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): December 16, 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 [X]

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 8.01 Other Events.

Kiromic BioPharma, Inc. announced on December 16, 2020 the submission of two investigational new drug (IND) applications with the U.S. Food and Drug Administration (FDA) for the initiation of:

--- Phase 1 clinical trial of an intravenously (IV) administered allogenic CAR-T for epithelial ovarian carcinoma (EOC) and malignant pleural mesothelioma (MPM) and

--- Phase 1 clinical trial of an intrapleural/intraperitoneal (IP) administered allogenic CAR-T for EOC and MPM.

A copy of the press release is attached as Exhibit 99.1 and is incorporated herein by reference.

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

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: December 17, 2020

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

Kiromic Announces Submission of Two IND Applications for PD1 Gamma-delta CAR - T cell Therapy with the FDA

Houston, Texas, December 16, 2020 /Business Wire/ -- Kiromic Biopharma, Inc. (Nasdaq: KRBP), a target discovery and gene-editing company utilizing artificial intelligence and its proprietary neural network platform with a therapeutic focus on immuno-oncology, announced today the submission of two investigational new drug (IND) applications with the U.S. Food and Drug Administration (FDA) for the initiation of:

--- Phase 1 clinical trial of an intravenously (IV) administered allogenic CAR-T for epithelial ovarian carcinoma (EOC) and malignant pleural mesothelioma (MPM) and

--- Phase 1 clinical trial of an intrapleural/intraperitoneal (IP) administered allogenic CAR-T for EOC and MPM.

Kiromic's proprietary PD1 Gamma-delta CAR (PD1-GDT CAR) T cell therapy is a novel method for "off-the-shelf" allogeneic CAR T cells derived from healthy donors. We believe our proprietary gamma-delta T cell manufacturing and distribution will offer significant advantages over competitive manufacturing technologies.

The intial dose escalation component of each CAR-T trial is projected to enroll approximately 12 patients over 4 months at two sites.

The first in-human dosing is targeted for 1Q-2021.

"It's an exciting time to see our technology go into the clinic. This is the culmination of +25 years of research and development which has spanned the globe with international contributions and scientific collaborations from the sharpest minds of our time. Our gamma-delta T-cells are designed to offer clinicians a treatment option with:

-- higher efficacy,

-- higher safety (reducing graft vs. host risks), and

-- lower manufacturing and distribution costs vs. cellular therapy technologies of the past," says Dr. Maurizio Chiriva-Internati, PhD, CEO of Kiromic.

"This first in-human off-the-shelf allogenic gamma-delta chPD1 CAR-T cell therapy trial will mark a major milestone, not only for Kiromic, but also for clinicians who have been frustrated with the lack of CAR T cell treatment options for solid malignancies, since current CAR T cell therapies are

only approved for hematologic malignancies, with all of the drawbacks of autologous based platforms" commented Dr. Scott Dahlbeck, MD, Chief Medical Officer of Kiromic.

"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. The Company is fully ready for this IND filing and has the clinical manufacturing capability to supply its clinical trials," commented Mr. Tony Tontat, CFO, COO of Kiromic.

"Kiromic's proprietary PD1 Gamma-delta CAR (PD1-GDT CAR) T cell therapy is a novel method for "off-the-shelf" allogeneic CART T Cells derived from healthy donors. As we continue to grow our targets and our clinical programs, our IP portfolio is continually being fortified in all major geographies, and we look forward to updating our investors in upcoming presentations and filings," commented Mr. Gianluca Rotino, Chief of Strategy and Innovations of Kiromic.

About Epithelial Ovarian Carcinoma

Ovarian tumors grow rapidly and metastasize early with a very aggressive disease course, either through direct extension from the ovarian/fallopian tumor to neighboring organs (bladder/colon), or by detaching from the primary tumor, and then spreading and adhering to intraperitoneal organs.

Epithelial ovarian carcinoma represents the vast majority of ovarian cancers and the most common histologic subtype is high grade serous epithelial ovarian carcinoma. Unlike most other cancers, ovarian carcinoma rarely disseminates through the vasculature, although pelvic and/or para-aortic lymph nodes can be involved. When ovarian cancer spreads to the mesothelium of the organs within the peritoneal cavity, it can result in encasement of these organs with significant pain and eventual obstruction of the stomach, large, and small intestines.

Despite advances in surgical techniques and intensive combination chemotherapy approaches, the survival rate substantially decreases after ovarian cancer has metastasized to pelvic organs (such as the uterus, fallopian tubes, bladder, and rectum), metastasized across the pelvic cavity to the abdominal organs and tissue (such as the omentum, small intestine, and retroperitoneal lymph nodes), or metastasized beyond the peritoneal cavity to distant parenchymal organs such as the liver and lung.

The ovarian cancer tumor microenvironment (TME) within the peritoneal cavity is a key element in the support of ovarian cancer growth, and only by addressing the TME, along with the ovarian cancer tumor cell itself, will significant advances be achieved.

Since ovarian cancer 5 year survival statistics have improved only slightly over the last few decades, innovative approaches such as Kiromic's administration of a PD1-GDT CAR, which is designed to address the TME of EOC, are desperately needed.

About Malignant Pleural Mesothelioma

Patients with a diagnosis of mesothelioma are generally considered to be incurable, and typically present late, with multiple signs and symptoms such as shortness of breath, chest pain, cough,

hemoptysis, dysphagia, weight loss, fatigue, night sweats, and face/arm swelling which often precludes surgical options. Chemotherapy and radiation therapy are also options but are often only palliative, with or without an attempted surgical resection.

If the patient is one of the few considered to be a surgical candidate, the surgical objective will be to obtain a maximal cellular reduction (MCR), followed by chemotherapy +/- radiation therapy. Yet even with an MCR and adjuvant therapies, the vast majority of patients still experience a recurrence, most of which are local, and when the tumors do recur, second line treatments are essentially palliative.

Hence, the majority of patients suffering from this disease need innovative and novel treatment options, as most patients will ultimately die of their disease with a poor remaining quality of life due to symptoms such as severe shortness of breath and chest pain, due to hardening of the pleura associated with the inevitable disease progression. Innovative approaches such as Kiromic's administration of a PD1-GDT CAR, which is designed to address the tumor microenvironment (TME) of MPM are urgently needed.

About Kiromic

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. 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.

For more information, please visit the company's website at www.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 Forms 10-Q, 8-K and other reports filed with the SEC.

Contact:

Tony Tontat
Chief Financial Officer
(844) 539 - 2873
ttontat@kiromic.com