# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 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 11, 2022

# Kiromic BioPharma, Inc.

	(Exact name of	registrant as specified	in its charter)			
	Delaware (State or other jurisdiction of incorporation) 7707 Fannin Street,	001-39619 (Commission File Number)		46-4762913 (IRS Employer Identification No.)		
	Houston, TX		77054			
	(Address of principal execu	utive offices)	(Zip Code)			
		ne number, including area c Not Applicable or former address, if changed sinc	, ,			
	eck the appropriate box below if the Form 8-K filing of the following provisions:	g is intended to simultaneous	ly satisfy the filing oblig	ation of the registrant under		
	Written communications pursuant to Rule 425 ur	der the Securities Act (17 CF	FR 230.425)			
	Soliciting material pursuant to Rule 14a-12 under	ng material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)				
	Pre-commencement communications pursuant to	commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))				
	Pre-commencement communications pursuant to	imencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))				
Sec	curities registered pursuant to Section 12(b) of the A	Act:				
	Title of each class	Trading Symbol(s)	Name of each excha	nge on which registered		
	Common Stock, par value \$0.001 per share	KRBP	The Nasdaq S	tock Market LLC		
	icate by check mark whether the registrant is an em 30.405 of this chapter) or Rule 12b-2 of the Securit					
			Eı	merging growth company		
	in emerging growth company, indicate by check ma inplying with any new or revised financial accounting					

### Item 7.01 Regulation FD Disclosure.

On April 11, 2022, Kiromic BioPharma, Inc. (the "Company") made available on its website a revised Company investor presentation. A copy of the presentation is attached hereto as Exhibit 99.1 and is incorporated by reference herein.

In accordance with General Instruction B.2 to Form 8-K, the information contained in this current report, including Exhibit 99.1 hereto, is being "furnished" with the Securities and Exchange Commission and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities under such section. Further, such information shall not be deemed to be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended, unless specifically identified as being incorporated therein by reference.

### Item 9.01 Financial Statements and Exhibits.

### (d) Exhibits.

The following documents are herewith filed or furnished as exhibits to this report:

Exhibit Number	Description		
99.1	Investor Presentation dated April 11, 2022.		
104	Cover Page Interactive Data File — the cover page 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.

Date: April 11, 2022 KIROMIC BIOPHARMA, INC.

By: /s/ Daniel Clark

Name: Daniel Clark Title: Interim Chief Financial

Officer



### **Forward Looking Statements**

This presentation 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
- · 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; 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," "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 (Registration No. 333-257427), originally filed with the Securities and Exchange Commission (SEC) on June 25, 2021, as amended, and in our Form 10-K for the fiscal year ended December 31, 2021 filed with the SEC on April 8, 2022 and elsewhere in this presentation. 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 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.



### **Contents**



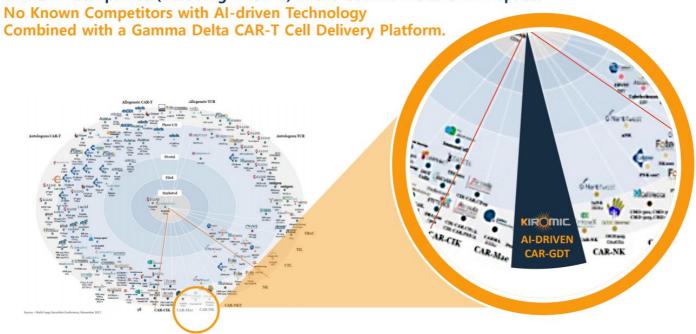
### **The Kiromic Difference**

- Diamond AI<sup>TM</sup> (Artificial Intelligence)
- Gamma Delta Chimeric Antigen Receptor (CAR) T-Cell Therapy: Mechanism of Action (MOA), Product Pipeline
- Current Good Manufacturing Practice (cGMP) Overview
- Current Status and Path Forward



# **Strategic Competitive Landscape**

6 Known Companies (including Kiromic) in the Gamma Delta CAR-T space.





**Billion** 

90%

**Of Cancers Are** Solid Malignancies<sup>2</sup>

<sup>1</sup>Global CAR-T Cell Therapy Market, By Product Type, By Tumor Type, By Indication, By Treatment Type, By Targeted Antigen, By End User, By Region, Competition, Forecast and Opportunities, 2017-2027 (ReportLinker)
<sup>2</sup>Blood Cancer, Yale Medicine, https://www.yalemedicine.org/conditions/blood-cancers

# KIROMIC

## The Kiromic Competitive Difference

### Allogeneic Gamma Delta Based CAR-T Cell Therapies

**Next Gen Allogeneic** Therapy

Allogeneic approach results in simplified and efficient supply chain (vein-to-vein lead time) with improved product availability.

Previous generation of autologous therapy results in manufacturing challenges that made repeat dosing challenging

**Solid Tumor** 

2

Potential broad treatment for solid malignancies that express Kiromic developed biomarkers such as Isomesothelin.

Solid tumors represent approx. 90% of new cancer cases<sup>1</sup>

Superior Safety<sup>2-4</sup>

1. Minimal to no Cytokine Release Syndrome (CRS)

2. Minimal to no Immune Cell Associated Neurotoxicity Syndrome (ICANS)

3. Minimal Graft versus Host Disease (GvHD) therefore no compatibility issues between donors and patients

4

100% efficacy in pre-Clinical animal models

Addressed issues related to low efficacy:

1. Suppressive Tumor micro-environment (TME)

2. T-Cell exhaustion and loss of efficacy

In-house Manufacturing

1.No lead time (Off-The-Shelf) vs up to 3-5 weeks for autologous Kymriah<sup>6</sup>

2. In-house cGMP manufacturing (full control and vertical integration of manufacturing process) including:

a. Unique In-house Vector production b. Cell therapy

production

6

**Greater Access** 

1.Outpatient treatment means reduced hospitalization and other treatment related costs – hospitals struggle to break even if given in the inpatient setting

2. Lower production cost – competitor costs \$373K and \$475K per treatment for Yescarta and Kymriah respectively

American Cancer Society 2020 Cancer Facts & Figures Leading sites of new cancer cases and deaths; epub.

"Aung X, et al. Mesothelin sionform 2 is a novel target for allogenet CAR gamma delta T cell therapy in solid tumors. AACR 2021;Abstract No. 1534

"Babber A, et al. Gamma delta T cells engineered with a chimeric PD-1 reporting reflectively controls PP-11 positive tumors in vitro and in vivo with minimal toxicities. AACR 2021; Abstract No.18148

"Su. Y, et al. Allogenet Vgamma/Worklaz T-cell immunotherapy exhibits promising clinical safety and prolongs the survival of patients with late-stage lung or liver cancer." Cell Mol Immunol 18(2):427-439.

"Parviot Ct, et al. T-cells expensing a chimier. PD-1-2pol To.Dizeta receptor reduce tumour burden in multiple murine syngeneic models of solid cancer. Immunology 16(0):280-294.

"WS Medicine Consumer Medicine Information; epub

"Massizer RT. CMT T-cell therapy to tal coct can exceed 515M per treatment. Cell Therapy Next; May 29, 2019.

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• The Kiromic Difference



### **Diamond AI<sup>TM</sup> (Artificial Intelligence)**

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# Artificial Intelligence and Bioinformatic Analytic Target Discovery, Validation & Development Platform

Algorithms and Large-Scale Genomics Analysis for Target Prediction

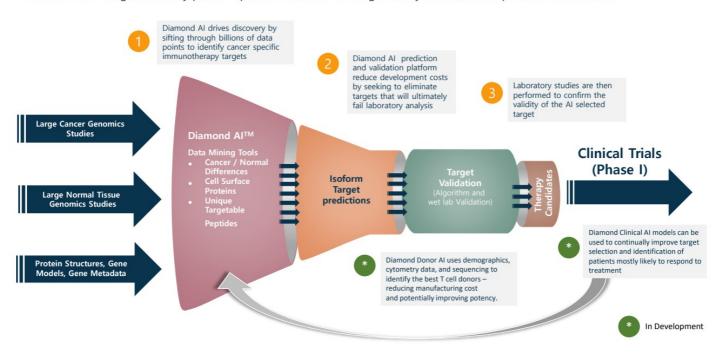




Machine and deep learning A.I. integrated with each stage of the Kiromic therapy production lifecycle.

### The Kiromic Difference - Diamond AI™ Target Discovery Platform

Diamond Al™ target discovery platform powers innovation and significantly reduces development time and cost.



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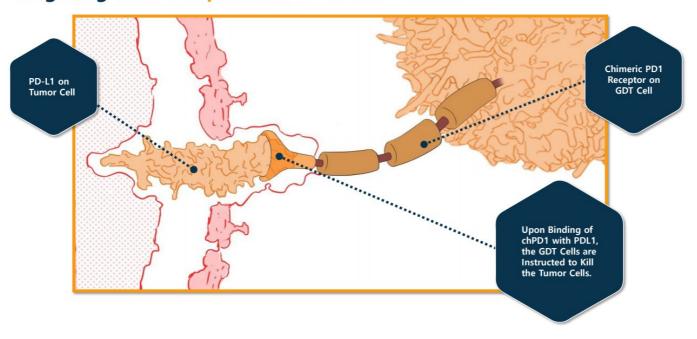
# Gamma Delta T-Cells (GDT): Guardians of the Immune System





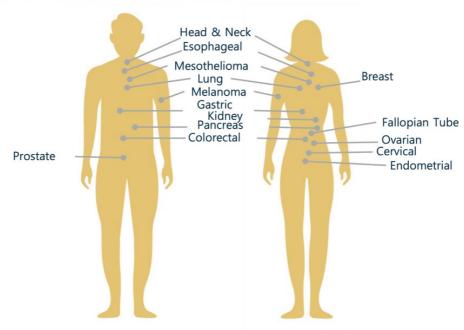


# GDT CAR-T Cell Therapy Mechanism of Action Targeting PDL-1 Expression In Tumor Tissues





# GDT CAR-T Cell Therapy (Procel™ and Isocel™) Multiple Potential Indications



### ROMIC )\*

# GDT CAR-T Cell Therapy $(Procel^{TM})^*$

# **Strong Efficacy**

# GDT CAR-T Cell Therapy (Procel™)\*

# **Strong Safety**

Procel<sup>tm</sup> Eradicates Established NCI-H226 Pleural Epithelioid Mesothelioma and Extends Survival.

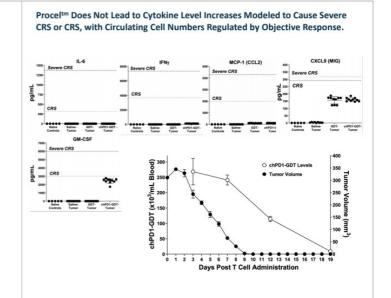
Tumor Eradication

Tumor Eradication

Overall Survival

Overall Survival

Days Post T Cell Administration



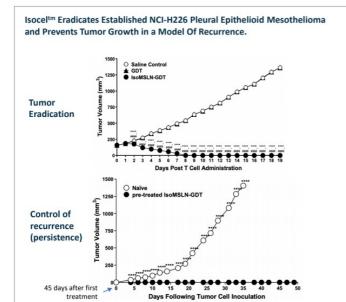
<sup>\*</sup>Preclinical models: nude mice with subcutaneous NCI-H226 cells injections

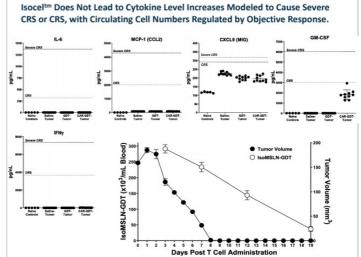
# GDT CAR-T Cell Therapy (Isocel™)\*

# **Strong Efficacy**

# GDT CAR-T Cell Therapy (Isocel™)\*

# **Strong Safety**





<sup>\*</sup>Preclinical models: nude mice with subcutaneous NCI-H226 cells injections

Kiromic's Product Pipeline
Kiromic has developed a robust pipeline of product candidates addressing solid cancers utilizing cell therapy with our GDT CAR-T platform which has been discovered and validated by our Diamond AI<sup>TM</sup> target discovery & validation platform.

Clinical Trial	Indication	Target	Discovery	Pre-Clinical	Phase I
ALEXIS - PRO-1 Procel <sup>TM</sup> Allogeneic, off-the-shelf GDT CAR-T therapy	Solid Tumors: Multi-Indication Dose Escalation PLUS Indication Specific Cohort Expansion	PD-L1			Q4 2022 Expected Beginning of Activation Process for ALEXIS-PRO-1 Clinical Trial
ALEXIS - ISO-1 IsoceI <sup>TM</sup> Allogeneic, off-the-shelf GDT CAR-T therapy	Solid Tumors: Multi-Indication Dose Escalation PLUS Indication Specific Cohort Expansion	Isoform of Mesothelin			Q4 2023 Expected Beginning of Activation Process for ALEXIS-ISO-1 Clinical Trial



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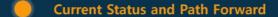
# Kiromic BioPharma 34,000 sq ft Facility Operations





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# Kiromic BioPharma's 2022 Upcoming Milestones\*



- Completion of cGMP Construction
   End of Q2 2022
- Submission of Amended IND for ALEXIS-PRO-1
   H2 2022
- Expected Beginning of Activation Process for ALEXIS-PRO-1 Clinical Trial

   End of Q4 2022

\*The milestones and timing of completion are based upon the company's current expectations in consultation with its partners and vendors.

# **Kiromic Value Proposition Summary**



# **Kiromic Leadership Team**



Pietro Bersani CPA, CGMA

CHIEF EXECUTIVE OFFICER (interim)

Scott Dahlbeck MD, PharmD

CHIEF OF STAFF OFFICER Dan Clark CPA, MBA

CHIEF FINANCIAL OFFICER

Michael Ryan PhD

CHIEF BIOINFORMATICS RESEARCH COMPUTING OFFICER





































### **Kiromic Board of Directors**



Michael Nagel Pietro Bersani CPA, CGMA Americo Cicchetti Frank Tirelli Karen Reeves

Chairperson

Director

Independent Director Independent Director Independent Director



















alliantgroup<sup>a</sup>



















## **Kiromic Financial Information**



	As of December 31, 2021	Capitalization Table (in shares, unless otherwise stated As of March 31, 2022		
	Cash \$25,353,900	Shares of Common Stock 15,585,587		
	Total Assets \$30,729,600	Representative Warrants Outstanding* 400,000 Exercise price of \$6.25 62,500 Exercise Price of \$15.00		
	Total Liabilities \$3,409,800	Stock Options Outstanding 367,244 Weighted Average Exercise Price of \$8.49		
	Stockholders' Equity \$27,319,800	Restricted Stock Units Outstanding 398,087 Grant Date Fair Value of \$7.67		

