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): May 22, 2023

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 7.01. Regulation FD.

Kiromic BioPharma, Inc. (the "Company") intends to conduct meetings with third parties in which its corporate slide presentation will be presented. A copy of the presentation materials is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Item 7.01 and the document attached as Exhibit 99.1 is being furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities and Exchange Act of 1934, as amended (the "Exchange Act"), nor otherwise subject to the liabilities of that section, nor incorporated by reference in any filing under the Securities Act of 1933 or the Exchange Act, except as shall be expressly set forth by specific reference in such a 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	Corporate Presentation of Kiromic BioPharma, Inc.
104	Cover Page Interactive Data File (embedded within the 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: May 22, 2023

By: /s/ Pietro Bersani
Pietro Bersani
Chief Executive Officer


KIROMIC
BioPharma
Revolutionizing CAR T-Cell Therapy
MAY 2023
NASDAQ: KRBP
Kiromic.com

Forward Looking Statements

This presentation contains forward-looking statements that involve substantial risks and uncertainties. Kiromic makes such forward-looking statements pursuant to the safe harbor provisions of the United States 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. In some cases, you can identify forward-looking statements by terms such as: "will," "potential," "could," "can," "believe," "intends," "continue," "plans," "expects," "anticipates," "estimates," "may," or the negative of these terms or other comparable terminology. These forward-looking statements include, but are not limited to, statements regarding: Kiromic's current and anticipated IND applications including statements regarding the scope of and timing for submission of an IND application; the Deltacel™ product platform; the sponsored research agreement and the data that will be generated as a result of such collaboration; the timing for submitting and activating Kiromic's IND applications; the benefits of utilizing non-genetically engineered Gamma Delta T cells as our first in-human study; Kiromic's ability to achieve its objectives; and the timing for the initiation and successful completion of Kiromic's clinical trials of its product candidates. These forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause actual results, levels of activity, performance, or achievements to be materially different from the information expressed or implied expressed or implied by these forward-looking statements. These risks and uncertainties include, but are not limited to, the risks and uncertainties discussed in our Annual Report on Form 10-K for the year ended December 31, 2022, and as detailed from time to time in our SEC filings. You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that the future results, levels of activity, performance, or events and circumstances reflected in the forward-looking statements will be achieved or occur. Moreover, neither we nor any other person assumes responsibility for the accuracy and completeness of the forward-looking statements. Such forward-looking statements relate only to events as of the date of this press release. We undertake no obligation to update any forward-looking statements except to the extent required by law.

Contents

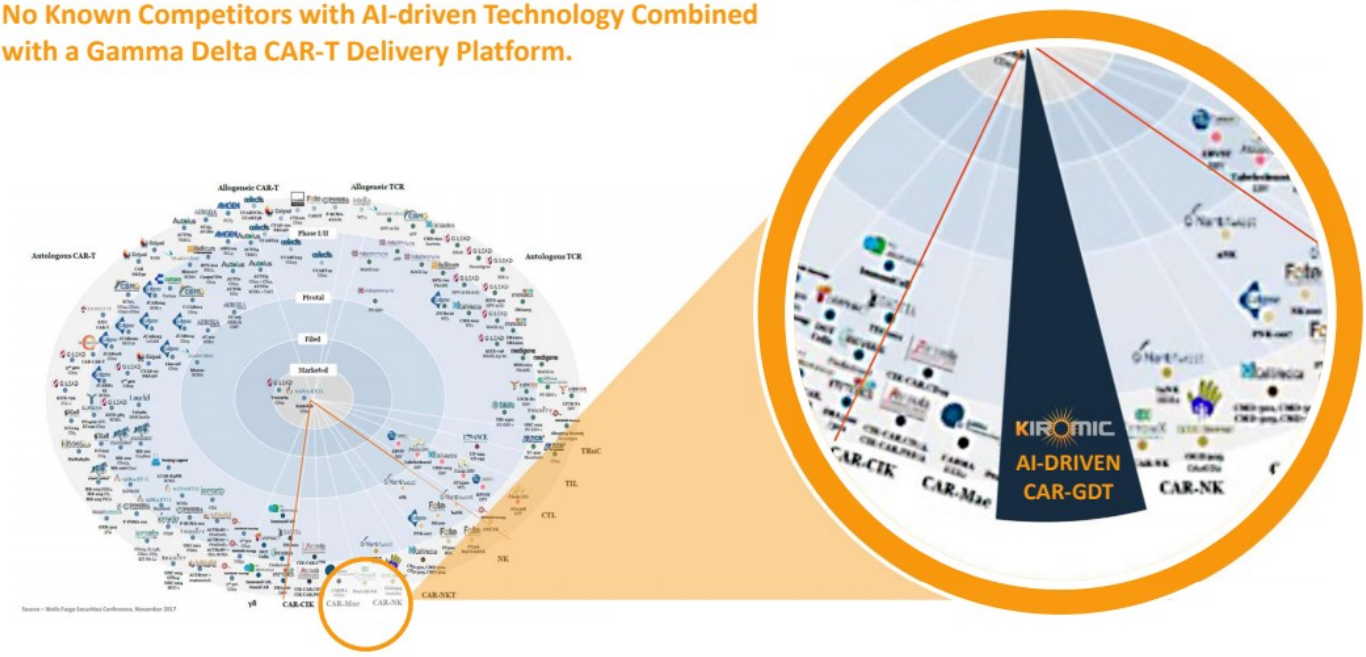
The Kiromic Difference

Kiromic BioPharma is the only cell therapy company combining AI-driven genetically edited Gamma Delta T-cells (GDT) with proprietary targeting technology to address solid malignancies.

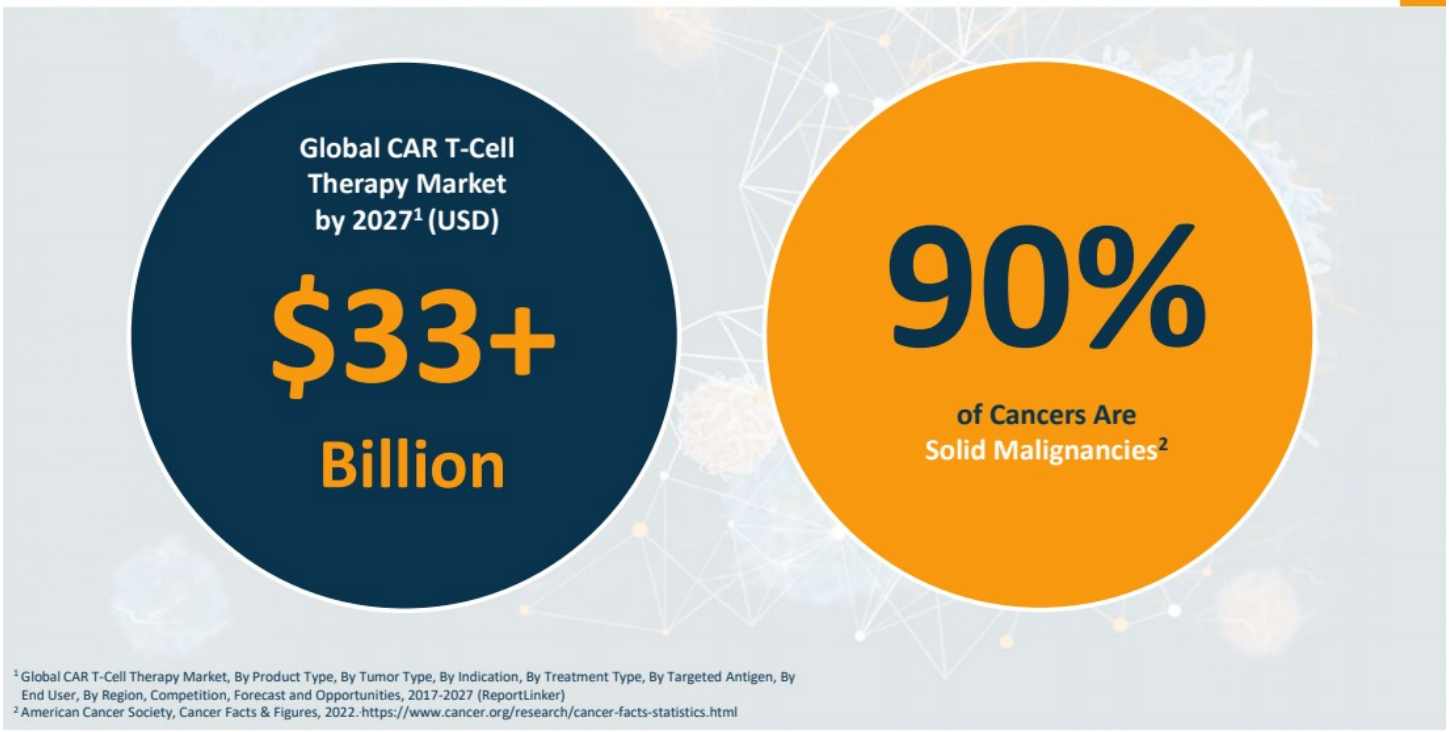
Strategic Competitive Landscape

7 Known Companies (including Kiromic) in the Gamma Delta T Cell Therapy space.

No Known Competitors with AI-driven Technology Combined with a Gamma Delta CAR-T Delivery Platform.



Solid Malignancy Market Opportunity



[1] 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)
[2] American Cancer Society, Cancer Facts & Figures, 2022. https://www.cancer.org/research/cancer-facts-statistics.html

Competitive Difference

Allogeneic Gamma Delta Based T-Cell Therapies

1 Next Gen Allogeneic Therapy

Allogeneic approach simplifies the supply chain and shortens the lead time.

Previous generation of autologous therapy makes repeat dosing challenging, and gene editing raises manufacturing costs and poses regulatory challenges.

2 Multi Indication Solid Tumor Therapies

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

Solid tumors represent approx. 90% of new cancer cases[1].

3 Superior Safety[2-4]

1. Minimal to no projected Cytokine Release Syndrome (CRS).

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

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

4 Superior Efficacy[5]

Strong efficacy in pre-Clinical animal models of CAR-T therapy.

Issues related to low efficacy:

1. Suppressive Tumor micro-environment (TME)
2. T-Cell exhaustion and loss of efficacy

5 In-house Manufacturing

1. Off-The-Shelf vs up to 3-5 weeks for autologous CAR-T such as Kymriah[6].

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 Lower Costs/ Greater Access[7]

1.Potential Outpatient treatment means reduced hospitalization and other treatment related costs.

2. Lower projected cost increases patient and health care professional access to these therapies, and also potentially provides important quality-of-life benefits for patients as well.

[1]American Cancer Society, Cancer Facts & Figures, 2022.https://www.cancer.org/research/cancer-facts-statistics.html
[2]Wang X, et al. Mesothelin isoform 2 is a novel target for allogeneic CAR gamma delta T cell therapy in solid tumors. AACR 2021;Abstract No. 1534
[3]Barber A, et al. Gamma delta T cells engineered with a chimeric PD-1 receptor effectively controls PD-L1 positive tumors in vitro and in vivo with minimal toxicities. AACR 2021; Abstract No.LB148
[4]Ku Y, et al. Allogeneic Vgamma9Vdelta2 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.
[5]Parriott G, et al. T-cells expressing a chimeric-PD1-Dap10-CD3zeta receptor reduce tumour burden in multiple murine syngeneic models of solid cancer. Immunology 160(3):280-294.
[6]NPS Medicine; Consumer Medicine Information; epub
[7]Maziarz RT. CAR T-cell therapy total cost can exceed $1.5M per treatment. Cell Therapy Next; May 29, 2019.

Contents

Artificial Intelligence and Bioinformatic Analytic Discovery & Development Platform

Algorithms and Large-Scale Genomics Analysis for Target Prediction

Diamond AI™

Artificial Intelligence Neural Network

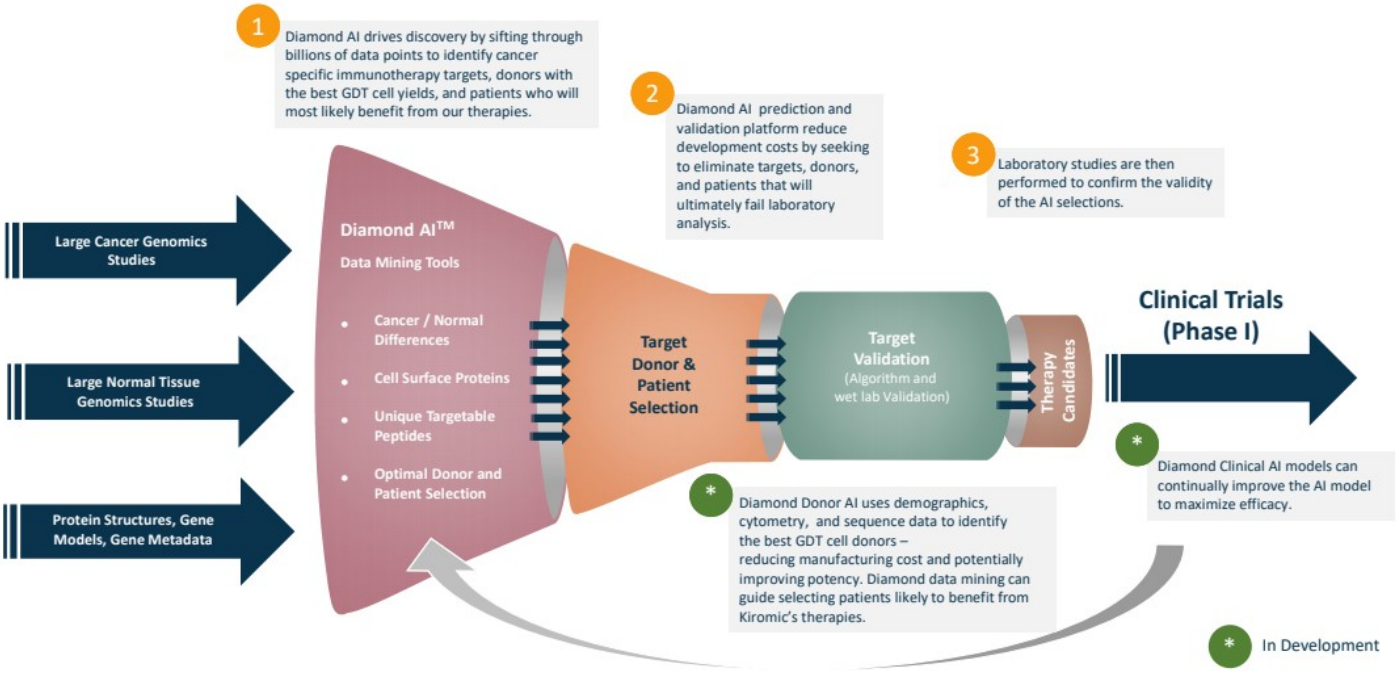
A.I. integrated with each stage of the Kiromic therapy production lifecycle

Discovering New Multi-tumor Targets

Identifying Optimal Donors and Patients to Maximize the Therapy Success

The Kiromic Difference - Diamond AI™ Target Discovery Platform

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



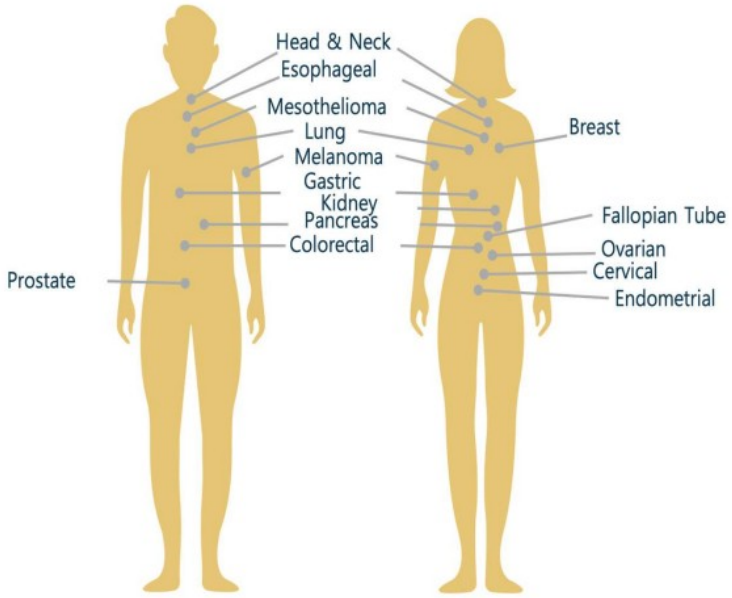
Contents

Kiromic GDT Cell Therapy - Deltacel

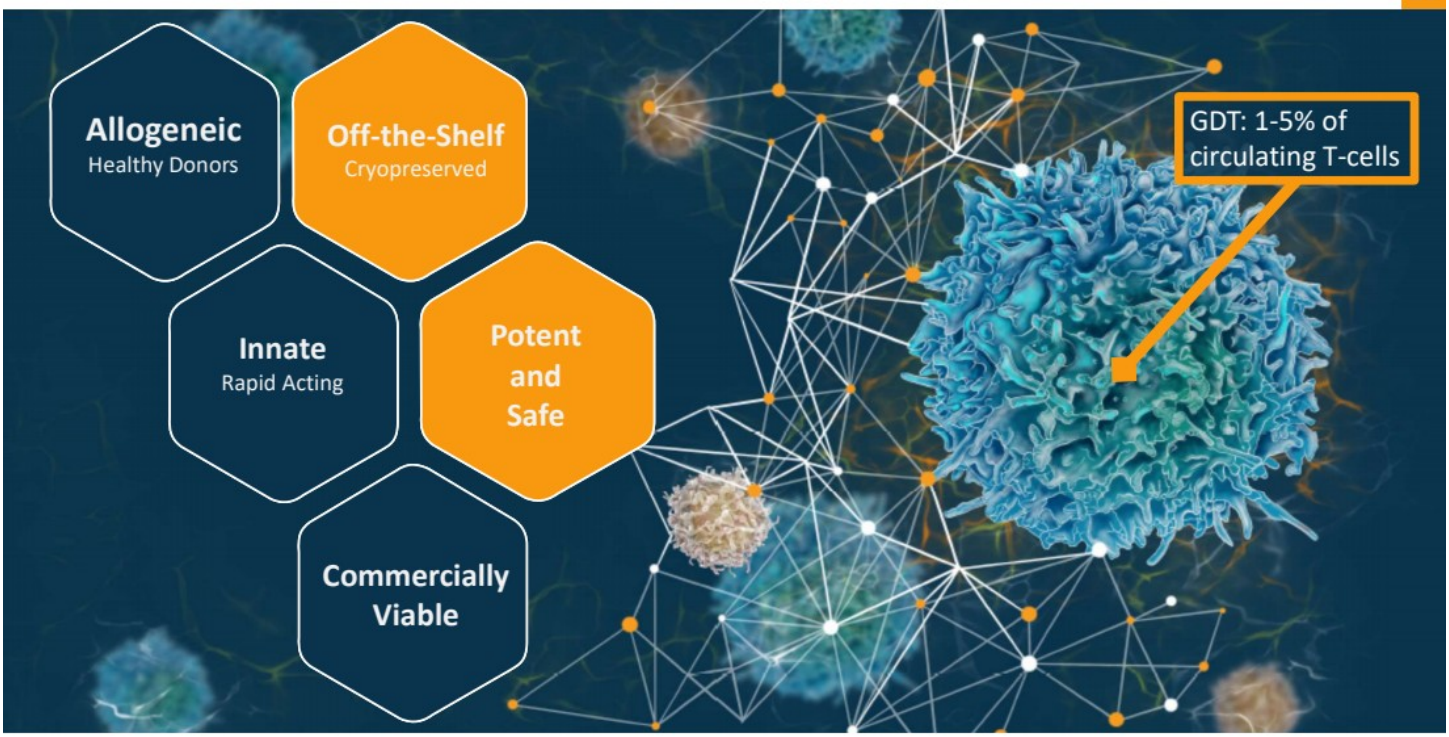
Multiple Potential Indications

Deltacel

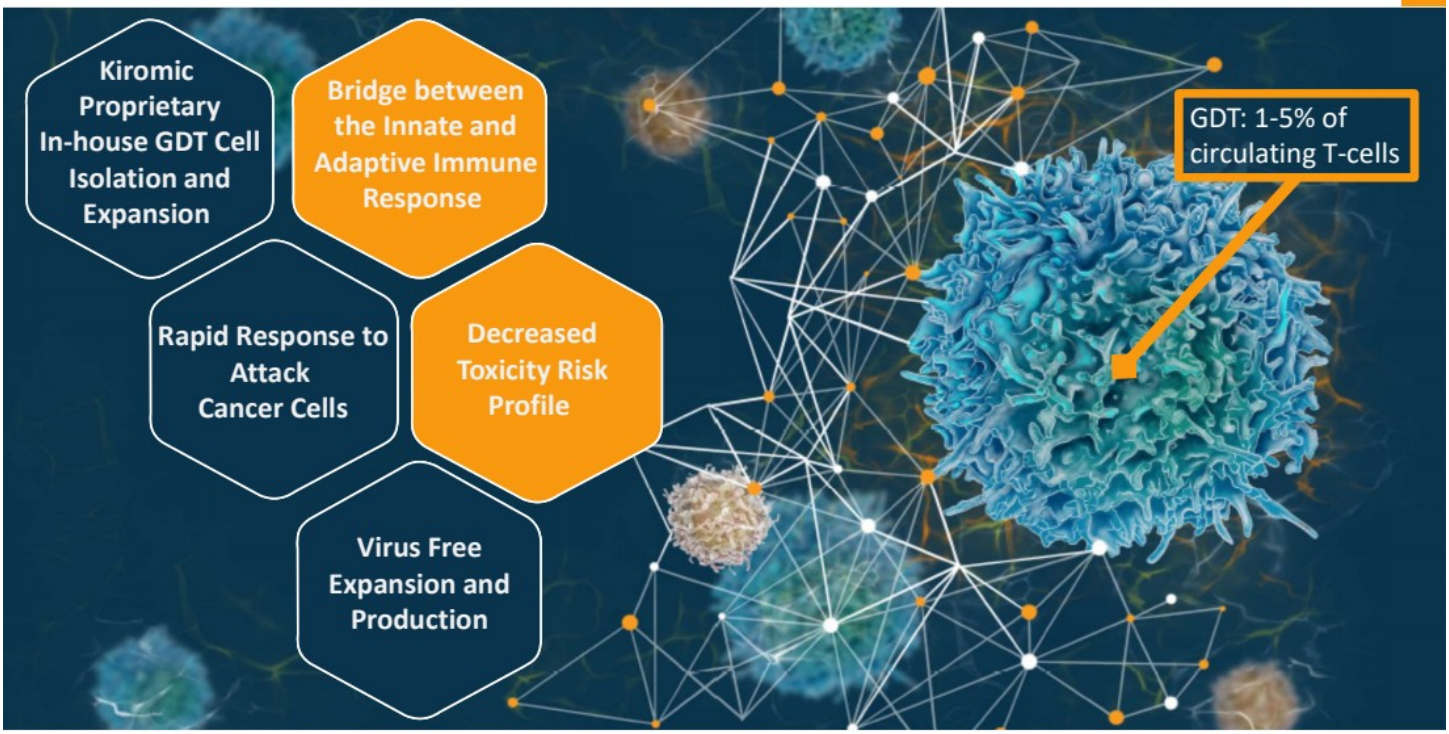
Non-viral, non-engineered, off-the-shelf product candidate targeting stress ligands on cancer cells



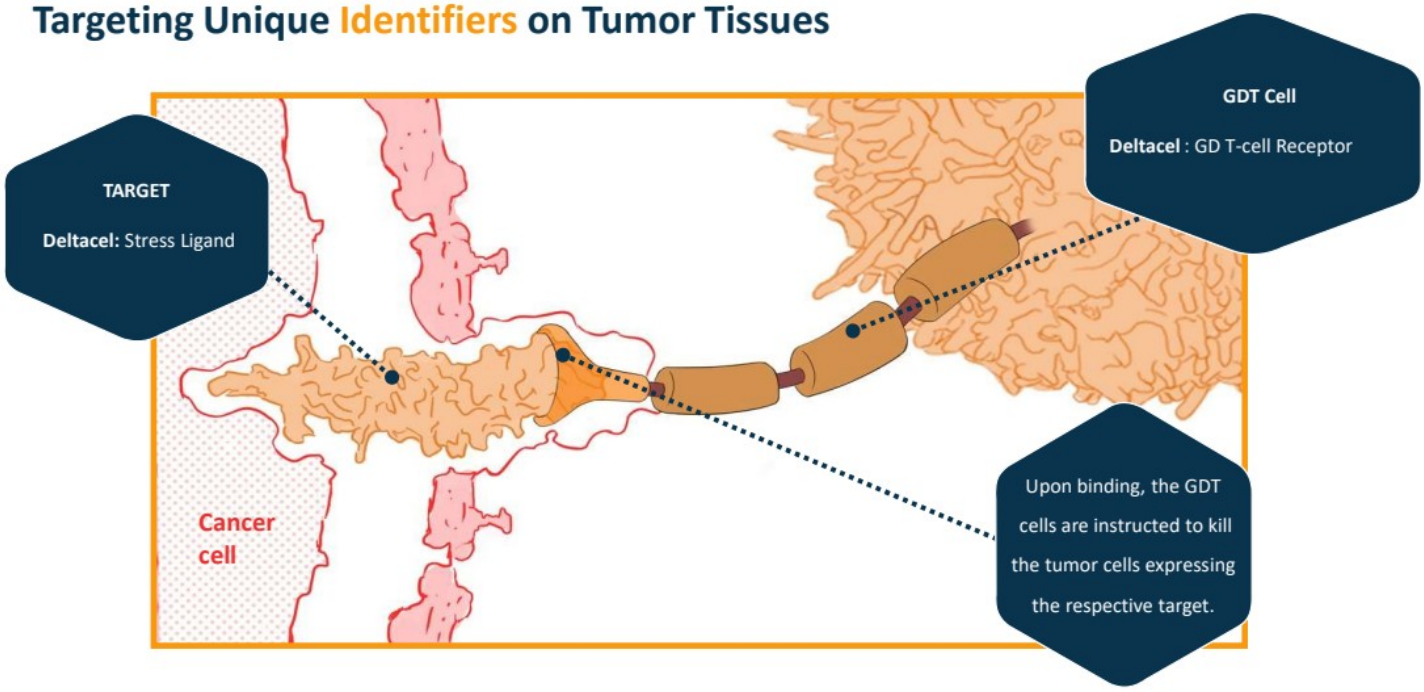
Gamma Delta T-Cells (GDT): Guardians of the Immune System



Deltacel: Non-Viral Gamma Delta T-Cell Development



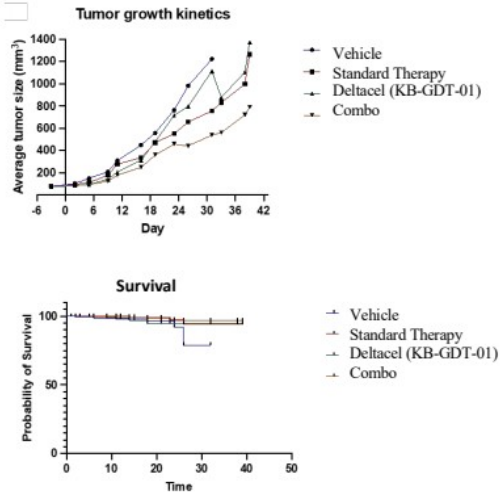
GDT Cell Therapy Mechanism of Action: Targeting Unique Identifiers on Tumor Tissues



KB-GDT-01 T-Cell Therapy (Deltacel)

Strong Efficacy

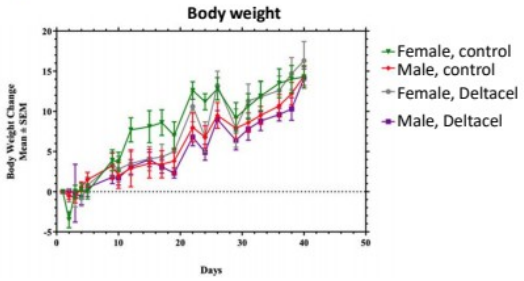
Deltacel™ effectively controls established A549 NSCLC tumors in immunocompromised mice when combined with a low-dose radiation



KB-GDT-01 T-Cell Therapy (Deltacel)

Strong Safety

Deltacel™ does not cause any macroscopic or microscopic toxicity, even when given at over 8x the maximum dose that will be tested in the clinical trial



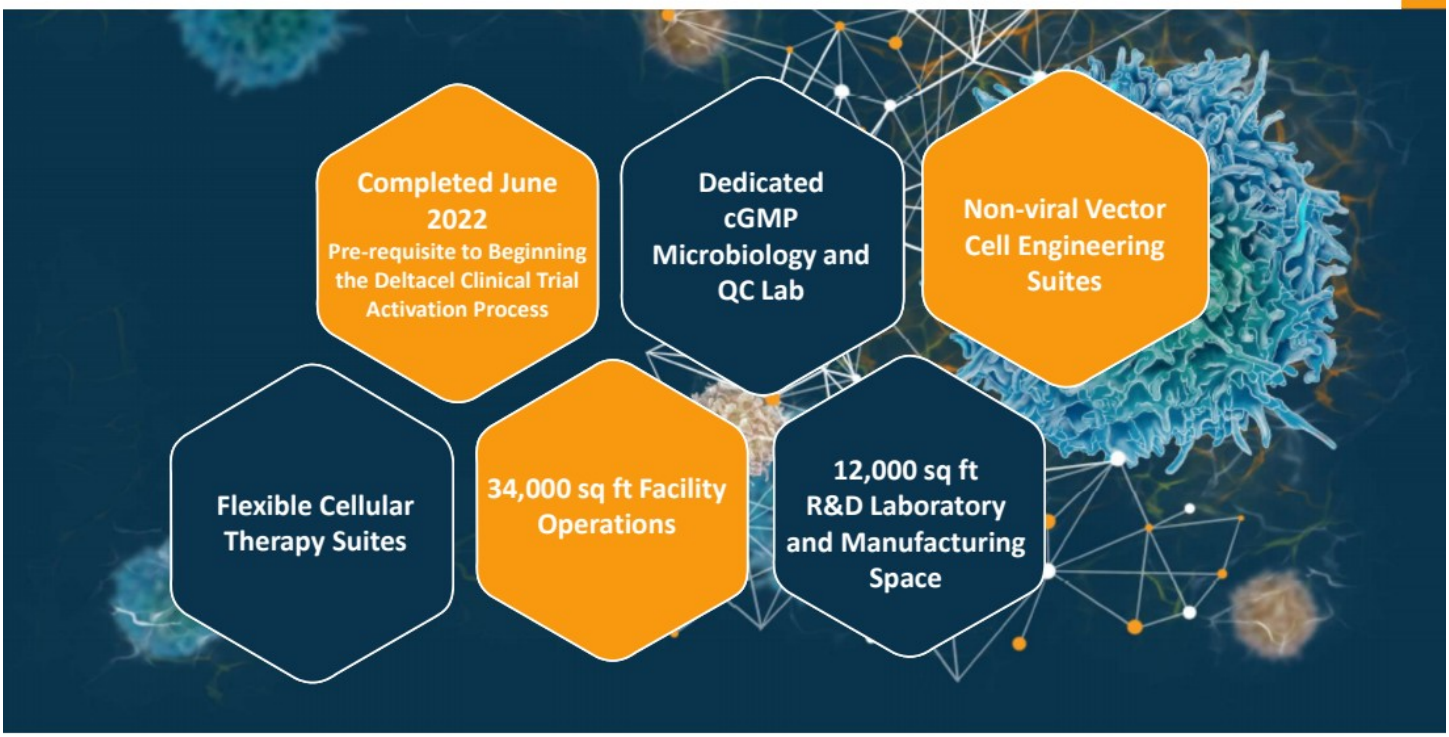
- ✓ There were no treatment-associated impacts on body weights, food consumption, or cage-side/clinical observations. Macroscopic evaluations at necropsy did not identify any evidence of test article-related toxicity. Microscopic histopathological evaluations showed no evidence of Deltacel-related toxicity
- ✓ Clinical pathology evaluations determined that all fluctuations among individual and mean values of tested analytes were considered sporadic, and not related to the administration of Deltacel.
- ✓ Plasma cytokine analysis showed that Deltacel administration did not result in the overproduction of inflammatory cytokines which may pose a safety concern.

Pipeline

Clinical Trial Candidate		Target	Pre-Clinical	Phase I
IND #1 ACCEPTED for NSCLC **Deltacel in combination with low-dose radiation** Allogeneic, Non-Viral, Non-engineered off-the-shelf GDT therapy	Sponsored Research Agreement MD Anderson Yes	Universal Non-Engineered		**Q2 2023** Expected Beginning of Activation Process for IND #1 Clinical Trial
IND #2 **Procel™ in combination with low-dose radiation** Allogeneic, off-the-shelf, GDT CAR-T therapy	Yes	PD-L1		**H1 2025*** Expected Beginning of Activation Process for IND #2 Clinical Trial
ALEXIS - PRO-1 **Procel™** Allogeneic, off-the-shelf, GDT CAR-T therapy	No	PD-L1		**H1 2025 *** Expected Beginning of Activation Process for ALEXIS-PRO-1 Clinical Trial
IND #3 **Isocel™ in combination with low-dose radiation** Allogeneic, off-the-shelf, GDT CAR-T therapy	Yes	Isoform of Mesothelin		**H1 2025 *** Targeting Beginning of Activation Process for IND #3 Clinical Trial
ALEXIS - ISO-1 **Isocel™** Allogeneic, off-the-shelf, GDT CAR-T therapy	No	Isoform of Mesothelin		**H1 2025 *** Targeting Beginning of Activation Process for ALEXIS-ISO-1 Clinical Trial

* Subject to sufficient financing to support the progression of the development of those additional clinical trial candidates.

In-House Manufacturing Creates De-Risked Value



Contents

Upcoming Milestones*

1. **IND AUTHORIZATION TO EVALUATE DELTACEL IN NON-SMALL CELL LUNG CANCER**
   - ✓ **MAY 1, 2023**
2. **Beginning of First in-Human Trial Activation for Deltacel**
   - **Q2 2023**
3. **Data Results from First Patient in Deltacel Clinical Trial**
   - **By End of Q4 2023**
4. **Initiation of Clinical Trials Expansion Cohort**
   - **H2 2024**
5. **Submission of new INDs for Procel and Isocel**
   - **H1 2025****

*The milestones and timing of completion are based upon the company's current expectations in consultation with its partners and vendors.
** Subject to sufficient financing to support the progression of the development of those additional clinical trial candidates..

Leadership Team

Pietro Bersani
CPA, CGMA

CEO

Leonardo Mirandola
Ph.D.

CSO/INTERIM COO

Scott Dahlbeck
MD, PharmD

COSO

Tim Simkiss
CPA, MBA

CONTROLLER

Board of Directors

Michael Nagel

Chairperson

Pietro Bersani
CPA, CGMA

Director

Americo Cicchetti

Independent Director

Summary Balance Sheet & Cap Table

Balance Sheet Data (As of March 31, 2023)	As Reported
Cash and Cash Equivalents	$2,054,300
Working Capital	$(6,751,700)
Total Assets	$13,108,000
Total Stockholders' Deficit	$(8,140,300)

Cap Table (As of March 31, 2023)	
Common Stock	979,243
Restricted Stock Units ($258.88 Weighted average grant date fair value)	632
Options ($287.58 Weighted average exercise price)	18,341
Warrants ($222.97 Weighted average exercise price)	15,416
Fully Diluted Common Shares	979,876

Value Proposition Summary


KIROMIC
BioPharma
Revolutionizing CAR T-Cell Therapy
MAY 2023
NASDAQ: KRBP
Kiromic.com