

**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): **March 31, 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 March 31, 2021, Kiromic Biopharma, Inc. issued a press release announcing financial and corporate results for the year ended December 31, 2020. 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 March 31, 2021

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: March 31 2021

By: /s/ Maurizio Chiriva Internati

Maurizio Chiriva Internati
Chief Executive Officer



Kiromic BioPharma Reports Fiscal Year 2020 Financial Results and Continued Corporate Progress
Completion of \$15 million IPO
Longwood University Licensing Agreement of chPD1
Two IND Application Filings for chPD1, Isomesothelin, Allogeneic Gamma Delta, CAR-T Therapies
GMP Facility Completion, Certification

HOUSTON, TX – MARCH 31, 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 financial results for the year ended December 31, 2020, and provided an update on its corporate developments.

“Kiromic BioPharma achieved important scientific and operational milestones during the year that we believe have us well positioned for preparing our staff and our facilities for the first in-human dosing in Q3 2021,” said Dr. Maurizio Chiriva-Internati, CEO and President of Kiromic BioPharma. “We are thankful to our employees and collaborators who have maintained this high level of execution in the middle of the hard challenges posed by the COVID-19 pandemic.”

Our approach and goal is to defeat cancer by developing immunotherapies that rely on 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

- **Initial Public Offering Completion** - On October 20, 2020, we completed our IPO, raising \$15 million of gross proceeds, significantly strengthening the Company’s balance sheet to support the continued development of our promising pipeline of targeted cancer therapies.
- **Two IND Application Filings** – On December 17, 2020 we filed two applications with the U.S. Food and Drug Administration (“FDA”). The first IND was for a Phase 1 clinical trial of intravenously (“IV”) administered allogenic CAR-T for epithelial ovarian carcinoma (“EOC”) and malignant pleural mesothelioma (“MPM”). The second IND was for a Phase 1 clinical trial of an intrapleural/intraperitoneal (IP) administered allogenic CAR-T for EOC and MPM.

Since filing the original INDs in December 2020, the Company has had communications with the FDA, and numerous consults with scientific board and clinical advisors regarding resubmission. In March 2021, we announced that we planned to resubmit the two INDs.

The revised INDs will be for first in-human dosing of our Off-the-Shelf, Allogenic Gamma-Delta T cell therapy for metastatic and progressive locally advanced solid malignancies.

The revised INDs have protocols which retain approximately 80% of the original INDs.

- **Longwood University Licensing Agreement** – On November 30, 2020, we executed a licensing agreement for chPD1 with Longwood University. This marks a major milestone for Kiromic CAR-T development. With chPD1, we believe our chimeric PD1 CAR-T will be able to overcome the challenging tumor micro-environment (TME) which has plagued other CAR-T programs, while making Kiromic the only CAR-T development program with a built-in capability to meet other CAR-T programs head-on who do not have a bundled chPD1 CAR-T.
- **GMP Facility Completion** – As of September 30, 2020, the key features of the GMP facility have been completed, clearing the path for the production of off-the-shelf Gamma-Delta-T cells, a novel approach to CAR-T cell therapy, which will be evaluated in the upcoming clinical trials.

FY 2020 Financial Highlights

Cash Position: Cash and cash equivalents were \$10,150,500 as of December 31, 2020, compared to \$1,929,100 as of December 31, 2019. The increase was primarily due to cash inflows of \$15,805,600 attributable to financing activities related to the issuance of common stock from the initial public offering, issuance of Series B Preferred Stock and proceeds net of repayments from the Paycheck Protection Program loan. These inflows were offset by outflows of \$6,126,600 and \$1,457,600 attributable to operating activities and investing activities, respectively.

R&D Expenses: Research and development expenses were \$5,052,900 for the year ended December 31, 2020, compared to \$1,201,700 for the year ended December 31, 2019. The increase was primarily attributable to augmented headcount, increased square footage to our Houston, TX leased facilities, in-vitro experimentation costs, and intellectual property costs.

G&A Expenses: General and administrative expenses were \$14,144,000 for the year ended December 31, 2020, compared to \$2,503,700 for the year ended December 31, 2019. This increase was primarily due to increased stock compensation expenses and personnel expenses.

Net Loss: Net loss was \$19,200,200 for the year ended December 31, 2020, compared to a net loss of \$3,727,900 for the year ended December 31, 2019.

Dr. Chiriva-Internati continued, “Developing live-cell therapies by leveraging artificial intelligence is central to transforming the cost and efficiency of the immune-oncology field and improving the potential for off-the-shelf therapies for cancer patients. We believe our approach will help us design more efficient pre-clinical validation studies and more targeted clinical trials, thereby accelerating our drug candidates’ time to approval and eventually to market. DIAMOND is central to our process in achieving this outcome rapidly and with reduced costs.” concluded Dr. Chiriva-Internati.

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.

Contact:

Tony Tontat
Chief Financial Officer
628-777-3167
Bus.dev@kiromic.com

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. 333-238153), originally filed with the Securities and Exchange Commission (SEC) on May 11, 2020, as amended, 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. You are advised, however, to review any further disclosures we make on related subjects in our subsequent Forms 10-Q, 8-K and other reports filed with the SEC.

KIROMIC BIOPHARMA, INC.
Consolidated Balance Sheets

	December 31, 2020	December 31, 2019
Assets		
Current Assets:		
Cash and cash equivalents	\$ 10,150,500	\$ 1,929,100
Inventories	—	22,200
Prepaid expenses and other current assets	588,800	89,100
Total current assets	<u>10,739,300</u>	<u>2,040,400</u>
Property and equipment, net	2,066,000	587,900
Other assets	24,400	24,400
Total Assets	<u>\$ 12,829,700</u>	<u>\$ 2,652,700</u>
Liabilities and Stockholders' Equity:		
Current Liabilities:		
Accounts payable	\$ 665,200	\$ 452,400
Accrued expenses and other current liabilities	334,200	221,300
Interest payable	200	—
Loan payable	105,600	—
Note payable	362,400	—
Total current liabilities	<u>1,467,600</u>	<u>673,700</u>
Total Liabilities	<u>1,467,600</u>	<u>673,700</u>
Commitments and contingencies (Note 9)		
Stockholders' Equity:		
Series A-1 Preferred Stock, \$0.0001 par value: 24,000,000 shares authorized as of December 31, 2020 and 2019; 0 and 21,822,301 shares issued and outstanding as of December 31, 2020 and 2019, respectively	—	9,134,700
Series B Preferred Stock, \$0.0001 par value: 16,500,000 and 14,130,435 shares authorized as of December 31, 2020 and 2019, respectively; 0 and 9,869,659 shares issued and outstanding as of December 31, 2020 and 2019, respectively	—	1,306,900
Preferred Stock, \$0.0001 par value: 19,500,000 and 21,869,565 shares authorized as of December 31, 2020 and 2019, respectively; 0 shares issued and outstanding as of December 31, 2020 and 2019	—	—
Common stock, \$0.001 par value: 300,000,000 shares authorized as of December 31, 2020 and 2019; 7,332,999 and 2,863,812 shares issued and outstanding as of December 31, 2020 and 2019, respectively	1,200	—
Additional paid-in capital	52,988,700	13,965,000
Accumulated deficit	<u>(41,627,800)</u>	<u>(22,427,600)</u>
Total Stockholders' Equity	<u>11,362,100</u>	<u>1,979,000</u>
Total Liabilities and Stockholders' Equity	<u>\$ 12,829,700</u>	<u>\$ 2,652,700</u>

KIROMIC BIOPHARMA, INC.
Consolidated Statements of Operations

	Years Ended December 31,	
	2020	2019
Operating expenses:		
Research and development	\$ 5,052,900	\$ 1,201,700
General and administrative	14,144,000	2,503,700
Total operating expenses	<u>19,196,900</u>	<u>3,705,400</u>
Loss from operations	<u>(19,196,900)</u>	<u>(3,705,400)</u>
Other expense		
Interest expense	(3,300)	(22,500)
Total other expense	<u>(3,300)</u>	<u>(22,500)</u>
Net loss	<u>\$ (19,200,200)</u>	<u>\$ (3,727,900)</u>
Net loss per share, basic and diluted	\$ (4.42)	\$ (1.39)
Weighted average common shares outstanding, basic and diluted	4,505,867	2,862,809
