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 21, 2024

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 OTC QB Market

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 Disclosure

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 Exhibits

(d) Exhibits.

99.1	Kiromic BioPharma, Inc. Corporate Presentation

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 21, 2024

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


KIROMIC
BioPharma
Revolutionizing CAR T-Cell Therapy
May 2024
OTCQB: 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.

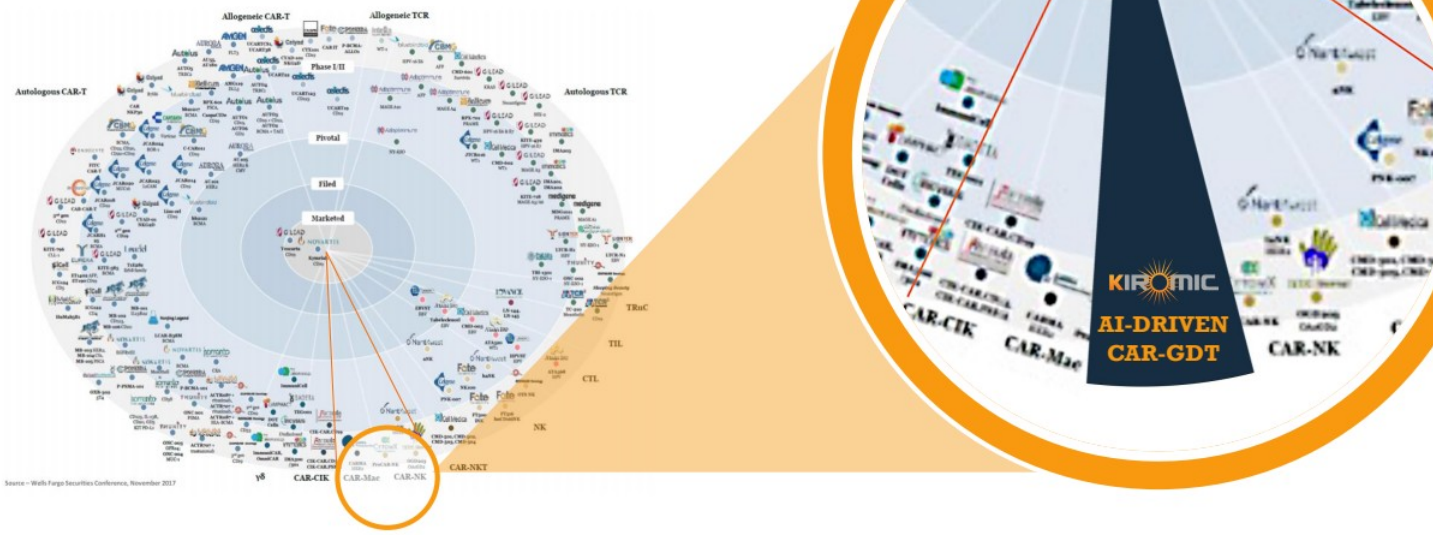
Contents

The Kiromic Difference

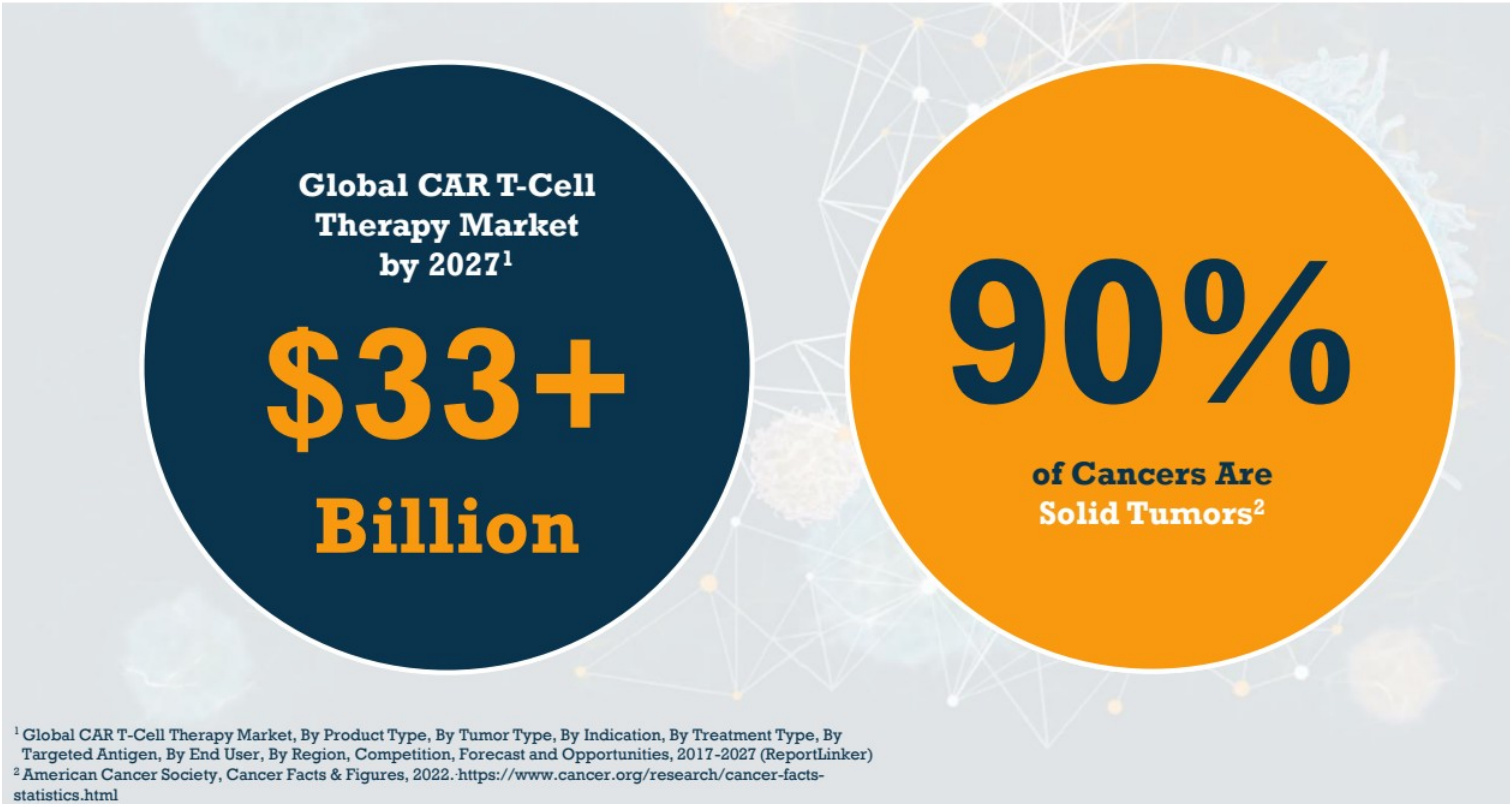
Competitive Landscape

8 Known Companies Working 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

Superior Specificity for Multiple Solid Tumors

- **Potential broad treatment** for solid malignancies that express Kiromic-developed biomarkers such as Iso-mesothelin.
- Solid tumors represent ~90% of new cancer diagnoses but finding specific targets to treat them has been challenging.
- Kiromic tackles the issue by identifying new cancer-specific targets.

Vertical Integration

- In-house **cGMP manufacturing**
- In-house **QC/EM lab**
- In-house **product and process development** (R&D and MSAT)

Superior Efficacy from γδT Cells

- **Strong efficacy** demonstrated in preclinical animal models.
- In solid tumors, the benefit of infiltrating conventional T cells may vary.
- In contrast, GDT cells are the infiltrating immune cells most likely to be associated with positive outcomes, as shown in an analysis of 18,000 tumors from 39 indications[1]

Lower Costs/ Greater Access[2]

1. Outpatient treatment means reduced hospitalizatic and other treatment-related costs.

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

1. Gentles AJ, Newman AM, Liu CL, *et al*. The prognostic landscape of genes and infiltrating immune cells across human cancers. Nat Med. 2015 Aug;21(8):938-945.
2. 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

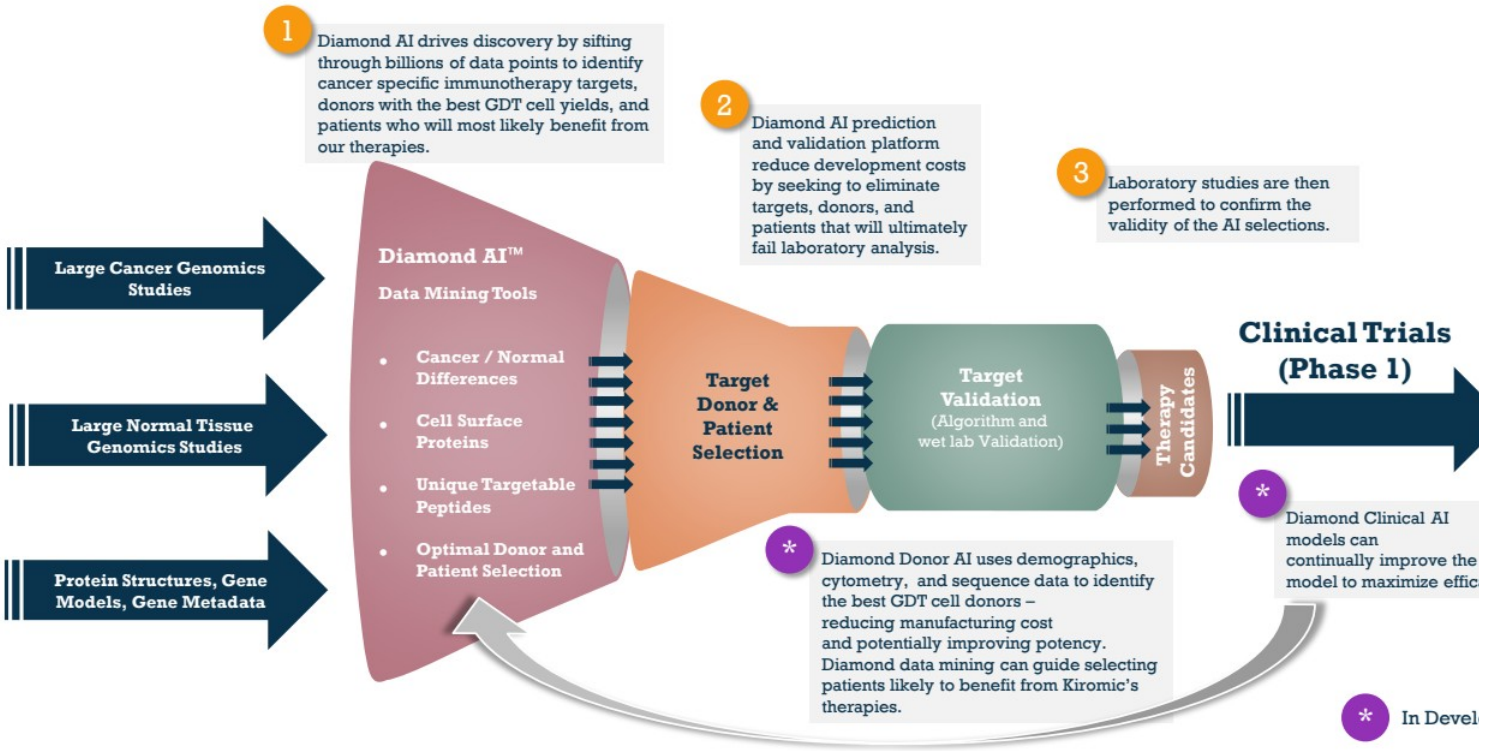
Diamond AI™

Artificial Intelligence Neural Network

- ✓ **AI 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 Pipeline

Multiple Indications

Deltacel™

Unmodified, off-the-shelf product candidate targeting stress ligands on cancer cells

Initial indication: NSCLC in combination with targeted, low-dose radiation

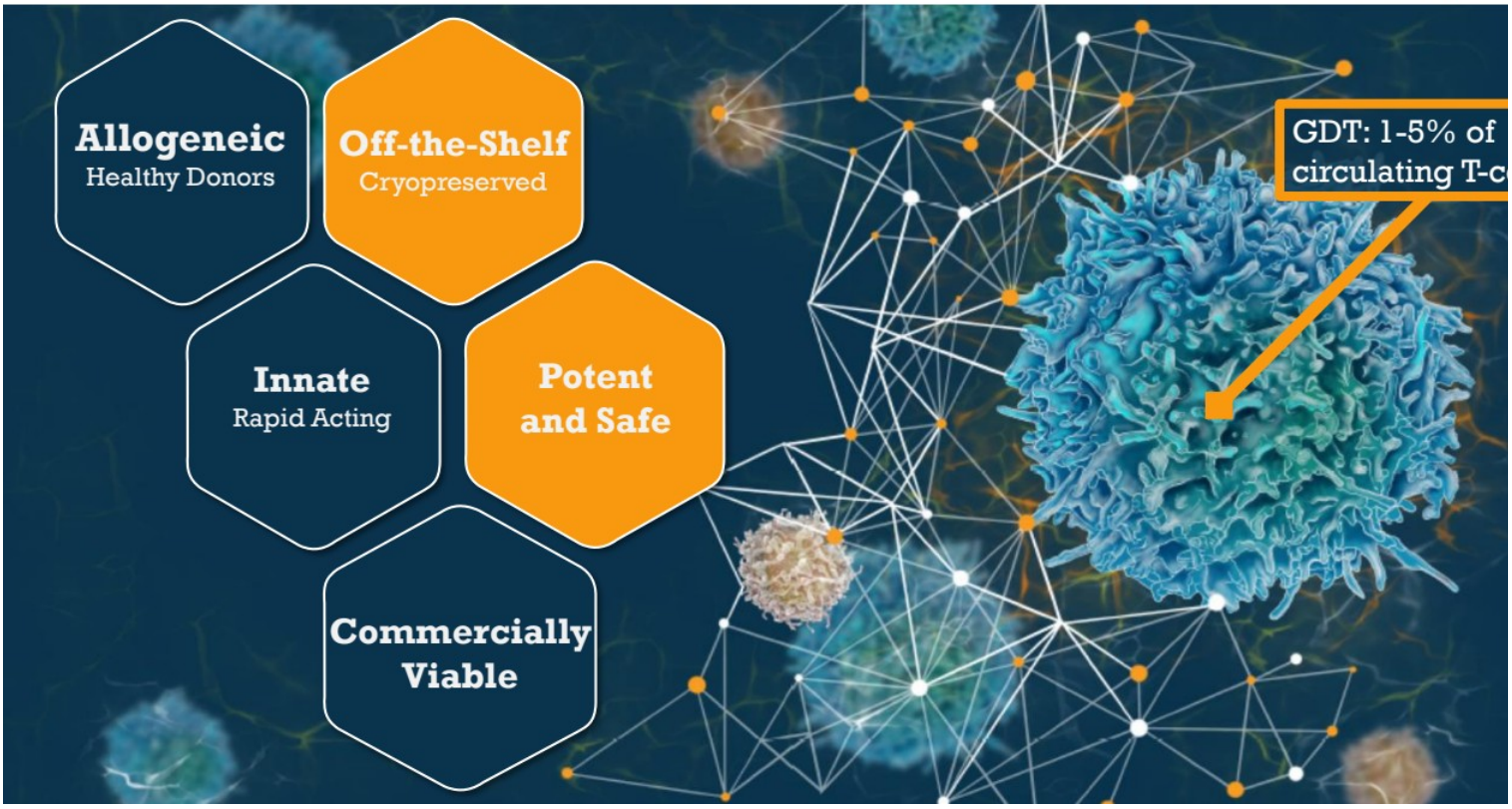
Isocel™

Engineered off-the-shelf product candidate targeting a tumor-specific variant of mesothelin in ovarian cancer, mesothelioma and pancreatic cancer

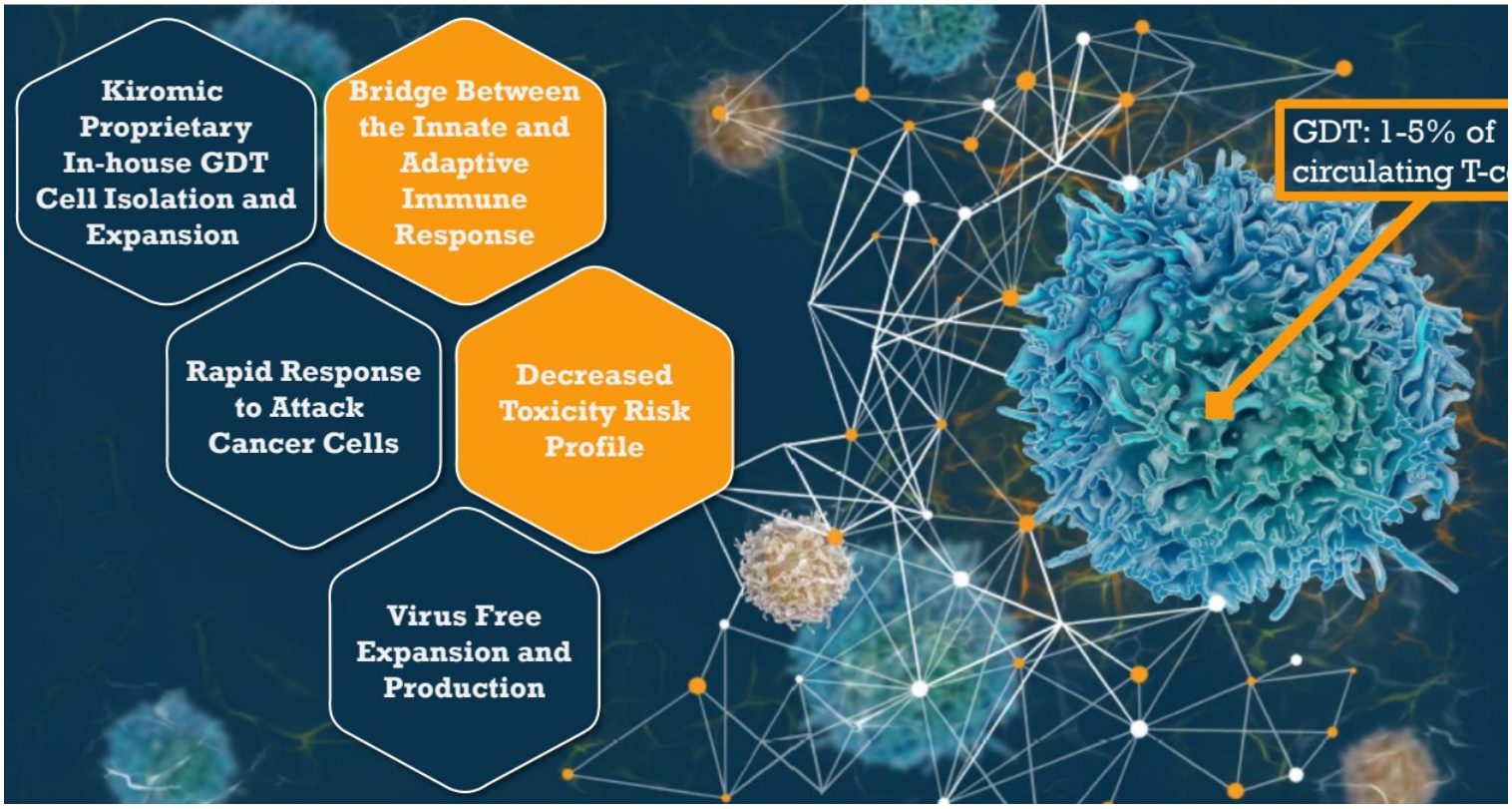
Procel™

Engineered off-the-shelf product candidate targeting PDL-1+ tumors

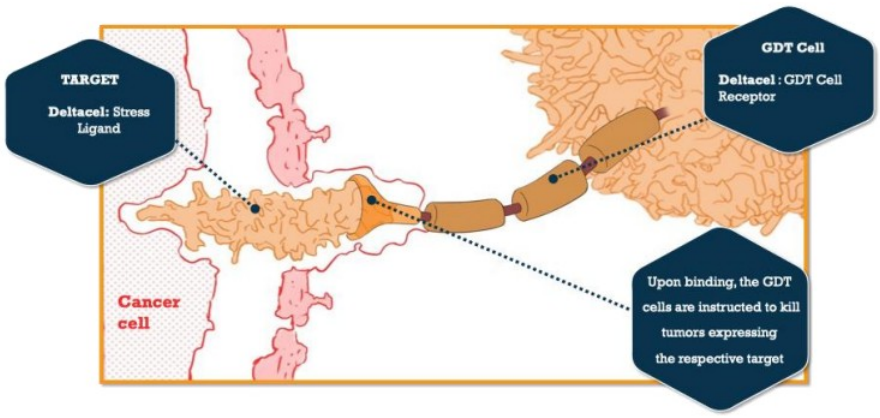
Gamma Delta T-Cells: Guardians of the Immune System

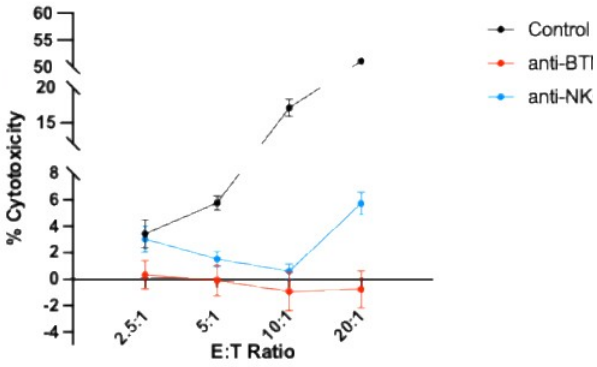


Deltacel: Non-Viral Gamma Delta T-Cell Development



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

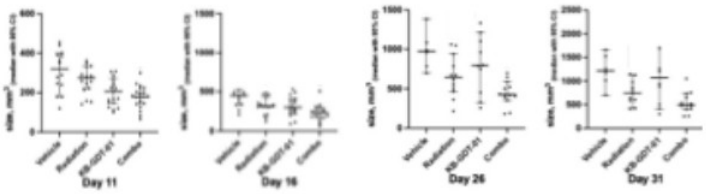




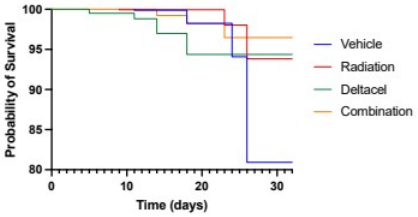
KB-GDT-01 T-Cell Therapy (Deltacel) Strong Efficacy

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

Tumor Size



Survival

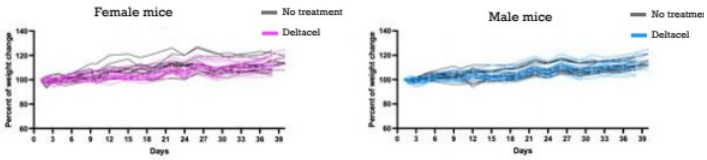


KB-GDT-01 T-Cell Therapy (Deltacel) Strong Safety

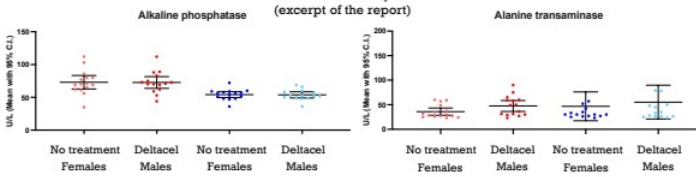
Deltacel™ does not cause any macroscopic or microscopic toxicit even when given at over 8x the maximum dose that will be tested the clinical trial

1. Deltacel did not impact body weights, food consumption, or macroscopic evaluations a necropsy.
2. Microscopic histopathological evaluations showed no evidence of toxicity.
3. Blood chemistry tests showed no impact on organ functions.
4. Plasma cytokine analysis showed that Deltacel administration did not result in the overproduction of inflammatory cytokines, commonly associated to cytokine release syndrome.

Percent body weight



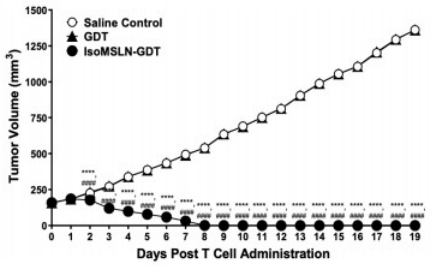
Blood chemistry (excerpt of the report)



GDT CAR T-Cell Therapy (Isocel)* Strong Efficacy

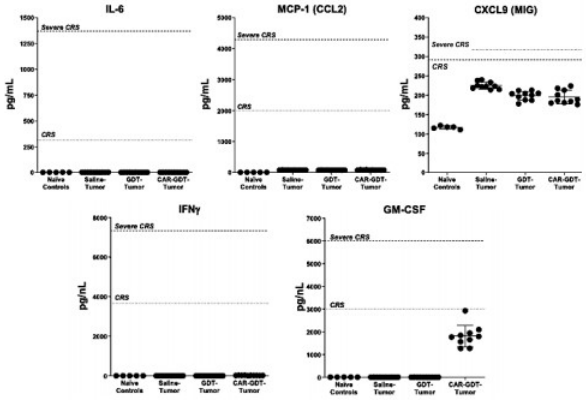
Isocel eradicates established NCI-H226 pleural epithelioid mesothelioma and prevents tumor growth in a model of recurrence.

Tumor eradication



GDT CAR T-Cell Therapy (Isocel)* Strong Safety

Isocel does not lead to cytokine level increases modeled to cause severe CRS or CRS, with circulating cell numbers regulated by objective response.

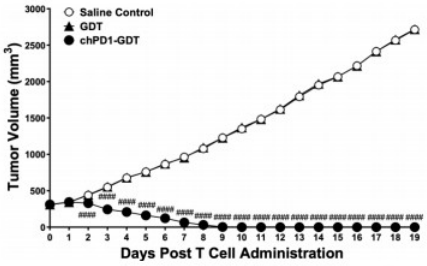


*Preclinical models: nude mice with subcutaneous NCI-H226 cells injections

GDT chPD1 T-Cell Therapy (Procel)* Strong Efficacy

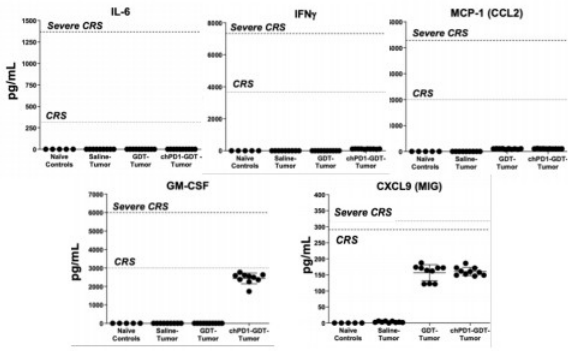
Procel eradicates established NCI-H226 pleural epithelioid mesothelioma and extends survival.

Tumor eradication



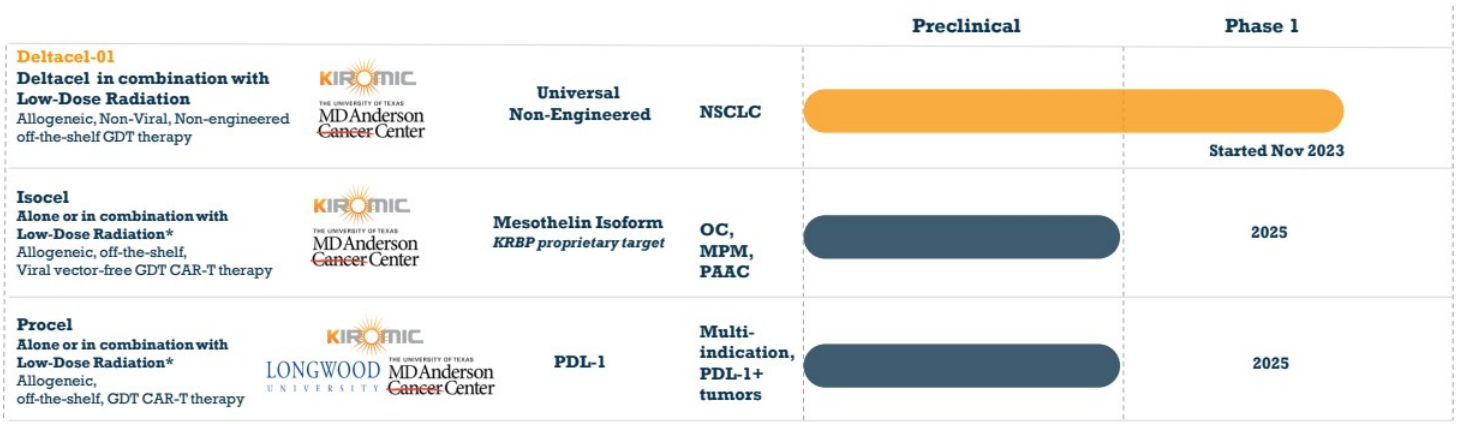
GDT chPD1 T-Cell Therapy (Procel)* Strong Safety

Procel does not lead to cytokine level increases modeled to cause severe CRS or CRS, with circulating cell numbers regulated by objective response.



*Preclinical models: nude mice with subcutaneous NCI-H226 cells injections

Clinical Development Strategy



* This program may result in two clinical trials, one with and one without low-dose radiation, depending on the pre-clinical evidence.

In-House cGMP Manufacturing Creates De-Risked Value

Contents

Deltacel-01 Phase 1 Clinical Trial

Evaluating Deltacel in Stage 4 Metastatic Non-small Cell Lung Cancer (NSCLC)

- Open-label, multicenter trial enrolling up to 48 patients
- Patients receive two IV Deltacel infusions with four courses of low-dose, localized radiation over a 10-day period

- **Primary objective:**
  - Safety of Deltacel in combination with low-dose radiation

- **Secondary outcome measures:**
  - Objective response, progression-free survival, overall survival, time to progression, time to treatment response and disease control rates

Early Results

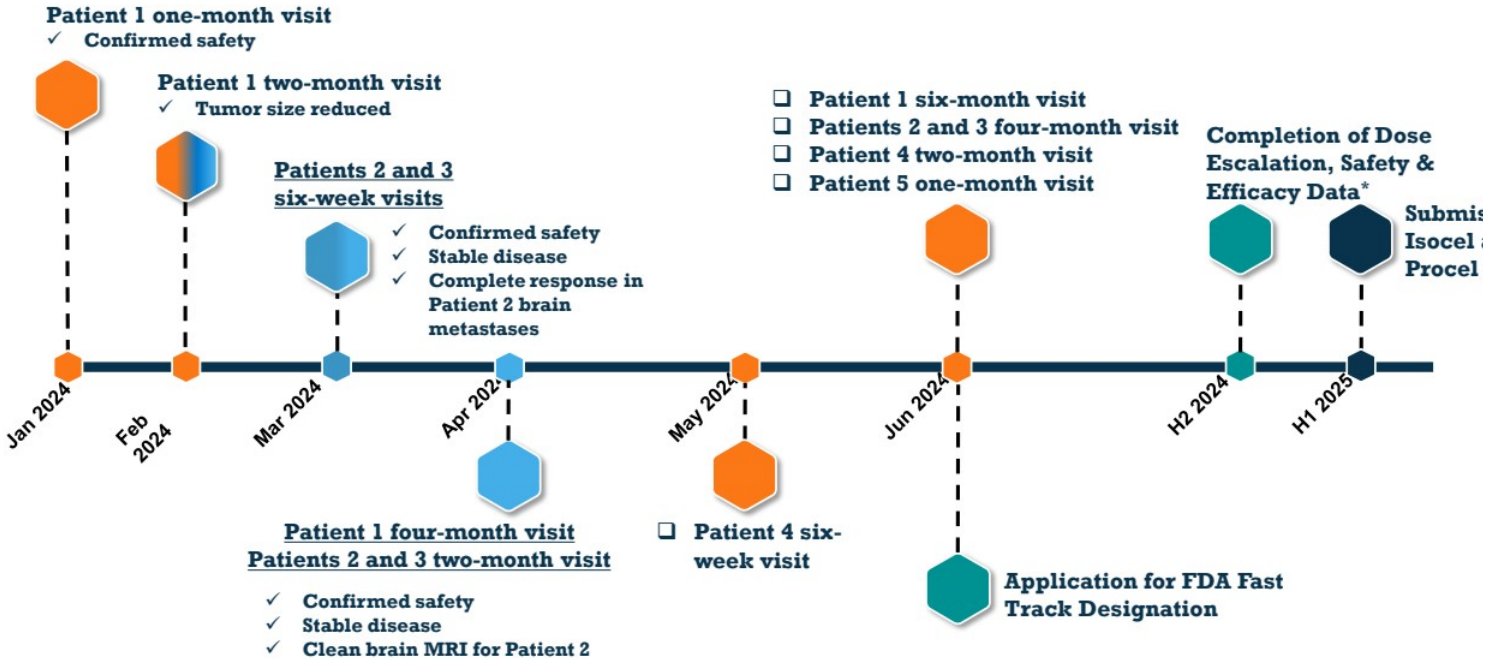
Patient	Safety	Six Weeks Post-treatment	Two Months Post-treatment	Four Months Post-treatment
1	✓ No dose limiting toxicities	✓ Stable disease	✓ Tumor size reduction by 6.6%* ✓ Tumor metabolism reduction by 20%**	✓ Stable diseas (compared w month follow
2	✓ No dose limiting toxicities	✓ Stable disease ✓ Complete resolution of brain lesions	✓ Stable disease ✓ Confirmed clean brain imaging ✓ No new brain lesions	❑ Expected in J
3	✓ No dose limiting toxicities	✓ Stable disease	✓ Stable disease	❑ Expected in J

Kiromic's Fast-Track Designation Application (to be filed in June 2024) will be based on these safety and efficac

* As assessed by PET/CT
** As assessed by FDG uptake

- Patient 4 was enrolled in April 2024
- Patient 5 is expected to be enrolled in May 2024
- Patient 6 is expected to be enrolled in June 2024

Recent and Upcoming Milestones



* The milestones and timing of completion are based on the company's current expectations in consultation with its partners and vendors.
** Subject to obtaining 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
M.D., Pharm.D.

COSO

Brian Hungerford
CPA,CGMA

CFO

Board of Directors

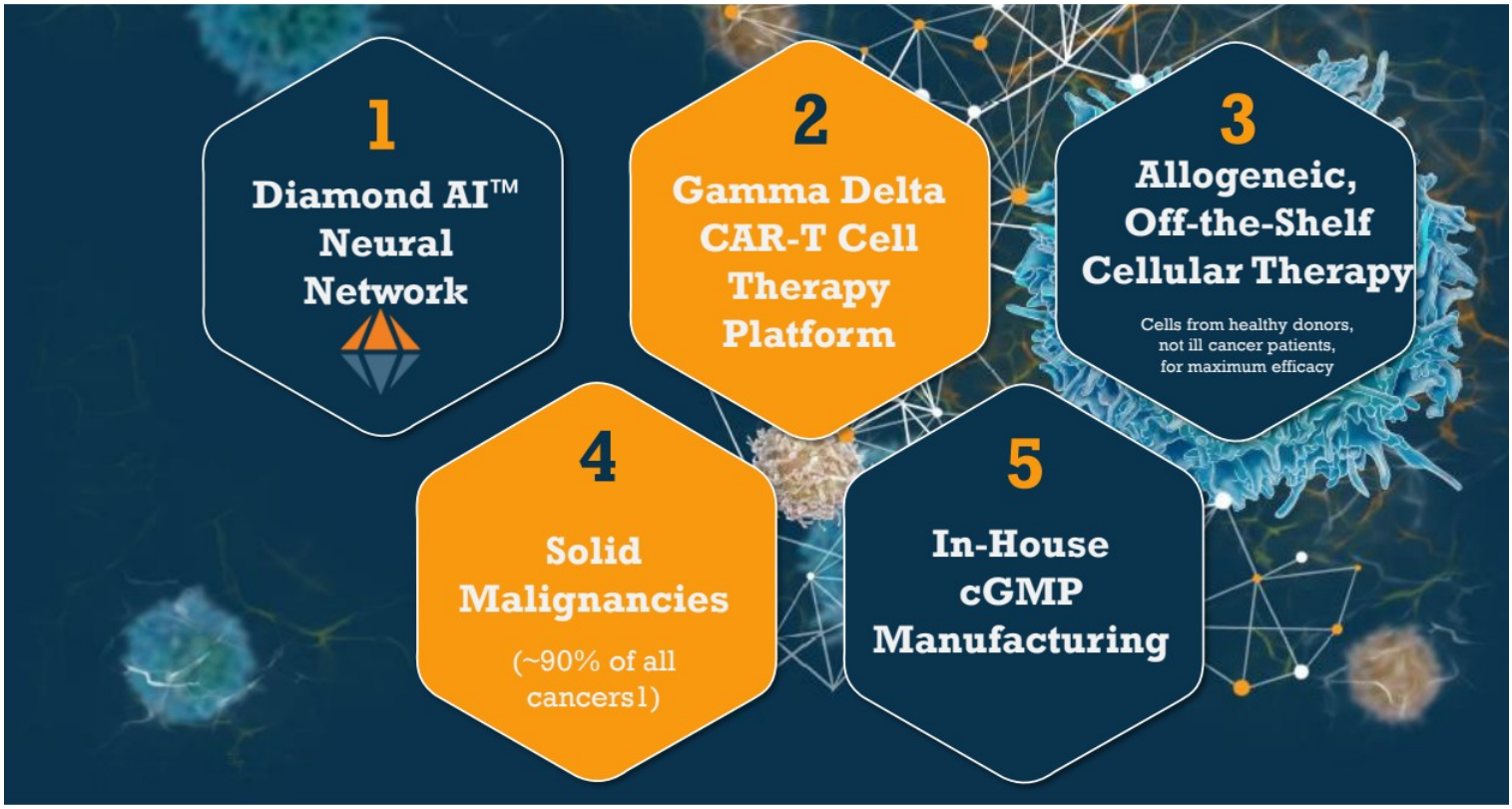
Michael Nagel	Pietro Bersani CPA, CGMA	Pam Misajon	Michael Catlin
Chairperson	Director	Independent Director	Independent Director

Summary Balance Sheet & Cap Table

Balance Sheet Data (As of March 31, 2024)	As Reported (In Thousands)
Cash and Cash Equivalents	**$3,676**
Working Capital	**($13,525)**
Total Assets	**$12,628**
Total Stockholders' Deficit	**($7,212)**

Cap Table (As of March 31, 2024)	Common Stock Equivalents
Common Stock	1,288,235
Restricted Stock Units ($3.19 Weighted average grant date fair value)	440
Options ($101.04 Weighted average exercise price)	18,093
Warrants	15,416
Convertible Preferred Share Shares ($14MM principal & $6.50 share conversion) ($8MM principal & $2.50 share conversion)	5,833,973
Convertible Notes ($4.8MM principal & $6.50 share conversion) ($4.8MM principal & $5.00 share conversion) ($2.4MM principal & $2.50 share conversion)	3,025,431
Fully Diluted Common Shares	10,181,588

Value Proposition Summary

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