ELUTIA

Medicine *Humanized*™

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

**Matt Ferguson**
Chief Financial Officer

September 13, 2023

# 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 future financial condition, 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 to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements due to various factors, including, but not limited to our ability to enhance our products, expand our product indications and develop, acquire and commercialize additional product offerings; the impact on our business of the recall of a single lot of our FiberCel product and the discontinuation of its sales by our distribution partner; our dependence on our commercial partners and independent sales agents to generate a substantial portion of our net sales; our ability to maintain our relationships with our existing contract manufacturing customers and enter into agreements with new contract manufacturing customers, or if existing contract manufacturing customers reduce purchases of our products; our ability to successfully expand, manage and maintain our direct sales force; our ability to achieve or sustain profitability; the adverse impacts of the novel strain of coronavirus disease, COVID-19 or any other future pandemic, epidemic or outbreak of an infectious disease in the United States or worldwide; adverse changes in general domestic and global economic conditions and instability and disruption of credit markets; the Company’s ability to continue as a going concern; physician awareness of the distinctive characteristics, benefits, safety, clinical efficacy and cost-effectiveness of our products; the continued and future acceptance of our products by the medical community; our ability to obtain regulatory approval or other marketing authorizations by the FDA and comparable foreign authorities for our products and product candidates; and our ability to obtain, maintain and adequately protect our intellectual property rights and other important factors discussed under the caption “Risk Factors” section of Elutia’s public filings with the Securities and Exchange Commission (“SEC”), including our Annual Report on Form 10-K for the year ended December 31, 2022, as such factors may be updated from time to time in our other filings with the SEC, including, our Quarterly Reports on Form 10-Q, accessible on the SEC’s website at www.sec.gov and the Investor Relations page of Elutia’s website at www.Elutia.com. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, levels of activity, performance, achievements or events and circumstances reflected in the forward-looking statements will occur. Except to the extent required by law, we do not undertake to update any of these forward-looking statements after the date of this presentation to conform these statements to actual results or revised expectations. Forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified.

This presentation may include a discussion of certain non-GAAP financial measures, including non-GAAP gross profit and non-GAAP gross margins. We use the 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. If non-GAAP financial measures are included in the presentation, a reconciliation of these non-GAAP financial measures to the most comparable GAAP financial measure is included as an appendix.

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

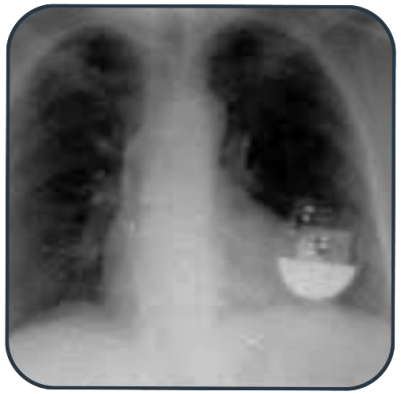
*Humanizing*

medicine
so patients can

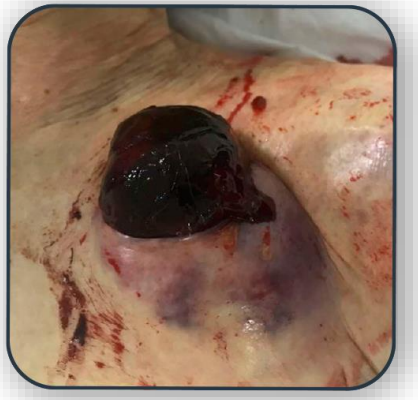
**thrive without compromise.**

- Elutia is a **commercial-stage** company with product platforms in CIED and breast reconstruction
- We are pioneering the **drug-eluting biomatrix (DEB),** which solves problems unaddressed by available alternatives
- We expect to **launch CanGarooRM in 2024,** a first-in-class active biomatrix with a therapeutic payload
- CanGarooRM has **market potential of $600M+** in the established pacemaker/cardiac implant space
- We intend to leverage our DEB platform technology by developing and commercializing products for **markets with similar unmet needs,** including neurostimulation, wound care, and breast reconstruction

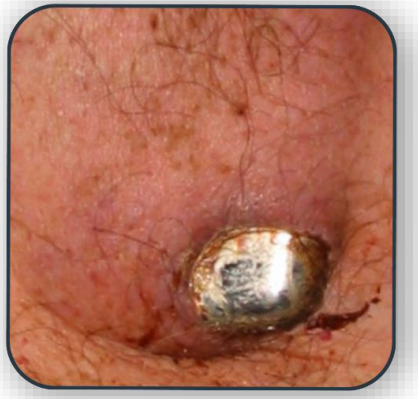
# Serious challenges arise from **device implantation**



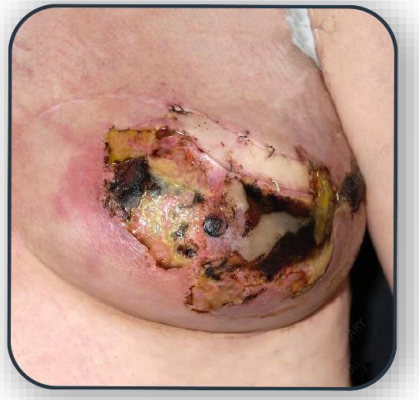
MIGRATION



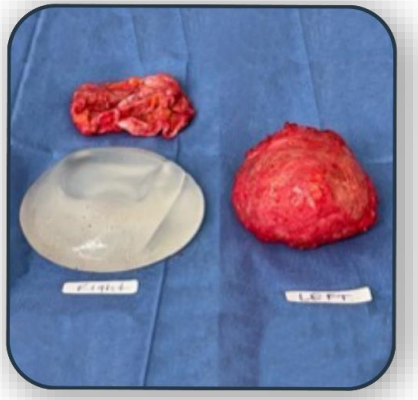
HEMATOMA



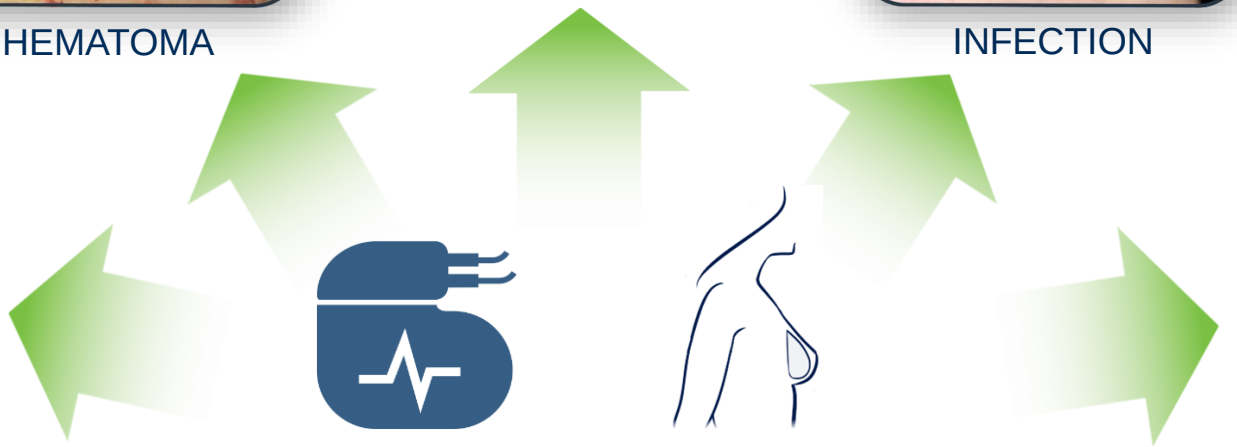
EROSION



INFECTION



FIBROSIS / CONTRACTURE



**7-11%**
pacemakers

**12-20%**
breast recon

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# Elutia is **breaking silos** to develop great solutions

Biologic
**Remodeling**

Pharmaceutical
**Activity**

Device
**Structure**

DEB™
DRUG-ELUTING BIOMATRIX

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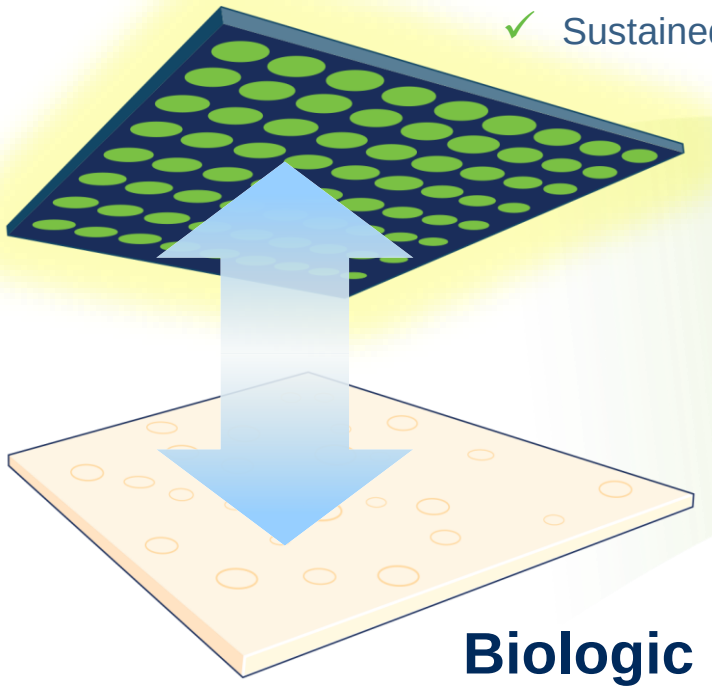
# Creating a **Compelling Combination**

## Therapeutic Payload

- ✓ Specific activity (antibiotic, etc.)
- ✓ Sustained release

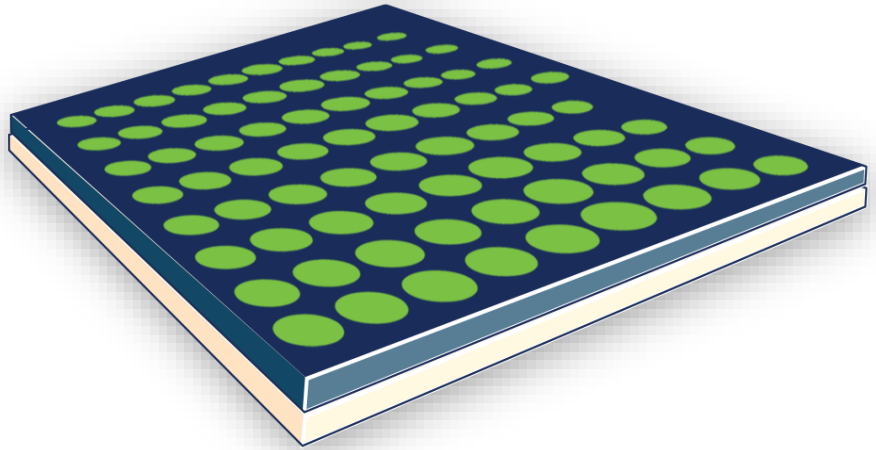


## Biologic Material

- ✓ Structural support
- ✓ Reduces inflammatory and fibrotic response

## The Drug-Eluting BioMatrix

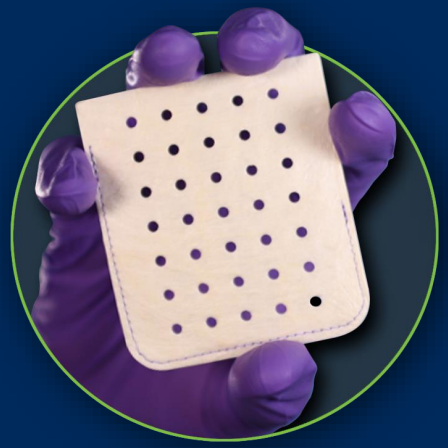
- ✓ Durable structural integrity
- ✓ Enhanced surgical site healing
- ✓ Targeted therapeutic delivery
- ✓ Remodels into patient's own healthy tissue




# A **Protected** Platform

- 40 issued U.S. patents
- Exclusive licensing agreement for SIS based ECM
- Specialized manufacturing facilities
- Proprietary product release assays

# Two Biologic Platforms



CanGaroo®

BIOENVELOPE

Cardiac Implantable Devices

SimpliDerm®

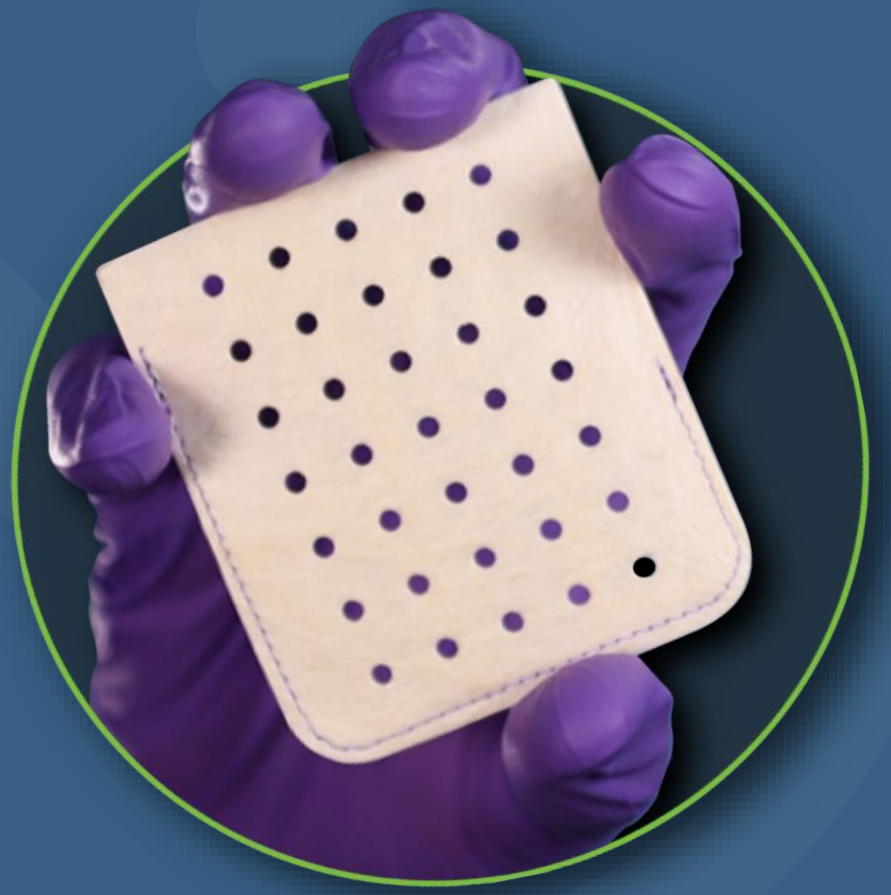
BIOMATRIX

Breast Reconstruction

# CanGaroo®
# &
# CanGaroo® RM

## DRUG-ELUTING BIOMATRIX

Creates a stable, healthy pocket for the placement of pacemakers, defibrillators, and neurostimulators.



# CanGarooRM Favorable market dynamics drive value

Medtronic **has the only antibiotic envelope on the market**

- Synthetic mesh containing antibiotics
- Medtronic acquired for up to $200M in 2014
- Targeted for CIED revision procedures

**Sales of $250-300 million per year (est), but…**

- Only addresses infection
- Synthetic does not support wound healing
- Does not fit larger devices (SCID)

**$600M**

**OPPORTUNITY**

in the pacemaker market with only **one other player**

# **Market Dynamics** – No one wants to be left without a pouch

**TYRX**
on the market

Medtronic
$300M annually
(est)

**CanGarooRM**
only other antibiotic pouch

Boston Scientific

Abbott

Biotronik

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# Next Generation CanGarooRM – The Obvious Choice

| Feature | TYRX | CanGaroo | CanGarooRM |
|---|---|---|---|
| Primary Placement | ✓ | ✓ | ✓ |
| Change Out | ✓ | ✓ | ✓ |
| Standard Incision | | ✓ | ✓ |
| Erosion/Thin Skinned | | ✓ | ✓ |
| Fibrosis and Inflammation | | ✓ | ✓ |
| Defibrillation Threshold | | ✓ | ✓ |
| Antibiotic Eluting | ✓ | | ✓ |

Introducing

## CanGarooRM

**Drug Eluting BioEnvelope**

with Rifampin and Minocycline

Coming to
Operating Theaters
Everywhere

**2024**

# Obtaining **FDA Approval** for CanGarooRM

**Received Not Substantially Equivalent Letter in March of 2023**

- Indicated that the review was satisfactory except for four items, two were administrative
- Two related to our IVE test
  1) FDA wanted an accelerated test (48hrs)
  2) Wanted >80% elution within that time

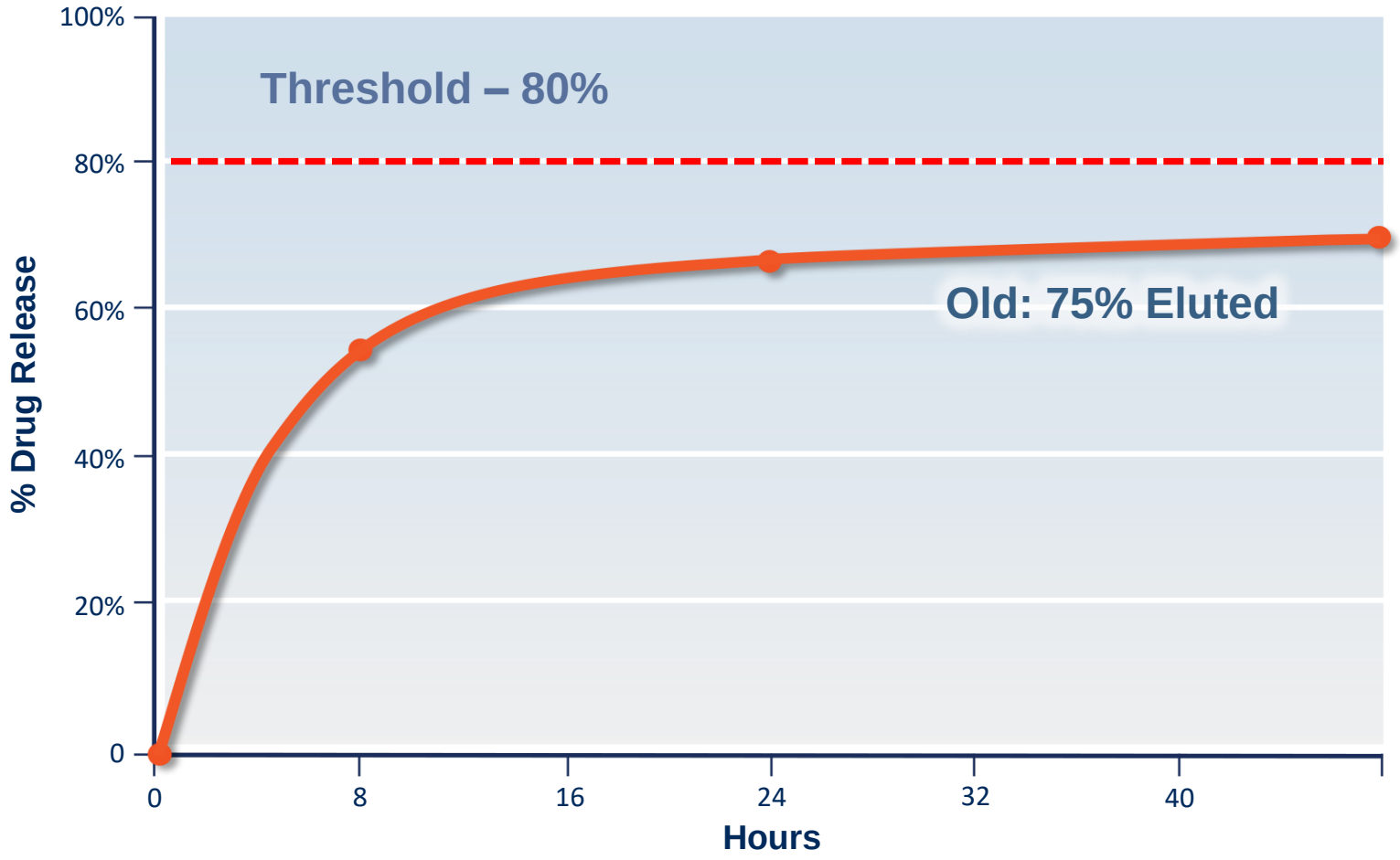
**Met with FDA to fully understand their request**

- Explained the device elutes the drug over weeks
- Suggested we try with non-physiologic conditions

**R&D team created a new test method specifically for CanGarooRM**

- Fully responsive to FDA's request
- Generated new IP

# **Generating the Data** FDA Requested

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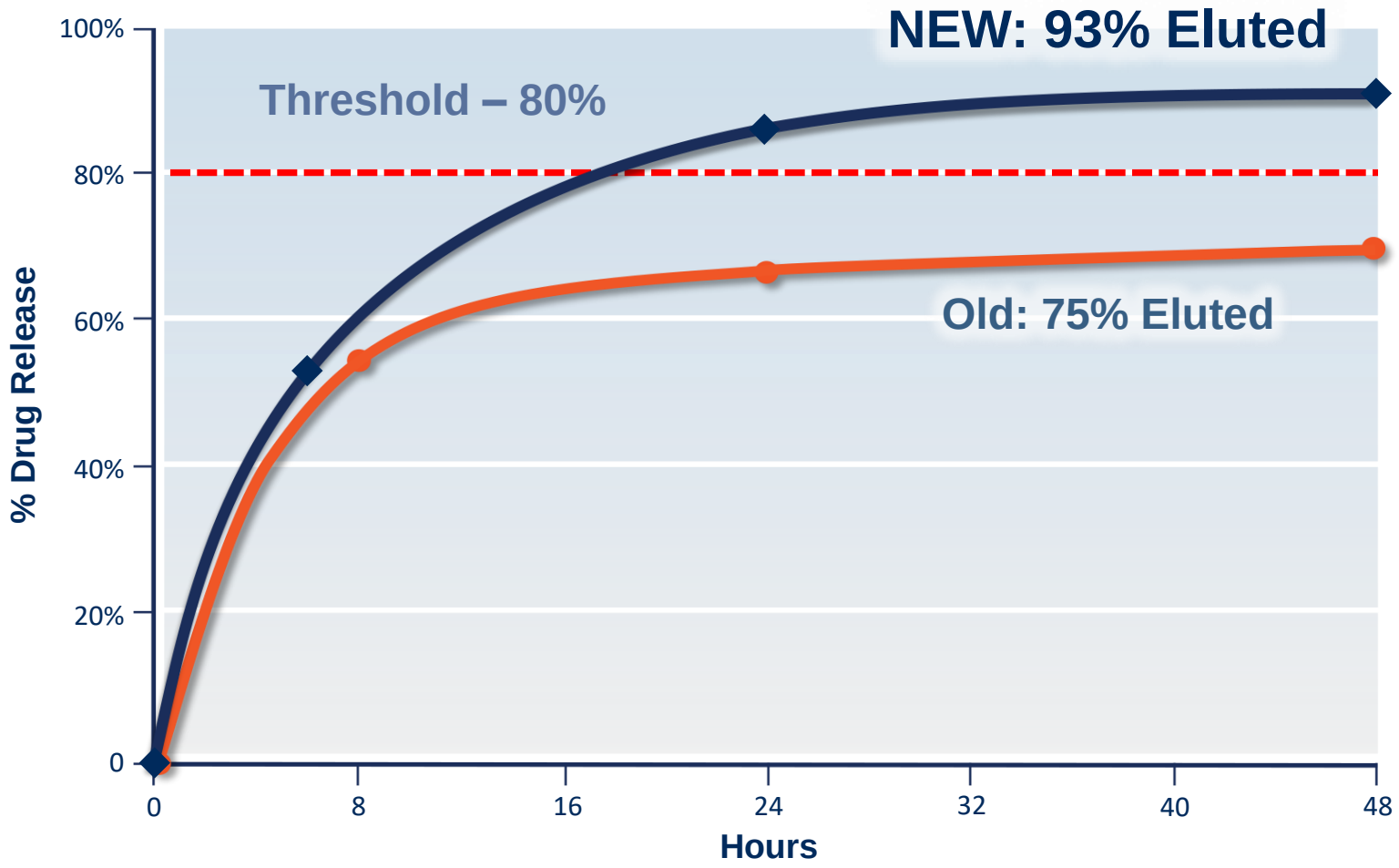
# **Generating the Data** FDA Requested




## New Methodology

- pH Optimization
- Agitation
- Surfactants
- Temperature Refinement

New Intellectual Property

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# Focused Pathway to **FDA Clearance of CanGarooRM**

## Remaining Items and Timeline for Approval

- Developing a revised drug elution test as requested by FDA
- Had collaborative discussions with FDA to develop testing plan
- Will submit new data and refile 510(k) with a significantly narrowed scope (4Q23)
- Only responding to four outstanding items
- Decision expected within 1H24

# SimpliDerm®

## BIOMATRIX

For use in the repair or replacement of tissue in postmastectomy reconstructive breast surgery.

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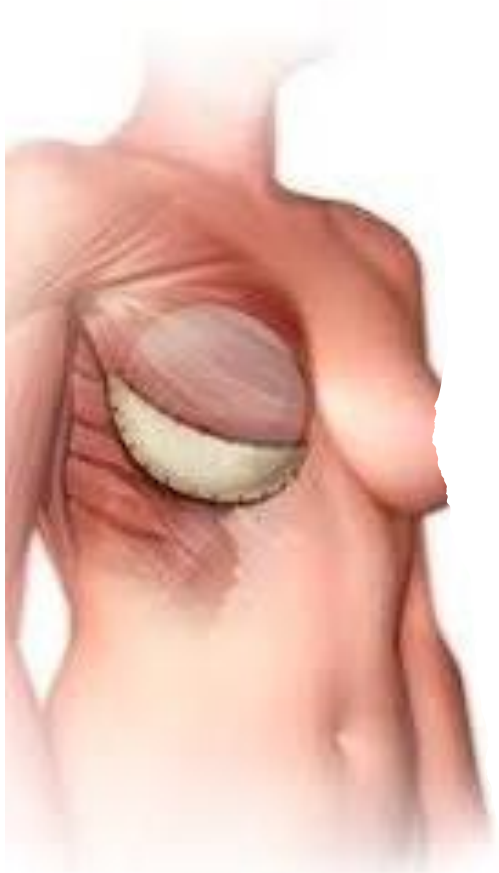
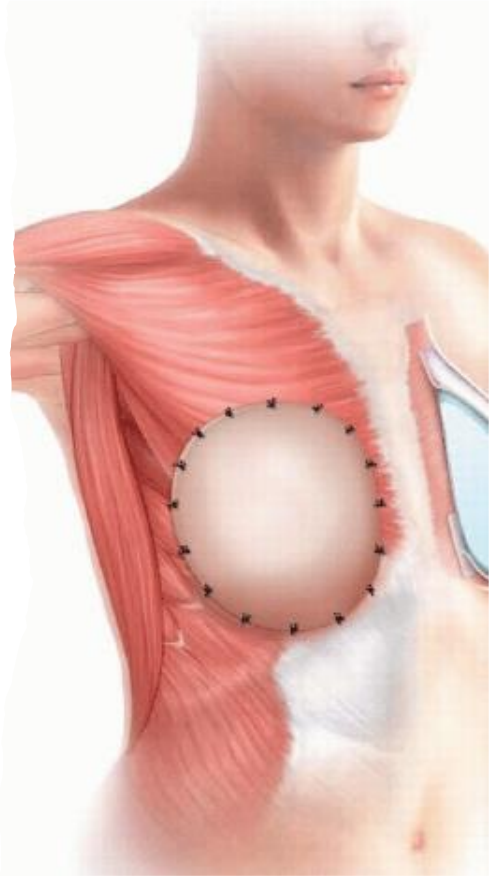
# **SimpliDerm** – Biomatrix critical for breast reconstruction



Subpectoral

- About 13% (1 in 8) of women will develop invasive breast cancer in their lifetimes
- This leads to approximately 140,000 mastectomies requiring reconstruction in the U.S.
- Alloderm is the market leader
  - Acquired by AbbVie as part of Allergan in 2020
  - Deemphasized marketing Alloderm

**Created an opening for SimpliDerm**



Prepectoral

"Breast Cancer Facts and Statistics". *BreastCancer.org*, Jan 18, 2023.
"Some women want flat chests after mastectomy. Some surgeons don't go along". *Washington Post*. Jun 11, 2022.

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

**SimpliDerm – simply a great product**

- ✓ Superior handling characteristics
- ✓ Prehydrated and sterile
- ✓ Lower pro-inflammatory M1 macrophage (TNFα) response
- ✓ Lower fibrotic response

**Results surgeons can see for themselves**

**Effective Distribution Network**

- Highly trained network of distributors
- New partnership with implant maker Sientra

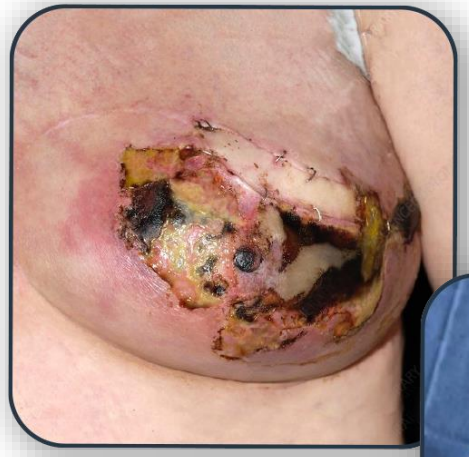
**140,000**

mastectomies requiring reconstruction in the U.S. Annually

"Breast Cancer Facts and Statistics". *BreastCancer.org*, Jan 18, 2023.
"Some women want flat chests after mastectomy. Some surgeons don't go along". *Washington Post*. Jun 11, 2022.

# SimpliDermRM – The future of breast reconstruction

- **1 out of 9** women experience a **significant infection** following breast reconstruction
- Increased risk for **capsular contraction**
- SimpliDermRM leverages our proprietary **antibiotic-eluting technology** from CanGarooRM
- IDE expected by **year-end 2024**

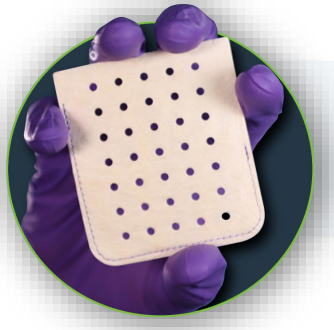


INFECTION

CAPSULAR CONTRACTURE

Bennett, K. G., *et al*. "Comparison of 2-Year Complication Rates Among Common Techniques for Postmastectomy Breast Reconstruction." *JAMA Surg.* 2018;153(10):901-908.
Yan, C., *et al*. "The cost of major complications associated with immediate two-stage expander/implant-based breast reconstruction." *J Plast Surg Hand Surg*. 2015;49(3):166-71.

# High Level **Development Strategy**

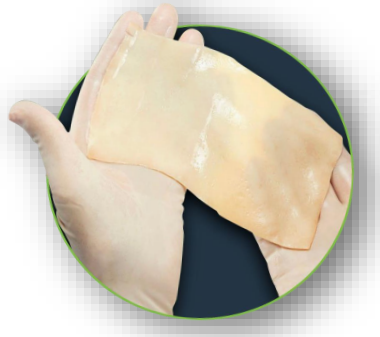


**CanGaroo®**
Cardiovascular

**CanGaroo® RM**
Cardiovascular

**CanGaroo® 360**

- Neuro Pain
- Urinary Incontinence
- Sleep Apnea
- Deep Brain Stim



**SimpliDerm®**
Breast Reconstruction

**SimpliDerm® RM**

- Breast Reconstruction

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# ELUTIA Positioned for Growth

*Humanizing*

medicine
so patients can

**thrive without compromise.**

- **Commercial-stage company** with with two established biomatrix product platforms
- Pioneering the **drug-eluting biomatrix** technology platform that solves real problems
- **CanGarooRM –** Expected to be the first drug-eluting biologic
  - Only other product in a $600M market
  - Expect clearance decision in 1H24
  - Expansion into adjacent markets (neurostim, sleep apnea)
- Positioning **SimpliDerm** to transform the breast reconstruction market by efficiently leveraging our DEB technology

# Thank you

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