# 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): April 19, 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 200**
**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 OTCQB 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 |
| 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: April 19, 2024

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


KIROMIC
BioPharma
Revolutionizing CAR T-Cell Therapy
April 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, 2023, 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.

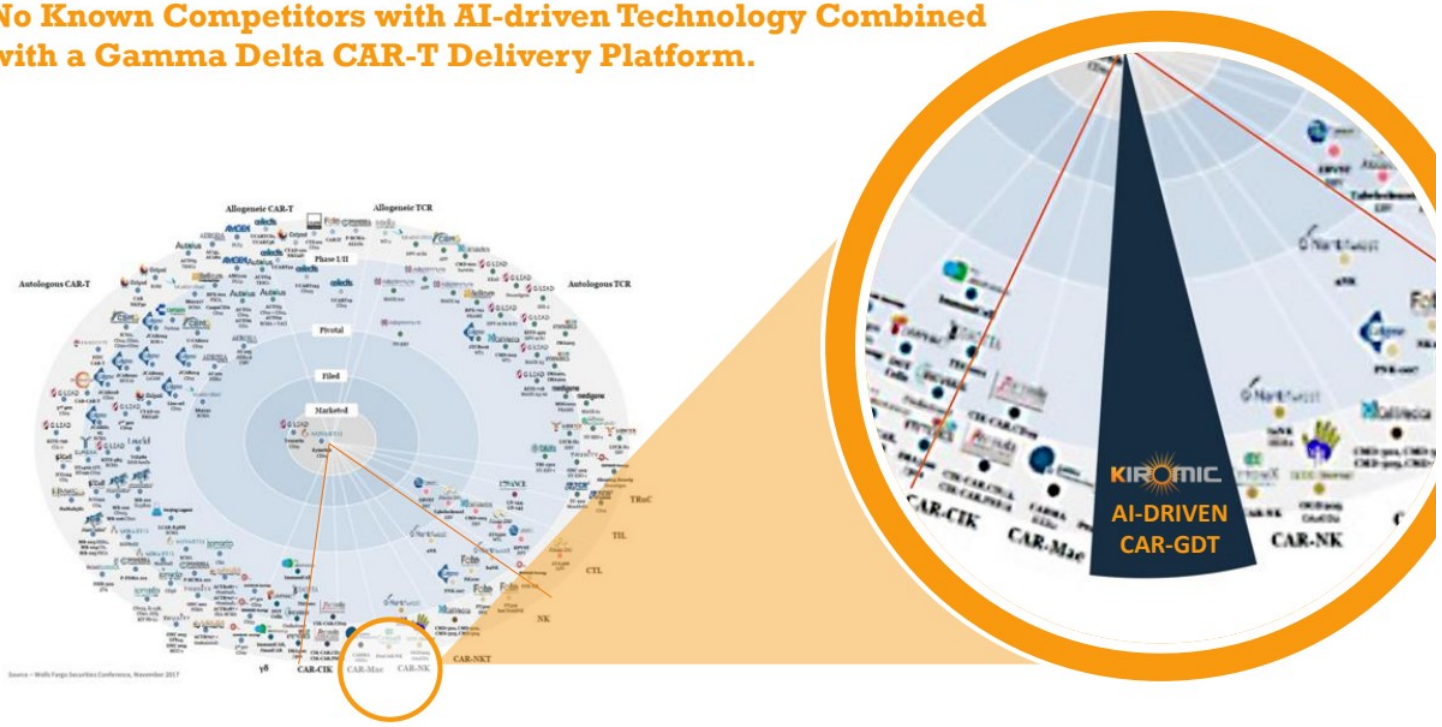
# Contents

# The Kiromic Difference

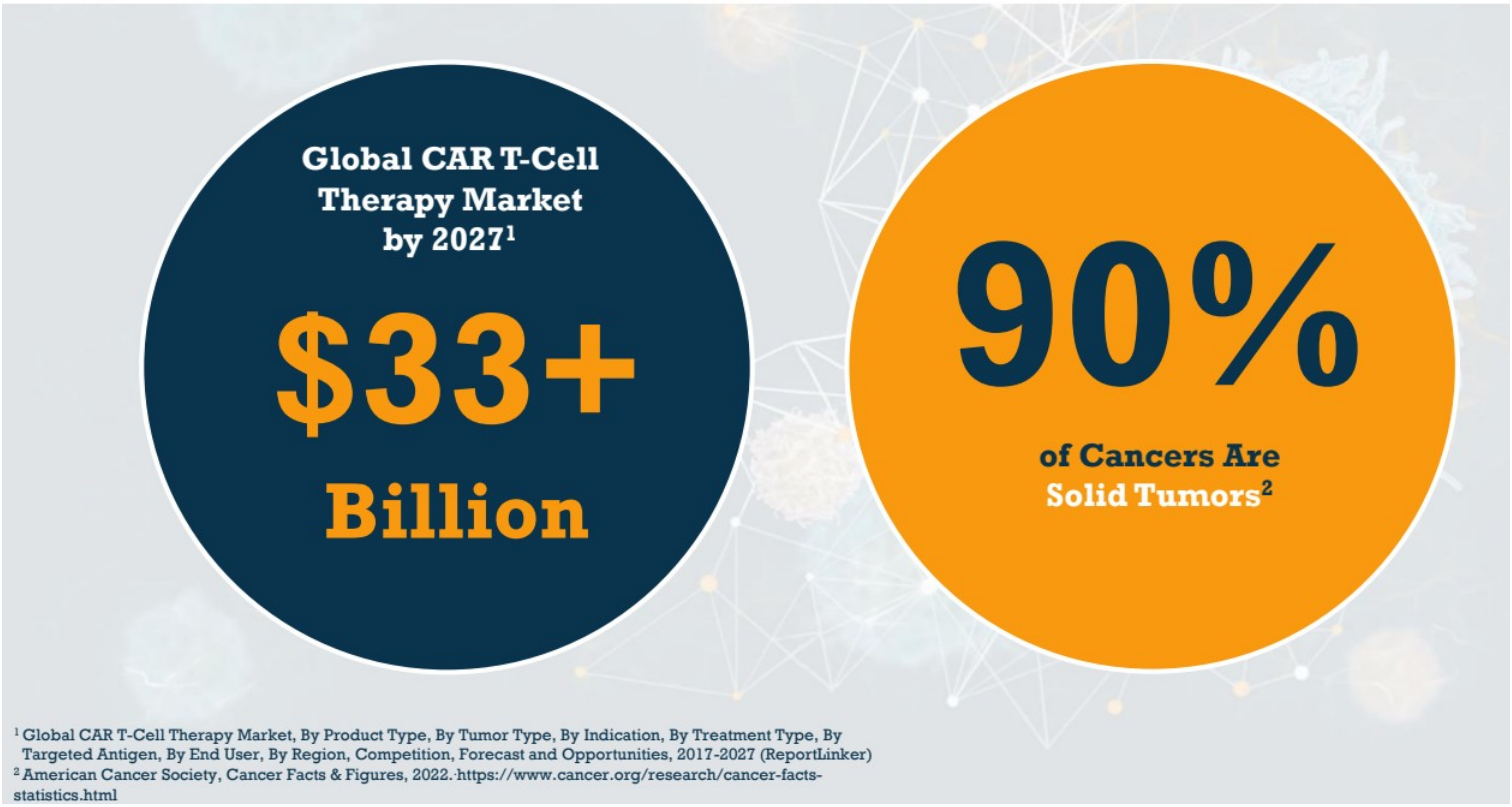
# Competitive Landscape

## 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 hospitalizatio 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

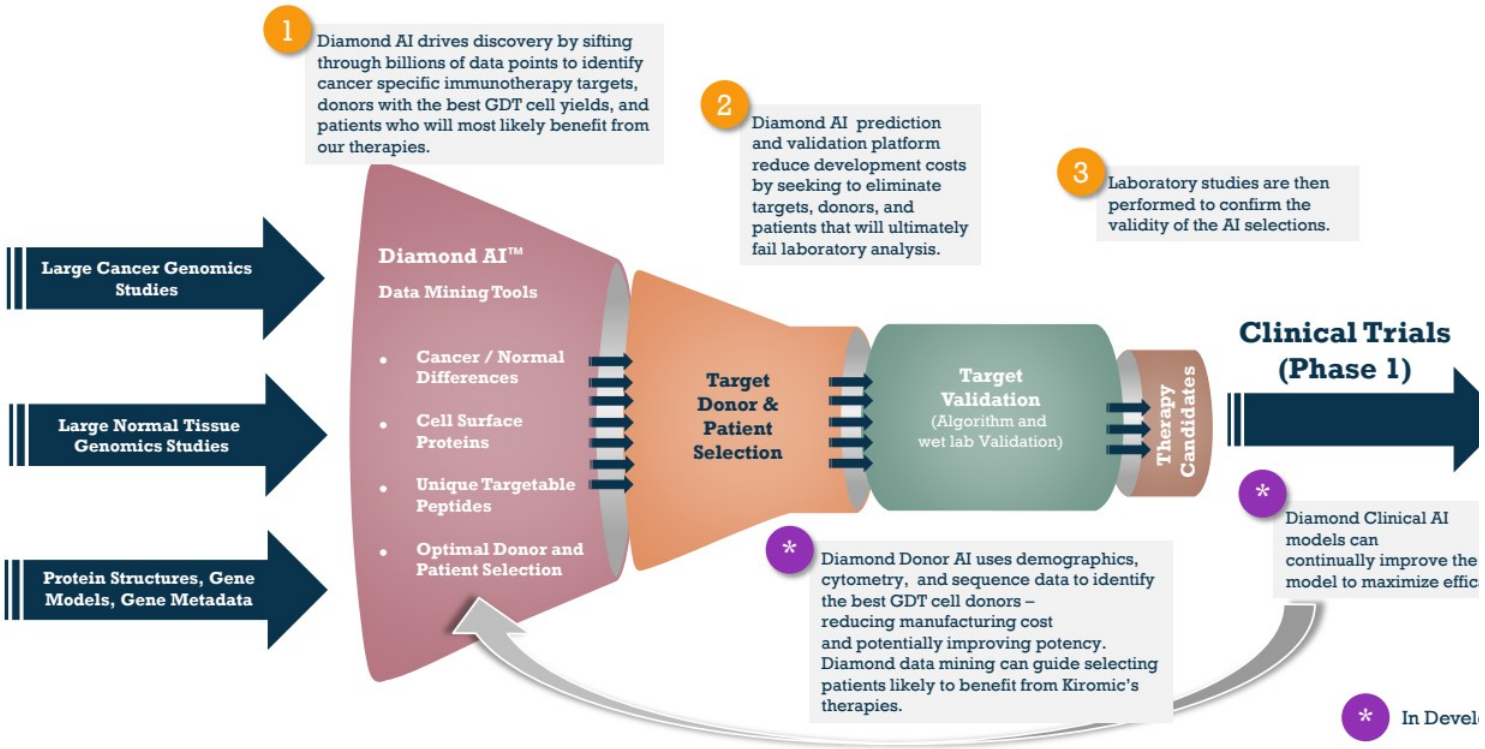

**AI Integrated with Each Stage of the Kiromic Therapy Production Lifecycle**

**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

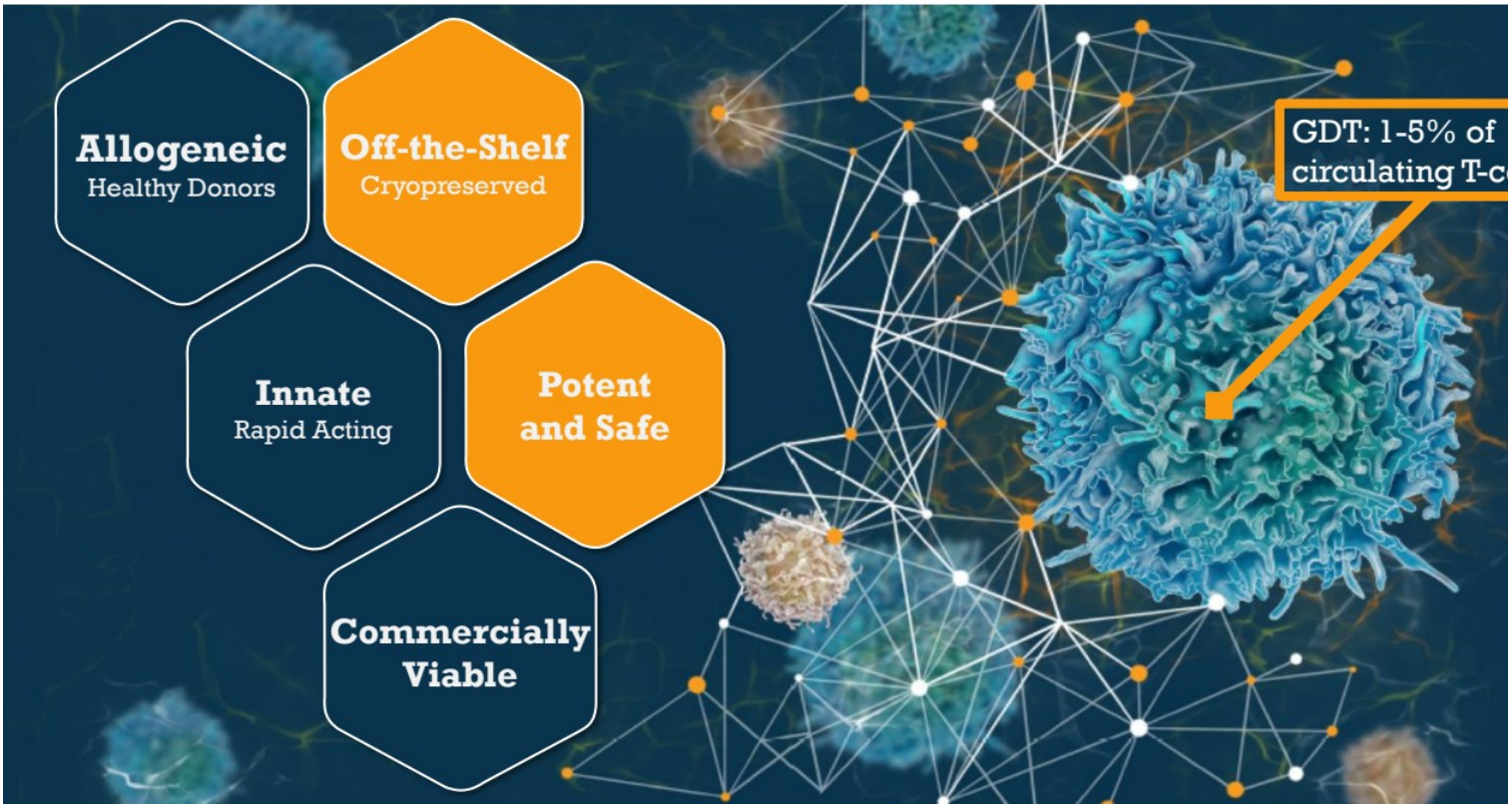
### Isocel™

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

### Procel™

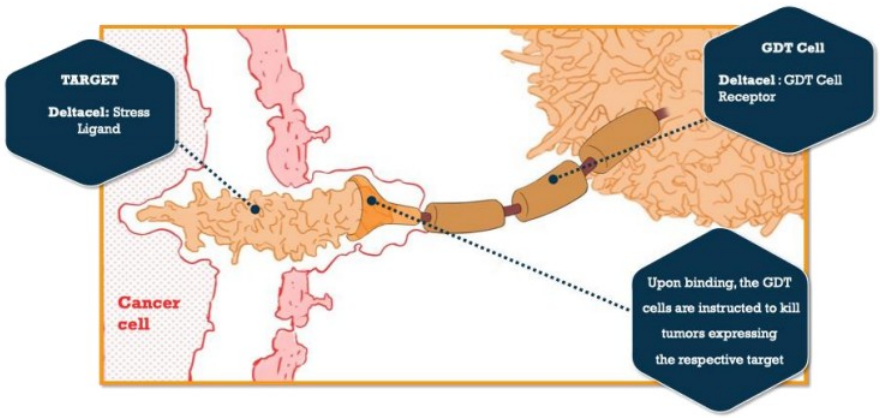
Engineered off-the-shelf product candidate targeting PDL-1+ tumors

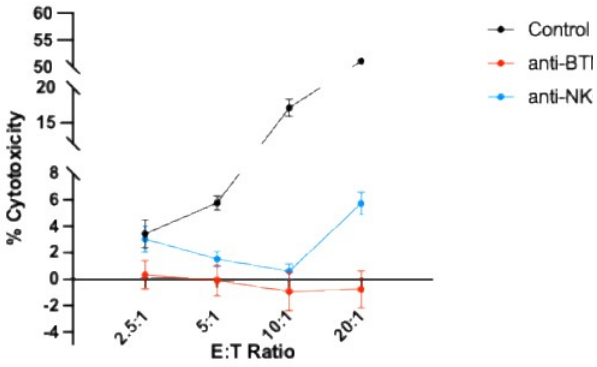
# Gamma Delta T-Cells: Guardians of the Immune System



# Deltacel: Non-Viral Gamma Delta T-Cell Development

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

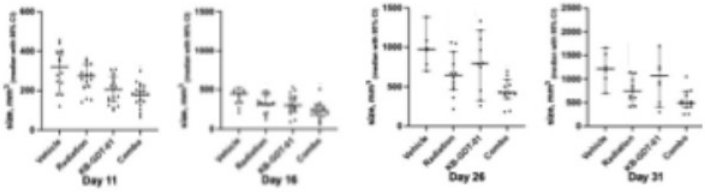


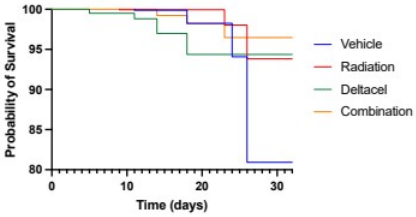
# KB-GDT-01 T-Cell Therapy (Deltacel) Strong Efficacy

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

Tumor Size




Survival

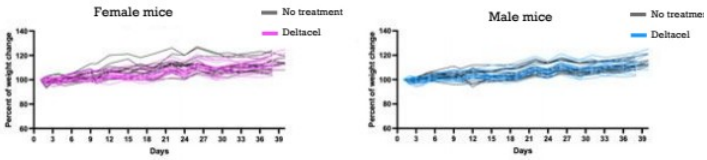



# KB-GDT-01 T-Cell Therapy (Deltacel) Strong Safety

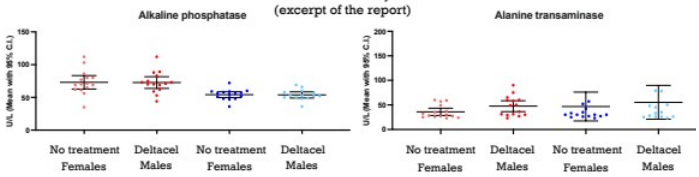
**Deltacel™ does not cause any macroscopic or microscopic toxicit even when given at over 8x the maximum dose that will be tested the clinical trial**

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



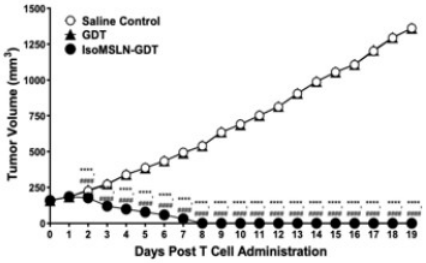

Blood chemistry (excerpt of the report)



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

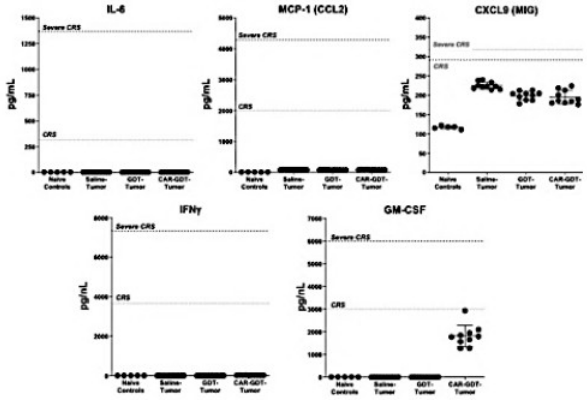
**Isocel eradicates established NCI-H226 pleural epithelioid mesothelioma and prevents tumor growth in a model of recurrence.**

**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.**

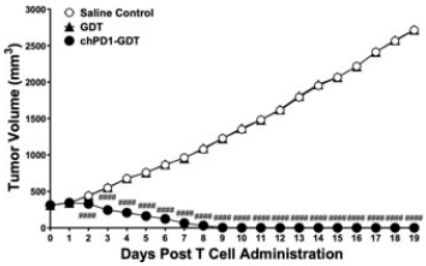



*Preclinical models: nude mice with subcutaneous NCI-H226 cells injections

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

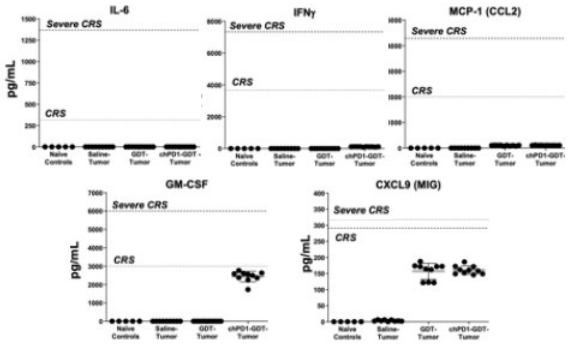
**Procel eradicates established NCI-H226 pleural epithelioid mesothelioma and extends survival.**

**Tumor eradication**



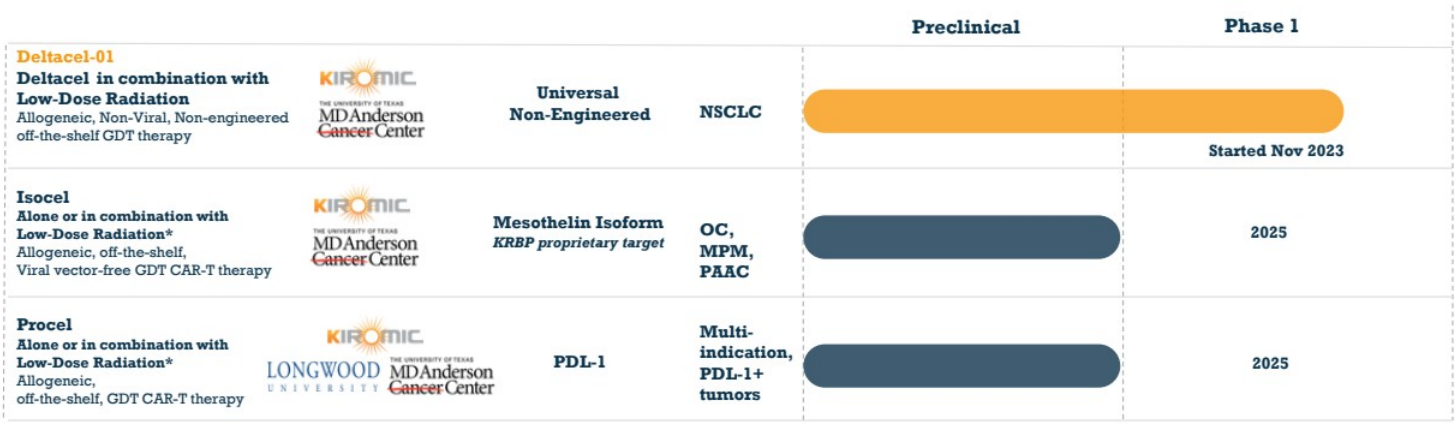

# GDT chPD1 T-Cell Therapy (Procel)* Strong Safety

**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

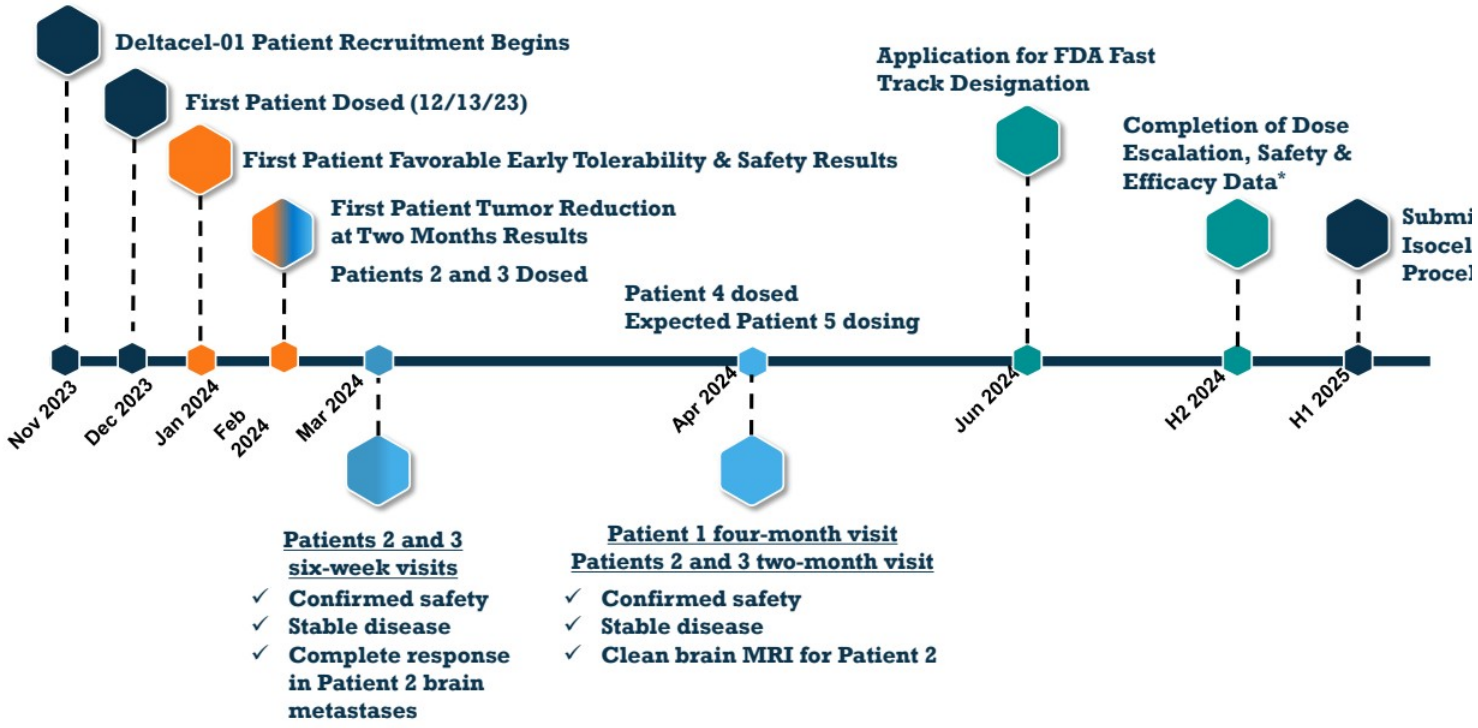
- **Secondary outcome measures:**
  - Objective response, progression-free survival, overall survival, time to progression, time to treatment response and disease control rates

### 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%<br>✓ Tumor metabolism reduction by 20% | ✓ Stable diseas (compared w month follow- |
| 2 | ✓ No dose limiting toxicities | ✓ Stable disease<br>✓ Complete resolution of brain lesions | ✓ Stable disease<br>✓ Confirmed clean brain imaging<br>✓ No new brain lesions | ❑ Expected in J |
| 3 | ✓ No dose limiting toxicities | ✓ Stable disease | ✓ Stable disease | ❑ Expected in J |

✓ Patient 4 completed treatment in April 2024
✓ Patient 5 expected to complete treatment in April 2024
❑ Early efficacy evaluation for both patients expected in May 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

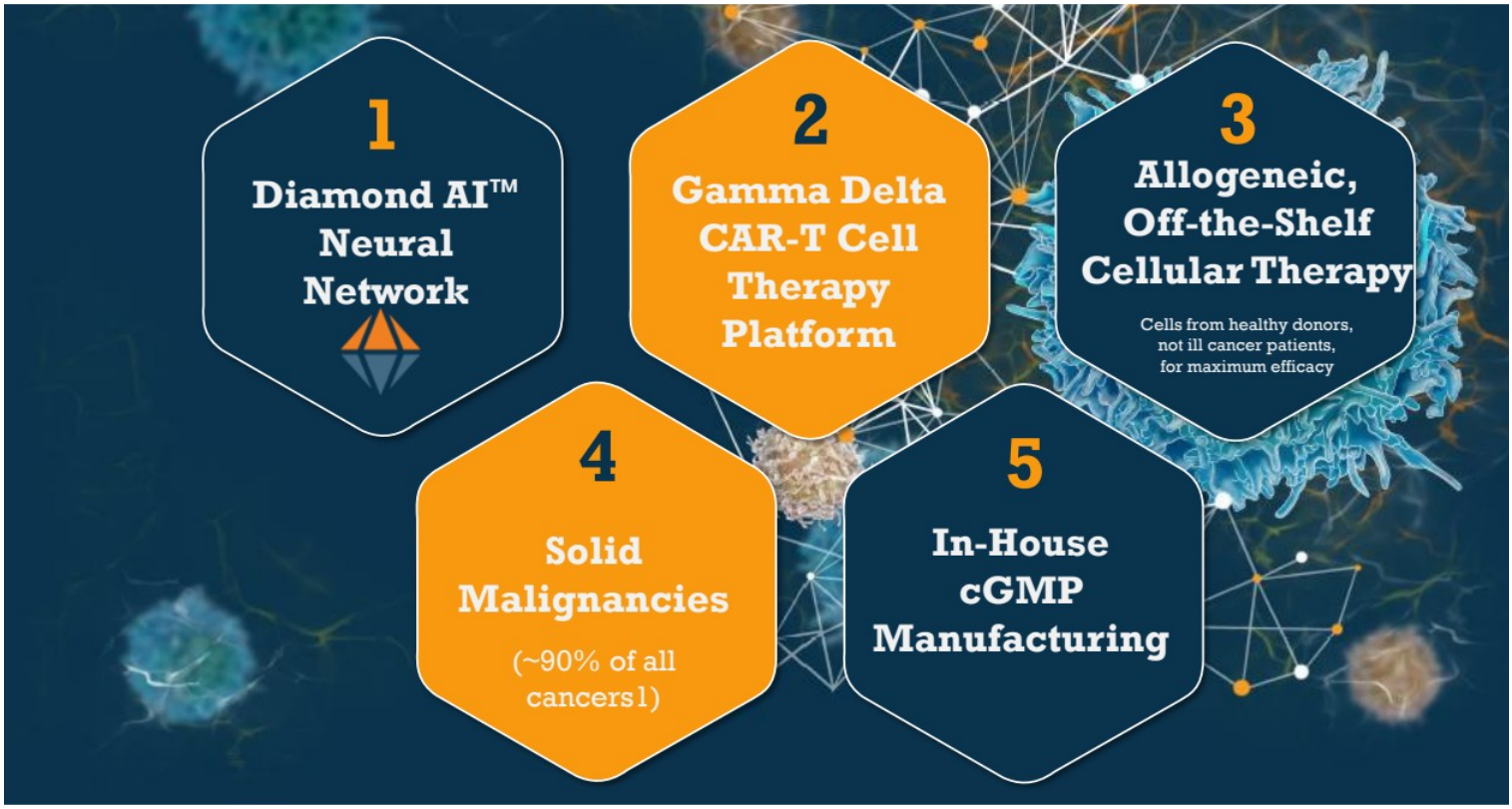
| Michael Nagel | Pietro Bersani | Pam Misajon | Michael Catlin |
|---|---|---|---|
| Chairperson | CPA, CGMA<br>Director | Independent Director | Independent Director |

# Summary Balance Sheet & Cap Table

| **Balance Sheet Data**<br>(As of December 31, 2023) | **As Reported**<br>**($ in 000s)** |
|---|---|
| **Cash and Cash Equivalents** | **$3,204** |
| **Working Capital** | **($15,948)** |
| **Total Assets** | **$12,169** |
| **Total Stockholders' Deficit** | **($9,121)** |

| **Cap Table**<br>(As of December 31, 2023) | **Common Stock Equivalents** |
|---|---|
| **Common Stock** | 1,258,460 |
| **Restricted Stock Units**<br>($4.13 Weighted average grant date fair value) | 30,167 |
| **Options**<br>($101.04 Weighted average exercise price) | 18,093 |
| **Warrants** | 15,416 |
| **Convertible Preferred Share Shares**<br>($14MM principal & $6.50 share conversion) | 2,493,151 |
| **Convertible Notes**<br>($4.8MM principal & $6.50 share conversion)<br>($4.8MM principal & $5.00 share conversion)<br>($2.0MM principal & $2.50 share conversion) | 3,670,030 |
| **Fully Diluted Common Shares** | 7,485,316 |

# Value Proposition Summary

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