
**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): November 30, 2020

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 November 30, 2020, Kiromic BioPharma, Inc. issued a press release announcing its financial results for the fiscal quarter ended September 30, 2020. 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:

<u>Exhibit No.</u>	<u>Description</u>
99.1	<u>Press Release of Kiromic BioPharma, Inc., dated November 30, 2020, reporting third quarter 2020 financial results and continued corporate progress.</u>

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: November 30, 2020

By: /s/ Maurizio Chiriva Internati

Maurizio Chiriva Internati

Chief Executive Officer



Kiromic BioPharma Reports Third Quarter 2020 Financial Results and Continued Corporate Progress
Provisional patent filing titled, "Mesothelin Isoform Binding Molecules and Uses Thereof"
Completed external validation of clinical samples of key Isoform Mesothelin targets
Completed Construction of Vivarium and Clean Room Facilities at the Houston Offices

HOUSTON, TX – NOVEMBER 30, 2020 – 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 third quarter ended September 30, 2020, and provided an update on its corporate developments.

"Kiromic BioPharma achieved important scientific and operational milestones during the quarter that have us well positioned for growth as we focus on being the leader in A.I.-enabled immune-oncology drug development," 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. Through their efforts, as of today nothing has come to our attention causing us to believe that we are not poised to file our two INDs for Epithelial Ovarian Cancer during 4Q-2020. The first IND will be our chimeric PD1 for ovarian cancer, and the second IND will be our isoform mesothelin in ovarian cancer."

Subsequent to the quarter end, on October 20, we completed a successful IPO, raising gross proceeds of \$15,000,000, significantly strengthening the Company's balance sheet to support the continued development of our promising pipeline of targeted cancer therapies. 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 crop of immunotherapies using older targets.

Corporate and Scientific Highlights

- **Intellectual Property Application Filing** - Kiromic BioPharma ("The Company") filed a United States provisional patent application on July 6, 2020, entitled "Mesothelin Isoform Binding Molecules and Uses Thereof," that discloses engineered gamma-delta T cells containing mesothelin isoform-directed molecules. This provisional application is expected to expire on July 7, 2021, and the Company plans to file at least an international PCT patent application claiming priority to the provisional application before it expires. The Company plans to build at least one patent family directed to engineered allogeneic effector cells, in support of its development of off-the-shelf allogeneic immunotherapy treatments to patients with indications of Isoform Mesothelin Epithelial Ovarian Cancer, and Isoform Mesothelin Malignant Pleural Mesothelioma.
 - **External Validation of Targets** - The Company completed external validation of Isoform Mesothelin targets including mesothelioma, ovarian cancer, and pancreatic cancer during the 3 months ended September 30, 2020.
 - **Clean Rooms and Vivarium Facility Construction Completion** - The Company completed construction of an \$820,000 leasehold improvement located at the Houston, TX based offices. The asset contains a current Good Lab Practices ("cGLP") Vivarium Facility, and current Good Manufacturing Practices
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("cGMP") Clean Rooms for clinical manufacturing. The cGLP Vivarium is currently being used to perform key *in vivo* non-clinical research to support the Company's clinical initiatives through an Initial New Drug ("IND") filing with the FDA. The cGMP suite consists of 5 clean rooms which will be used to manufacture the Company's off-the-shelf allogeneic therapies during clinical trials. Management plans to commence clinical trials only if IND applications are approved by the FDA.

Q3 2020 Financial Highlights

Cash Position: Cash and cash equivalents were \$469,300 as of September 30, 2020, compared to \$1,929,100 as of December 31, 2019. The decrease was primarily due to cash outflows of \$3,557,200 and \$1,013,100 attributable to operating activities and investing activities, respectively. The offsetting cash inflows of \$3,110,500 was attributed to financing activities related to the Company's Series B Preferred Stock issuance along with proceeds net of repayments from the Paycheck Protection Program loan.

R&D Expenses: Research and development expenses were \$1,225,700 for the quarter ended September 30, 2020, compared to \$272,100 for the quarter ended September 30, 2019. The increase was primarily attributable to augmented headcount, increased square footage to our Houston, TX leased facilities, and in-vitro experimentation costs.

G&A Expenses: General and administrative expenses were \$1,190,000 for the quarter ended September 30, 2020, compared to \$607,400 for the quarter ended September 30, 2019. This increase was primarily due to personnel expenses.

Net Loss: Net loss was \$2,415,700 for the quarter ended September 30, 2020, compared to a net loss of \$886,900 for the quarter ended September 30, 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.

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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. 333-238153) , 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.
Condensed Consolidated Balance Sheets
(Unaudited)

	September 30, 2020	December 31, 2019
Assets		
Current Assets:		
Cash and cash equivalents	\$ 469,300	\$ 1,929,100
Inventories	22,200	22,200
Prepaid expenses and other current assets	1,051,900	89,100
Total current assets	<u>1,543,400</u>	<u>2,040,400</u>
Property and equipment, net	1,612,300	587,900
Other assets	24,400	24,400
Total Assets	<u>\$ 3,180,100</u>	<u>\$ 2,652,700</u>
Liabilities and Stockholders' Equity:		
Current Liabilities:		
Accounts payable	\$ 1,672,900	\$ 452,400
Accrued expenses and other current liabilities	473,000	221,300
Loan payable	105,600	—
Total current liabilities	<u>2,251,500</u>	<u>673,700</u>
Total Liabilities	<u>2,251,500</u>	<u>673,700</u>
Commitments and contingencies (Note 8)		
Stockholders' Equity:		
Series A-1 Preferred Stock, \$0.0001 par value: 24,000,000 shares authorized as of September 30, 2020 and December 31, 2019; 21,822,301 shares issued and outstanding as of September 30, 2020 and December 31, 2019	9,134,700	9,134,700
Series B Preferred Stock, \$0.0001 par value: 16,500,000 and 14,130,435 shares authorized as of September 30, 2020 and December 31, 2019, respectively; 16,391,397 and 9,869,659 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	2,331,300	1,306,900
Preferred Stock, \$0.0001 par value: 19,500,000 and 21,869,565 shares authorized as of September 30, 2020 and December 31, 2019, respectively; 0 shares issued and outstanding as of September 30, 2020 and December 31, 2019	—	—
Common stock: 300,000,000 shares authorized as of September 30, 2020 and December 31, 2019; 4,989,269 and 2,863,812 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	—	—
Additional paid-in capital	27,525,500	13,965,000
Accumulated deficit	(38,062,900)	(22,427,600)
Total Stockholders' Equity	<u>928,600</u>	<u>1,979,000</u>
Total Liabilities and Stockholders' Equity	<u>\$ 3,180,100</u>	<u>\$ 2,652,700</u>

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	\$ 1,225,700	\$ 272,100	\$ 3,526,100	\$ 601,500
General and administrative	1,190,000	607,400	12,109,200	934,300
Total operating expenses	<u>2,415,700</u>	<u>879,500</u>	<u>15,635,300</u>	<u>1,535,800</u>
Loss from operations	<u>(2,415,700)</u>	<u>(879,500)</u>	<u>(15,635,300)</u>	<u>(1,535,800)</u>
Other expense				
Interest expense	—	(7,400)	—	(22,400)
Total other expense	<u>—</u>	<u>(7,400)</u>	<u>—</u>	<u>(22,400)</u>
Net loss	<u>\$ (2,415,700)</u>	<u>\$ (886,900)</u>	<u>\$ (15,635,300)</u>	<u>\$ (1,558,200)</u>
Net loss per share, basic and diluted	\$ (0.65)	\$ (0.32)	\$ (4.39)	\$ (0.55)
Weighted average common shares outstanding, basic and diluted	3,719,132	2,862,523	3,719,132	2,862,523
