |
|---|---|
| ***Chief Operations and Manufacturing Officer*** | *Appointed Chief Operating and Manufacturing Officer, Ignacio Nunez who previously served as:*<br><br>*-- Executive Director of Manufacturing at the Gene Therapy Program at the University of Pennsylvania*<br><br>*-- Head of Manufacturing and Operations Excellence at Novartis* |
| ***Chief Bioinformatics and Research Officer*** | *Appointed Chief Bioinformatics and Research Officer, Michael Ryan, PhD. Michael Ryan, PhD. Dr. Ryan had previously been the head of InSilico Solutions, LLC, a leading AI vendor for large academic institutions.* |

**Corporate Update**

| | |
|---|---|
| ***InSilico Solutions Membership Purchase Agreement*** | *Continued investment in AI and machine learning with the Membership Purchase Agreement of InSilico Solutions, LLC.* |

**Scientific and Investor Presentations**

| | |
|---|---|
| ***Scientific Innovator Conference*** | *-- AACR 2021: 6 Scientific Posters Accepted for Presentation*<br>*-- Next-Gen Immuno Oncology Congress 2021* |
| ***Investor Conference*** | *Benzinga Global Small-cap Conference - Virtual Presentation* |

**HOUSTON, TX – AUGUST 13, 2021 – Kiromic BioPharma (NASDAQ: KRBP)**, a pre-clinical stage biotechnology company using its proprietary DIAMOND® artificial intelligence ("A.I.") platform to improve drug discovery and development with a therapeutic focus on immune-oncology, today announced its quarterly results for the three and six months ended June 30, 2021, and provided an update on its corporate developments.

"Kiromic achieved important scientific and operational milestones during the first half of the year that we believe have us well positioned for preparing our staff and our facilities for the first in-human dosing during the first quarter of 2022," said Dr. Maurizio Chiriva-Internati, PhD, CEO and President of Kiromic BioPharma.

"We are thankful to our employees and collaborators who have maintained this high level of execution this year. From their efforts, we submitted two investigational new drug applications to the United States Food and Drug Administration in May 2021."

Our approach and goal are to defeat cancer by developing immunotherapies by improving target discovery and validation. With better targets, we believe our therapies will be more effective than the current array of immunotherapies using older targets.

**Corporate and Scientific Highlights**

**Events that occurred during the three months ended June 30, 2021**

- **Re-Submission of Two IND Applications** - On May 17, 2021 and May 24, 2021, we announced re-submission of two investigational new drug ("IND") applications to the United States Food and Drug Administration. These INDs were for our ALEXIS-PRO-1 and ALEXIS-ISO-1 product candidates, respectively. ALEXIS-PRO-1 is our allogeneic gamma delta chimeric T cell therapy product candidate targeting PD-L1. ALEXIS-ISO-1 is our allogenic gamma delta CAR-T cell therapy product candidate targeting Isomesothelin (the isoform of Mesothelin).

  Since re-submitting the INDs, the FDA returned with comments on our allogeneic CAR-T products with respect to:

  - Tracing of all reagents used in manufacturing
  - Flow chart of manufacturing processes
  - Certificate of Analysis (COA) for the Company's CAR-T products (allogeneic CAR-T)

  We have an FDA response taskforce, staffed with sufficient and appropriate personnel to prepare the response to the FDA. The company's plans to submit the prepared response by the first half of September 2021. The commencement of the dosing of its first in human clinical trial is expected to be delivered in the first quarter of 2022.

- **Appointment of Chief Operating and Manufacturing Officer –** On June 7, 2021, we entered into an Executive Agreement with Mr. Ignacio Nunez to be our Chief Operating and Manufacturing Officer ("COMO"). The COMO will lead and manage the Company's functions/departments assigned by the CEO. The COMO will be responsible for the manufacturing function and will provide vision, leadership, and management to ensure we effectively and efficiently deliver research, clinical and commercial cell therapies. This position involves direct oversight and management of the manufacturing function to ensure the successful establishment of a new GMP facility and the commencement of manufacturing operations.

- **Membership Purchase Agreement with InSilico Solutions, LLC** - On June 14, 2021, we entered into a Membership Interest Purchase Agreement (the "Purchase Agreement") with InSilico Solutions, LLC ("InSilico") and Michael Ryan (the "Seller") pursuant to which the Company acquired all of the outstanding membership interests of In Silico from the Seller for an aggregate purchase price of $540,000 (the "Purchase Price"). The Purchase Price is payable in full through (i) the delivery to the Seller of a number of shares of the Company's stock that is equal to $400,000 and (i) the delivery to the employees of In Silico of the Company's restricted stock units under the Company's 2021 Omnibus Equity Incentive Plan that is equal to $140,000.

  InSilico is a bioinformatics services company that performs data analysis and software tool development for genome-wide research projects. Their headquarters is located in Fairfax, VA. InSilico performs contract research and collaborate on grant funded research with academic, government, and commercial organizations located throughout the United States.

  With this acquisition, Kiromic will bring in-house a team of experts in bioinformatics and AI in order to lengthen its lead in the race for an AI technology with the capability to select the optimal bio-markers needed for cutting edge immunotherapeutics such as CAR-T cell therapy.

**Events occurring after June 30, 2021 until August 13, 2021**

- **Closing of Public Offering** – On July 2, 2021, we received net proceeds of $37,121,200 from a public offering, after deducting underwriting discounts and commissions of $2,399,900 and other offering expenses of $478,900 incurred. The Company issued and sold 8,000,000 shares of common stock in the public offering at a price of $5.00 per share. In connection with the public offering, 400,000 representative warrants were issued with a price of $6.25 per share.

  This public offering significantly strengthens the Company's balance sheet to support clinical trials for our ALEXIS-ISO-1 and ALEXIS-PRO-1 product candidates, GMP facility expansion, intellectual property protection and reinforcement, IND applications and IND enabling trials and working capital and general corporate purposes.

- **Completion of InSilico Acquisition –** On July 26, 2021, we announced the completion of the InSilico acquisition.

- **Communications with the FDA** - Supported by IQVIA, instead of simply addressing the FDA's questions with a written response only (WRO), we took the decision to apply for a Type A meeting with the FDA. The Type A meeting will address the clinical hold issues and will allow us to discuss path toward our first-in-human dosing.

**Q2 2021 Financial Highlights**

**Cash Position:** Cash and cash equivalents were $3,070,400 as of June 30, 2021, compared to $10,150,500 as of December 31, 2020. The difference is attributable to cash outflows of $6,344,100, $590,600, and $145,400 for operating activities, investing activities, and financing activities respectively.

**R&D Expenses:** Our research and development expenses increased by $1,385,800, or 108.92%, to $2,658,100 for the three months ended June 30, 2021, from $1,272,300 for the three months ended June 30, 2020. Our research and development expenses increased by $2,243,300, or 97.52%, to $4,543,700 for the six months ended June 30, 2021, from $2,300,400 for the six months ended June 30, 2020. The increase was attributable to increased headcount, manufacturing, and experimentation costs for our ALEXIS-ISO-1 product candidate.

**G&A Expenses:** Our general and administrative expenses decreased by $7,780,500, or 77.08%, to $2,314,100 for the three months ended June 30, 2021 from $10,094,600 for the three months ended June 30, 2020. Our general and administrative expenses decreased by $6,534,100, or 59.54%, to $4,385,100 for the six months ended June 30, 2021 from $10,919,200 for the six months ended June 30, 2020. This decrease was primarily due to reduced stock compensation expenses.

**Net Loss:** Our net loss decreased to $8,928,800 during the six months ended June 30, 2021 compared to $13,219,600 during the six months ended June 30, 2020.

**About Kiromic BioPharma**

Kiromic BioPharma, Inc. is a preclinical stage biopharmaceutical company which is focused on discovering, developing, and commercializing novel immune-oncology applications through its robust product pipeline, which are in the pre-IND validation stages of the United States Food and Drug Administration clinical trial process. The pipeline development is leveraged through the Company's proprietary target discovery engine called "DIAMOND." Kiromic's DIAMOND is big data science meeting target identification, dramatically compressing man-years and billions of drug development dollars to develop a live drug. The Company maintains offices in Houston, Texas. The Company has not generated any revenues to date. For more information, please visit the company's website at www.kiromic.com.

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**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;
- 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; and
- relevant government policies and regulations relating to our industry.

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 Registration Statement on Form S-1 (file no. 333-257427) , originally filed with the Securities and Exchange Commission (SEC) on June 25, 2021, 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 report relate only to events or information as of the date on which the statements are made in this report. 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.**
**Condensed Consolidated Balance Sheets**
**(Unaudited)**

| | June 30, 2021 | December 31, 2020 |
|---|---|---|
| **Assets** | | |
| **Current Assets:** | | |
| Cash and cash equivalents | $ 3,070,400 | $ 10,150,500 |
| Prepaid expenses and other current assets | 875,600 | 588,800 |
| **Total current assets** | 3,946,000 | 10,739,300 |
| Property and equipment, net | 2,468,700 | 2,066,000 |
| Other assets | 24,400 | 24,400 |
| **Total Assets** | $ 6,439,100 | $ 12,829,700 |
| | | |
| **Liabilities and Stockholders' Equity:** | | |
| **Current Liabilities:** | | |
| Accounts payable | $ 1,124,100 | $ 665,200 |
| Accrued expenses and other current liabilities | 350,900 | 334,200 |
| Interest payable | — | 200 |
| Loan payable | — | 105,600 |
| Note payable | 91,600 | 362,400 |
| **Total current liabilities** | 1,566,600 | 1,467,600 |
| | | |
| **Total Liabilities** | 1,566,600 | 1,467,600 |
| | | |
| Commitments and contingencies (Note 8) | | |
| **Stockholders' Equity:** | | |
| Common stock, $0.001 par value: 300,000,000 shares authorized as of June 30, 2021 and December 31, 2020; 7,387,500 shares and 7,332,999 shares issued and outstanding as of June 30, 2021 and December 31, 2020, respectively | 1,300 | 1,200 |
| Additional paid-in capital | 55,327,800 | 52,988,700 |
| Accumulated deficit | (50,456,600) | (41,627,800) |
| **Total Stockholders' Equity** | 4,872,500 | 11,362,100 |
| | | |
| **Total Liabilities and Stockholders' Equity** | $ 6,439,100 | $ 12,829,700 |

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

| | Three Months Ended June 30, | | Six Months Ended June 30, | |
|---|---|---|---|---|
| | **2021** | **2020** | **2021** | **2020** |
| Operating expenses: | | | | |
| Research and development | $ 2,658,100 | $ 1,272,300 | $ 4,543,700 | $ 2,300,400 |
| General and administrative | 2,314,100 | 10,094,600 | 4,385,100 | 10,919,200 |
| Total operating expenses | 4,972,200 | 11,366,900 | 8,928,800 | 13,219,600 |
| Loss from operations | (4,972,200) | (11,366,900) | (8,928,800) | (13,219,600) |
| Other income (expense) | | | | |
| Gain on loan extinguishment | — | — | 105,800 | — |
| Interest expense | (2,100) | — | (5,800) | — |
| Total other income (expense) | (2,100) | — | 100,000 | — |
| Net loss | $ (4,974,300) | $ (11,366,900) | $ (8,828,800) | $ (13,219,600) |
| Net loss per share, basic and diluted | $ (0.68) | $ (3.80) | $ (1.21) | $ (4.52) |
| Weighted average common shares outstanding, basic and diluted | 7,345,147 | 3,077,085 | 7,345,147 | 3,077,085 |

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

| | Six Months Ended June 30, | |
|---|---|---|
| | **2021** | **2020** |
| Cash flows from operating activities: | | |
| Net loss | $ (8,828,800) | $ (13,219,600) |
| Adjustments to reconcile net loss to net cash used for operating activities: | | |
| Depreciation | 202,400 | 68,500 |
| Stock compensation expense | 2,213,800 | 10,331,000 |
| Gain on loan extinguishment | (105,800) | — |
| Changes in operating assets and liabilities: | | |
| Prepaid expenses and other current assets | 151,500 | (141,500) |
| Accounts payable | 41,800 | 291,000 |
| Accrued expenses and other current liabilities | (19,000) | 66,800 |
| **Net cash used for operating activities** | (6,344,100) | (2,603,800) |
| Cash flows from investing activities: | | |
| Purchases of property and equipment | (590,600) | (762,300) |
| **Net cash used for investing activities** | (590,600) | (762,300) |
| Cash flows from financing activities: | | |
| Repayments of note payable | (270,800) | — |
| Exercise of stock options | 125,400 | — |
| Proceeds from warrant exercise | — | 4,900 |
| Proceeds from loan payable | — | 115,600 |
| Proceeds from Series B Preferred Stock issuance | — | 3,000,000 |
| **Net cash (used for) provided by financing activities** | (145,400) | 3,120,500 |
| Net change in cash and cash equivalents | (7,080,100) | (245,600) |
| Cash and cash equivalents: | | |
| Beginning of year | 10,150,500 | 1,929,100 |
| End of period | $ 3,070,400 | $ 1,683,500 |
| | | |
| Supplemental disclosures of non-cash investing and financing activities: | | |
| Accruals for property and equipment | $ 14,500 | $ 45,000 |
| Cash paid for interest on note payable | $ 5,800 | $ — |
| Accruals for deferred public offering costs | $ 438,300 | $ 594,200 |
| Warrants underlying Series B Preferred Stock issuance | $ — | $ 2,668,300 |