# ELUTIA Medicine Humanized

**C. Randal Mills** PhD Chief Executive Officer

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May 9, 2024

## **Forward-Looking Statements**

This presentation of Elutia Inc. ("Elutia," "we," "us," "our" or the "Company") (together with any other statements or information that we may make or discuss in connection herewith) contains forward-looking statements. All statements other than statements of historical facts, including but not limited to statements regarding clearance of CanGarooRM with the U.S. Food and Drug Administration ("FDA"), the market potential and viability of CanGarooRM, our future financial condition, our results of operations, including, without limitation, cash flow improvement, business strategies, development plans, industry trends, regulatory activities, market opportunity, competitive position, potential growth opportunities, our products, their targeted effects and expected commercial availabilities, our pipeline and investments in new products and technologies, approvals of future products or product uses, expectations regarding continued acquisitions, ability to close and execute on strategic transactions and the potential results of such transactions, are forward-looking statements. In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "aim," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions. Forward-looking statements are based on our management's current expectations, beliefs and assumptions and on information currently available to us. The future events and trends discussed in this presentation may not occur and actual results could differ materially and adversely from those anticipated or implied in the forward-looking statements.

The forward-looking statements in this presentation are only predictions. These statements involve known and unknown risks, uncertainties and other important factors that may cause the Company's actual results, performance or achievements expressed or implied by the forward-looking statements due to various factors, including, but not limited to: our ability to obtain regulatory approval or other marketing authorizations by the FDA and comparable foreign authorities for our products and product candidates; our ability to continue as a going concern; the risk of product liability claims and our ability to obtain or maintain adequate product liability insurance; our ability to defend against the various lawsuits related to FiberCel and VBM and avoid a material adverse financial consequence; our ability to achieve or sustain profitability; our ability to enhance our products, expand our product indications and develop, acquire and commercialize additional product offerings; our dependence on our commercial partners and independent sales agents to generate a substantial portion of our net sales; our dependence on a limited number of third-party suppliers and manufacturers, which, in certain cases are exclusive suppliers for products essential to our business; our ability to successfully realize the anticipated benefits of the sale of our Orthobiologics Business; physician awarenees of the distinctive characteristics, benefits, safety, clinical efficacy and cost-effectiveness of our products and/or greater resources than we do; pricing pressure as a result of cost-containment efforts of our customers, purchasing groups, third-party payors and governmental organizations could adversely affect our sales and profitability; our ability to obtain, maintain and adequately protect our intellectual property rights; and other important factors may be updated from time to time in our other filings with the Securities and Exchange Commission ("SEC"), including our Annual Report on Form 10-K for the year ended December 31, 2023

This presentation may include a discussion of certain non-GAAP financial measures, including non-GAAP gross profit, non-GAAP gross margins, EBITDA and adjusted EBITDA. We use non-GAAP financial measures to evaluate our ongoing operations and for internal planning and forecasting purposes. We believe that non-GAAP financial measures are helpful to investors for supplemental informational purposes. We recommend that you do not rely on any single financial measure to evaluate our business. Reconciliations of these non-GAAP financial measures to the most comparable GAAP financial measure are available in an appendix to this presentation and in the Company's earnings press release dated May 9, 2024.

This presentation may also contain statistical data, estimates and/or other information or data made by independent parties and/or by us relating to market size and growth, as well about our industry and business. Any such data or information that is based on estimates, forecasts, projections, market research, or similar methodologies, involve a number of assumptions and limitations and are inherently subject to uncertainties, and we have not independently verified the accuracy or completeness of these data. Neither we nor any other person makes any representation as to the accuracy or completeness of such data or undertakes any obligation to update such data after the date of this presentation. In addition, projections, assumptions and estimates of our future performance and the future performance of our industry or the markets in which we operate are necessarily subject to a high degree of uncertainty and risk.



# Introducing ELUTIA

**Our Mission** Humanizing Medicine so patients can thrive without compromise

Commercial-stage company with a **\$27M revenue** run rate and two high-growth proprietary product platforms:



We are pioneering the **drug-eluting biomatrix (DEB)** to solve complex surgical problems not addressed by current technology.

- We expect FDA clearance of our first DEB CanGarooRM in June
- CanGarooRM has a market potential of over \$600M



# **Business Highlights**

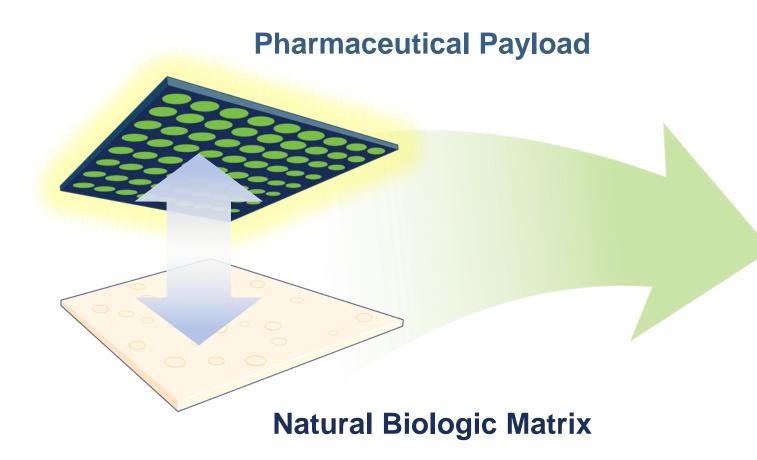


**SimpliDerm**<sup>®</sup>

YoY Revenue 55% growth CanGaroo® RM FDA Clearance June expected



## Drug-Eluting Biologics Solve These Problems Without Compromise



## **The Drug-Eluting BioMatrix**

- ✓ Structural integrity
- Surgical site healing
- ✓ Therapeutic delivery
- Regenerates patient's own tissue



Medicine Humanized™

# Cangaroo® & Cangaroo® RM ANTIBIOTIC-ELUTING BIOMATRIX



## Each year over **500,000** CIEDs are placed in the U.S.



Approximate market share by CIED manufacturer



# The unmet need for CanGaroo®RM



## Most CIED failures occur at the device-host interface



## TYRX introduced a synthetic antibiotic-eluting envelope





## Introducing CanGaroo® RM ANTIBACTERIAL ENVELOPE

Features	TYRX	CanGarooRM
Antibiotic Eluting	$\checkmark$	$\checkmark$
Standard Incision		$\sim$
Erosion/Thin Skinned		$\sim$
Fibrosis and Inflammation		$\checkmark$
Defibrillation Threshold		$\sim$

88%

TYRX users would start using

CanGaroo® RM ANTIBACTERIAL ENVELOPE

# A more complete solution for a \$600M market

2021 Marketing Survey. Data on file.



## Advancing towards FDA Clearance of CanGarooRM

## FDA interactions continue to be positive, working through final details

- Working collaboratively to ensure long-term success of our product
- Closing out remaining inquiries within the month
- FDA decision anticipated in June



# Focused Commercialization Strategy

## **Tiered Approach to Launch**

- Existing CanGaroo customers (356 centers)
- Abbott and Boston customers using TYRX
- Medtronic TYRX users and non-envelope physicians
- Scaling production at our manufacturing site in Atlanta

\$100M revenue opportunity



# SimpliDerm® BIOMATRIX





## Role of biomatrices in breast reconstruction



- About 13% (1 in 8) of women will develop invasive breast cancer in their lifetimes
- This leads to ~151,000 mastectomies requiring reconstruction in the U.S.





Subpectoral

Prepectoral

Breast Cancer Facts and Statistics". *BreastCancer.org*, Jan 18, 2023.



# SimpliDerm: Setting a New Standard

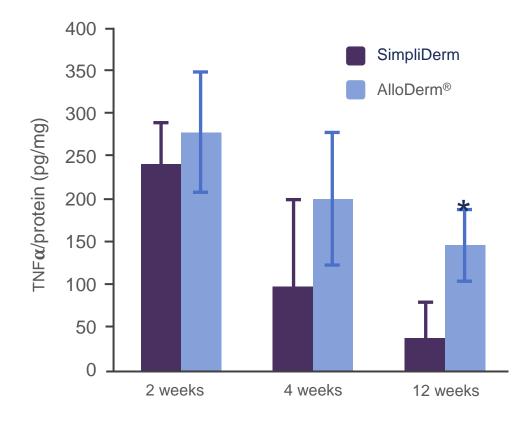
- Exceptional Handling and Consistency
  - Conforming and flexible
- Superior Sterility Assurance Level (SAL)
  - Pre-hydrated and terminally sterilized to a SAL of 10<sup>-6</sup>, surpassing that of competitive products
- Excellent Biocompatibility
  - Innovative processing minimizes potential for fibrosis and inflammatory response

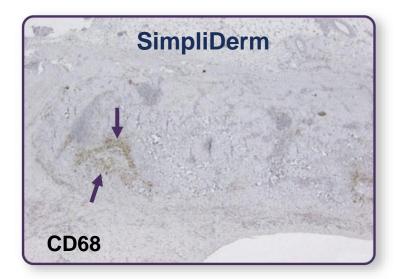


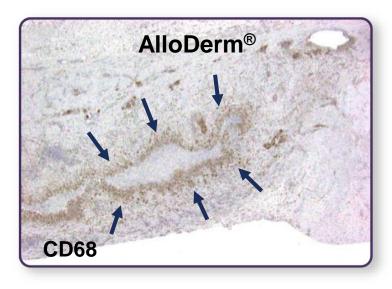


# Reduction of inflammatory response with SimpliDerm

#### Nonhuman Primate Model







\* P=0.034

Source: Ji et al., PRS Global Open, 2021

# Clinical demonstration of less immunogenicity Red Breast Syndrome and Acellular Dermal Matrix

Allison Podsednik Gardner, BA\* Aidee Nunez, NP† Mauricio De la Garza, MD\*†

Summary: Increasingly popular for use in breast reconstruction, acellular dermal matrix (ADM) can provide support and protection to implants. However, use of ADM may be associated with infection and complications, including red breast syndrome (RBS). RBS is an inflammatory event that typically presents with cutaneous erythema over the domain where the ADM is surgically implanted. As ADM use increases, presumably, more cases of RBS will occur. Thus, techniques and tools to mitigate or manage RBS are needed to improve patient outcomes. Here, we describe a case where RBS was diagnosed and interestingly resolved after exchange for a different brand of dermal matrix. This surgical resolution maintained excellent reconstructive results with no recurrent erythema over a follow-up period of 7 months. Although we cannot rule out RBS due to other variables, RBS due to patient hypersensitivity to certain ADMs has been documented in the literature. In this instance, our results suggest that revision with an alternate ADM brand may serve as a potential solution. (*Plast Reconstr Surg Glob Open 2023; 11:e5062; doi: 10.1097/GOX.00000000005062; Published online 12 June 2023.*)

The case study of red breast syndrome demonstrates SimpliDerm's rapid alleviation of inflammatory symptoms, and its competitive advantage.



## A \$1.6B opportunity to improve outcomes in breast recon

## SimpliDerm – simply a great product

### 55% growth in 1Q24

### **Effective Distribution Network**

- Highly trained, proprietary network of distributors
- Early stages of non-exclusive partnership (Sientra, recently acquired by Tiger)

## **Results surgeons can see for themselves**





## **Financial Update**

### 1Q 2024 vs 1Q 2023

- Net sales \$6.7M vs \$6.4M
- GAAP gross margin 42% vs 53%
- Adjusted gross margin<sup>1</sup> 55% vs 66%
- Operating expense \$11.3M vs \$11.7M
- Net loss \$18.0M vs \$8.0M
- Adjusted EBITDA<sup>2</sup> loss \$3.6M vs \$4.8M

### Cash balance of \$12.6M as of 3/31/2024

- 1. Adjusted gross margin is defined as gross profit excluding intangible asset amortization expense divided by net sales. See Elutia's earnings press release dated May 9, 2024 for a reconciliation of adjusted gross margin to GAAP gross margin
- Adjusted EBITDA is defined as net loss excluding interest expense, provision for income taxes, depreciation and amortization, income from discontinued operations, stock-based compensation, FiberCel litigation costs, loss on revaluation of warrant liability and gain on revaluation of revenue interest obligation. See Elutia's earnings press release dated May 9, 2024 for a reconciliation of net loss to adjusted EBITDA.





# **ELUTIA** Positioned for Growth

**Our Mission** Humanizing Medicine so patients can thrive without compromise

- Fully integrated company with R&D, manufacturing, sales, and two established biomatrix product platforms with \$27M in revenue.
- Pioneering the drug-eluting biomatrix (DEB) technology platform that solves serious complications
- CanGarooRM Expected to be the first drug-eluting biologic envelope
  - Expect clearance decision in June
  - o \$600M market, with only one competitor
- SimpliDerm has a \$14.3M run rate, growing at 55%
- Exceptional team and resources to execute growth plan



# Thank you





## Appendix



#### **ELUTIA INC.**

#### NON-GAAP RECONCILIATIONS OF ADJUSTED GROSS PROFIT AND ADJUSTED GROSS MARGIN

(Unaudited, in thousands, except share and per share data)

	Th	Three months ended March 31,			
		2024		2023	
Net sales	\$	6,694	\$	6,392	
Gross profit		2,843		3,374	
Intangible asset amortization expense		849		849	
Adjusted gross profit (non-GAAP)	\$	3,692	\$	4,223	
Gross margin		42.5%		52.8%	
Adjusted gross margin percentage (non-GAAP)		55.2%		66.1%	



#### ELUTIA INC.

#### NON-GAAP RECONCILIATIONS OF EBITDA AND ADJUSTED EBITDA

#### (Unaudited, in thousands, except share and per share data)

	Three months ended March 31,			
	2024		20	023
Net loss	\$	(17,994)	\$	(7,974)
Interest expense <sup>(1)</sup>		1,313		1,430
Provision for income taxes		8		12
Depreciation and amortization		864		947
Earnings before interest, taxes, depreciation and amortization ("EBITDA") (non-GAAP)		(15,809)		(5,585)
Income from discontinued operations		-		(1,807)
Stock-based compensation		2,197		684
FiberCel litigation costs <sup>(2)</sup>		1,785		1,911
Loss on revaluation of warranty liability <sup>(3)</sup>		9,637		-
Gain on revaluation of revenue interest obligation <sup>(4)</sup>		(1,443)		-
Adjusted EBITDA (non-GAAP)	\$	(3,633)	\$	(4,797)

1. Represents interest expense recorded on all outstanding long-term debt as well as the revenue interest obligation.

- 2. Represents FiberCel litigation costs consisting primarily of legal fees and the estimated and actual costs to resolve the outstanding FiberCel litigation cases offset by the estimated amounts recoverable and recovered under insurance, indemnity and contribution agreements for such costs.
- 3. Represents non-cash expense attributable to the revaluation of Common Warrants and Prefunded Warrants issued in connection with a private offering of Class A common stock on September 21, 2023.
- 4. Represents the gain on the revaluation of the revenue interest obligation. At each reporting period, the value of the revenue interest obligation is re-measured based on current estimates of future payments, with changes to be recorded in the consolidated statements of operations using the catch-up method.

