MediWound

# Next-Generation Enzymatic Therapeutics for Non-Surgical Tissue Repair

January 2025 I Nasdaq: MDWD

# Cautionary Note Regarding Forward-Looking Statements

This presentation contains “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act and other securities laws, including but not limited to the statements related to the commercial potential of our products and product candidates, the anticipated development progress of our products and product candidates, and our expected cash runaway. In some cases, you can identify forward-looking statements by terminology such as “believe,” “may,” “estimate,” “continue,” “anticipate,” “intend,” “should,” “plan,” “expect,” “predict,” “potential,” or the negative of these terms or other similar expressions. Forward-looking statements are not historical facts, and are based upon management’s current expectations, beliefs and projections, many of which, by their nature, are inherently uncertain. Such expectations, beliefs and projections are expressed in good faith. However, there can be no assurance that management’s expectations, beliefs and projections will be achieved, and actual results may differ materially from what is expressed in or indicated by the forward-looking statements. Important factors that could cause such differences include, but are not limited to the uncertain, lengthy and expensive nature of the product development process; market acceptance of our products and product candidates; the timing and conduct of our studies of our product candidates; our ability to obtain marketing approval of our products and product candidates in the U.S. or other markets; our expectations regarding future growth, including our ability to develop new products; risks related to our contracts with BARDA; our ability to maintain adequate protection of our intellectual property; competition risks; and the need for additional financing. These and other significant factors are discussed in greater detail in MediWound’s annual report on Form 20-F for the year ended December 31, 2023, filed with the Securities and Exchange Commission (“SEC”) on March 21, 2024, and other filings with the SEC from time-to-time. These forward-looking statements reflect MediWound’s current views as of the date hereof and MediWound undertakes, and specifically disclaims, any obligation to update any of these forward-looking statements to reflect a change in their respective views or events or circumstances that occur after the date of this release except as required by law

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NexoBrid development has been supported in whole or in part with federal funds from the U.S. Department of Health and Human Services; Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA), under contract HHSO100201500035C. This contract provided funding and technical support for the pivotal U.S. Phase 3 clinical study (DETECT), the randomized, controlled pivotal clinical trial for use in the pediatric population (CIDS), the marketing approval registration process for NexoBrid as well as its procurement and availability under the expanded access treatment protocol (NEXT). Additional projects for evaluation of NexoBrid funded under the BARDA contract include establishment of a pre-emergency use data package and development of the health economic model to evaluate the cost savings impact to enable market adoption in the United States.

We maintain our books and records in U.S. dollars and report under IFRS. Our revenue expectations for the full-year ended 2024, as well as our estimates concerning cash as of December 31, 2024, are preliminary, unaudited and are subject to change based on the completion of ongoing internal control, review, and audit procedures. As a result, these amounts may differ materially from the amounts that will be reflected in the Company’s consolidated financial statements for the year ended December 31, 2024. Accordingly, you should not place undue reliance on this preliminary estimate.

# **MediWound** - Company Highlights

## Validated enzymatic technology platform

14 successful clinical trials

120+ peer-reviewed publications

**Key approvals:** FDA/EMA/JPN

## Diversified portfolio

**NexoBrid®** - Eschar removal for severe burns

**EscharEx®** - Debridement of chronic wounds[1]

## Significant commercial opportunity

**NexoBrid®** - 2024 revenue of **$20M**

**EscharEx®** - Targets a **$2.5B U.S. market**[2]
Challenges a $375M+ dominant product

## Strategic global collaborations

Vericel, Mölnlycke, Kaken, MiMedx, BARDA, EIC, DoD, PolyMedics, Mankind, Solventum

## Solid balance sheet with strong investor base

**Cash of $44M**[3]
Runway through profitability

## cGMP certified sterile manufacturing facility

**6x scale-up** to support global demand to be fully operational by YE 2025

**1**. Investigational drug **2.** Primary Research, Alira Health analysis (2025) **3.** As of December 31, 2024 (does not include EIC funding)

# **Core Platform** - Enzymatic Technology

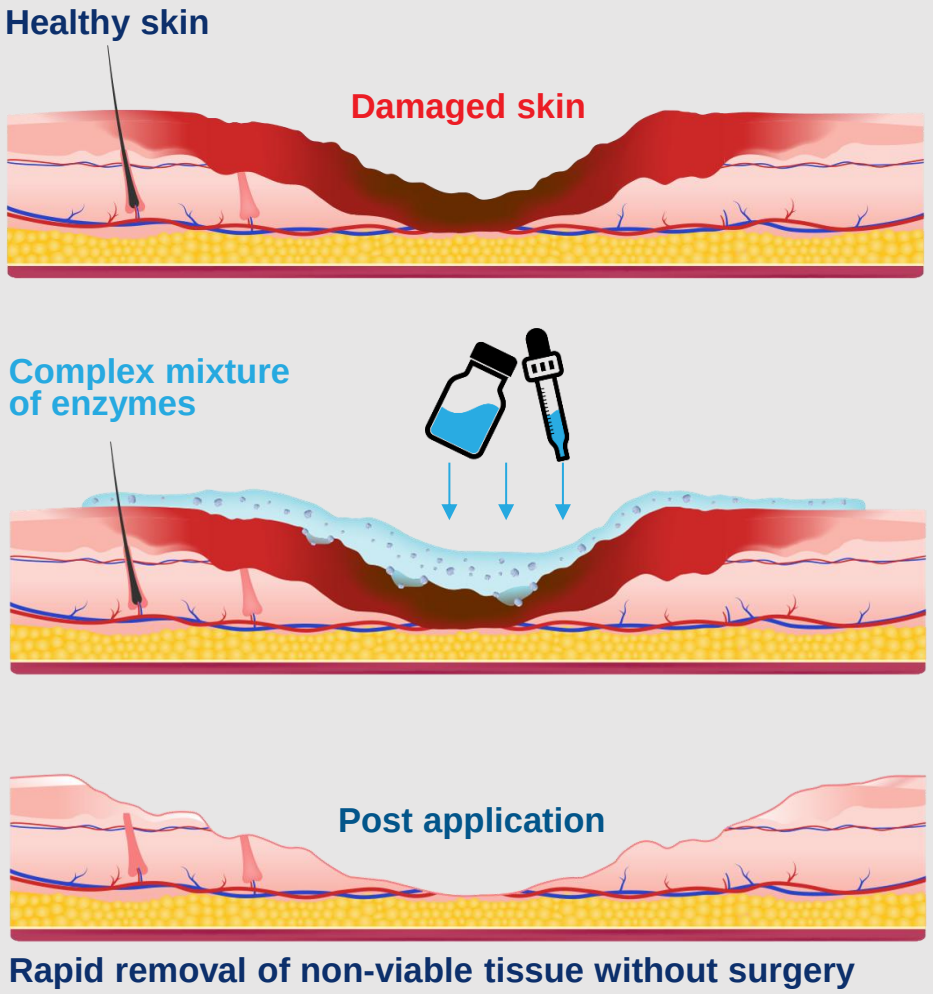
## Proprietary IP protected manufacturing process

1
Pineapple stem harvest

2
Protein extraction

3
Purification, enrichment, stabilization

4
Complex mixture of proteolytic enzymes




**Rapid removal of non-viable tissue without surgery**

# Multi-Billion Dollar Portfolio

## Commercial

### NexoBrid®

Disruptive therapy for burn care


**Indication:** Eschar removal in deep-partial and full thickness burns

**Classification:** Orphan biological drug

**Target users:** Hospitalized patients

**Status:** US/EU/JP approved for adult and pediatric patients

**TAM[1,2] (U.S.):** **$300M**

## Pipeline

### EscharEx®

Next-Gen enzymatic therapy for wound care[3]


**Targeted indication:** Debridement of chronic/hard-to-heal wounds

**Classification:** Biological drug

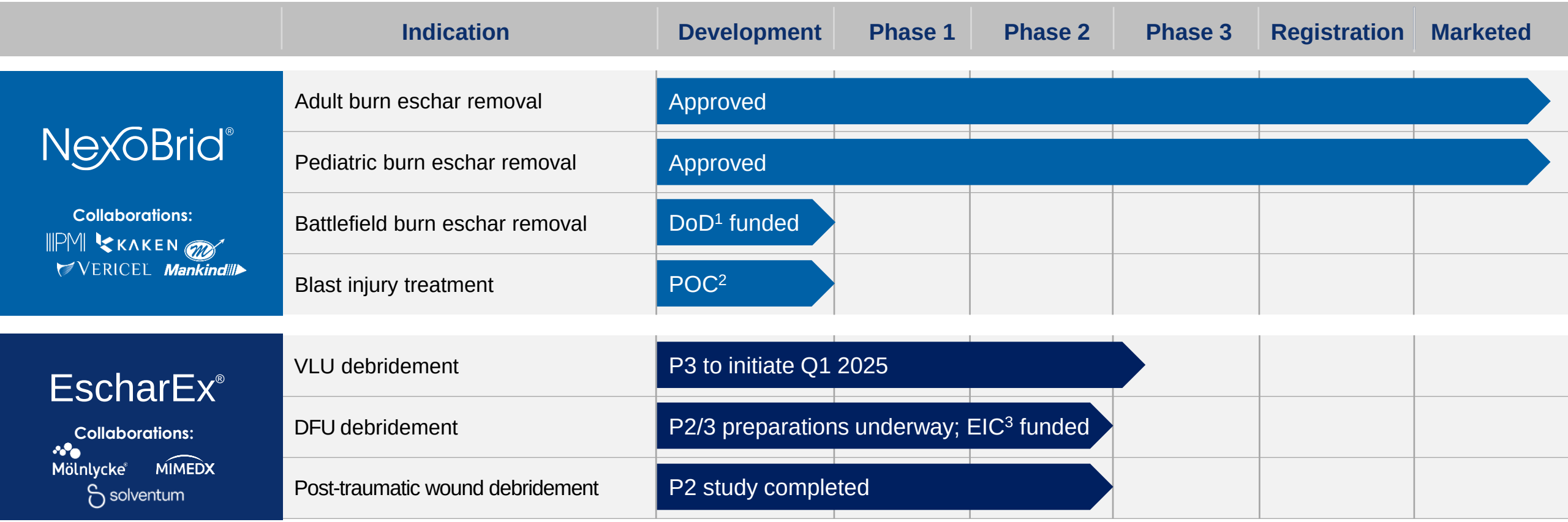
**Target users:** Patients in all wound care settings

**Development status:** Phase 3 VLU[4], Phase 2/3 DFU[5]

**TAM[6] (U.S.):** **$2.5B**

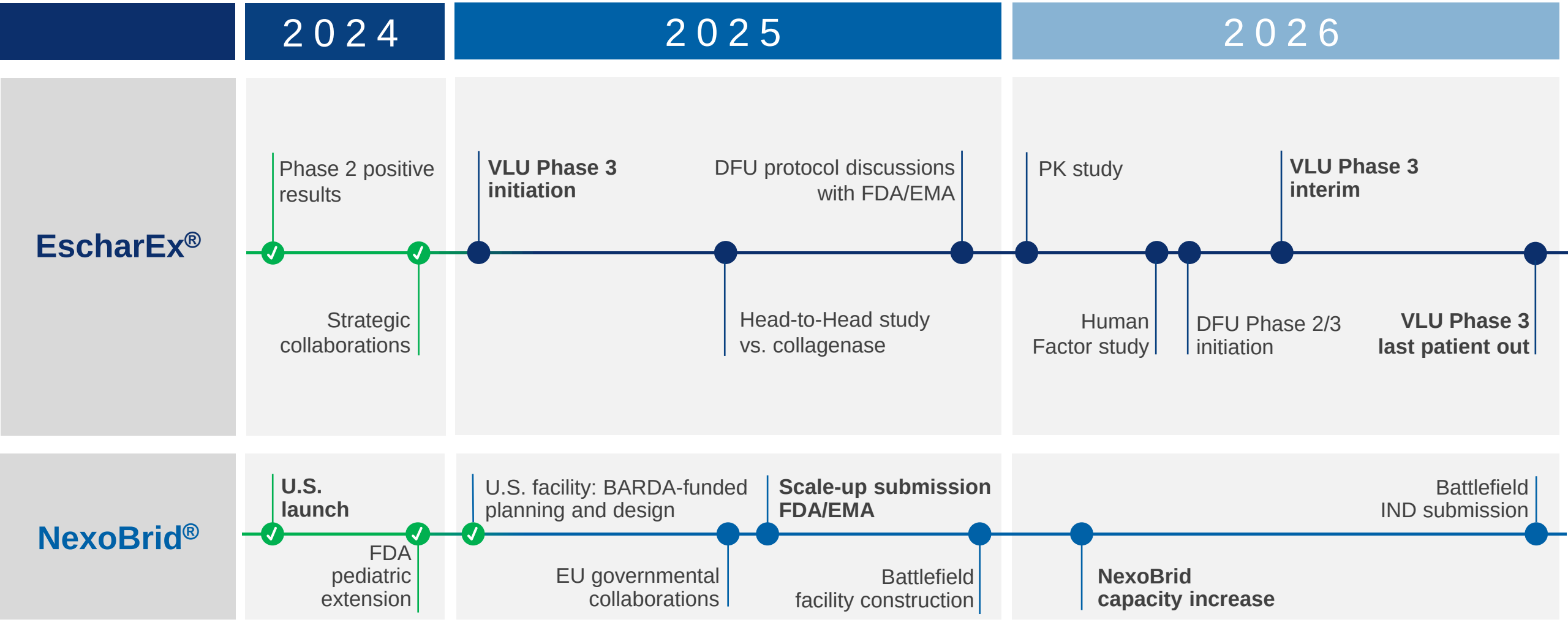
**1.** TAM - targeted addressable market **2.** ~90% of eligible patients require eschar removal; assumes NexoBrid average price of ~$9,000 per patient
**3.** Investigational drug **4.** Venous Leg Ulcers **5.** Diabetic Foot Ulcers **6.** Primary Research, Alira Health analysis (2025)

# Product Pipeline




**1.** U.S. Department of Defense **2.** Proof of Concept **3.** European Innovation Council

# Value Creating Milestones



# Financial Highlights

## BALANCE SHEET

**$44M in cash**[1]

No debt

**€**16.25M funding from EIC

## REVENUE

2024 revenue of **$20M**
NexoBrid® is profitable

Scale-up will potentially increase gross margin to **65%**

**$115M+** received from BARDA
**$15M** funded by DoD

## EQUITY

Outstanding shares: 10.8M
Fully diluted: 14.8M

Nasdaq | MDWD

**ANALYSTS:**

- Josh Jennings, MD - **Cowen**
- Francois Brisebois - **Oppenheimer**
- Swayampakula Ramakanth, PhD - **HCW**
- Jason McCarthy, PhD - **Maxim**

**1.** As of December 31, 2024 (does not reflect the EIC funding)

# NexoBrid®

(8.8% concentration)

Early, effective and selective non-surgical eschar removal for severe burns

| | |
|---|---|
| Validated & commercialized | Approved in 40+ countries including US, EU, JP; 14,000+ patients treated to date |

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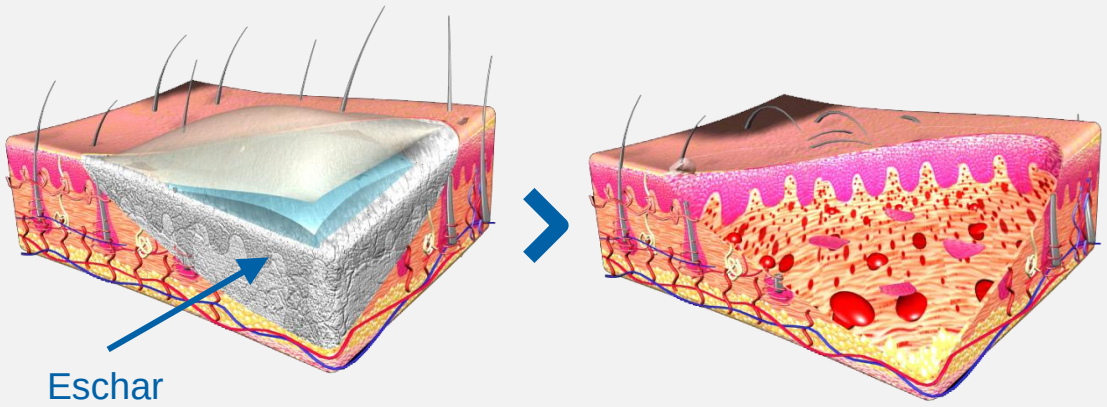
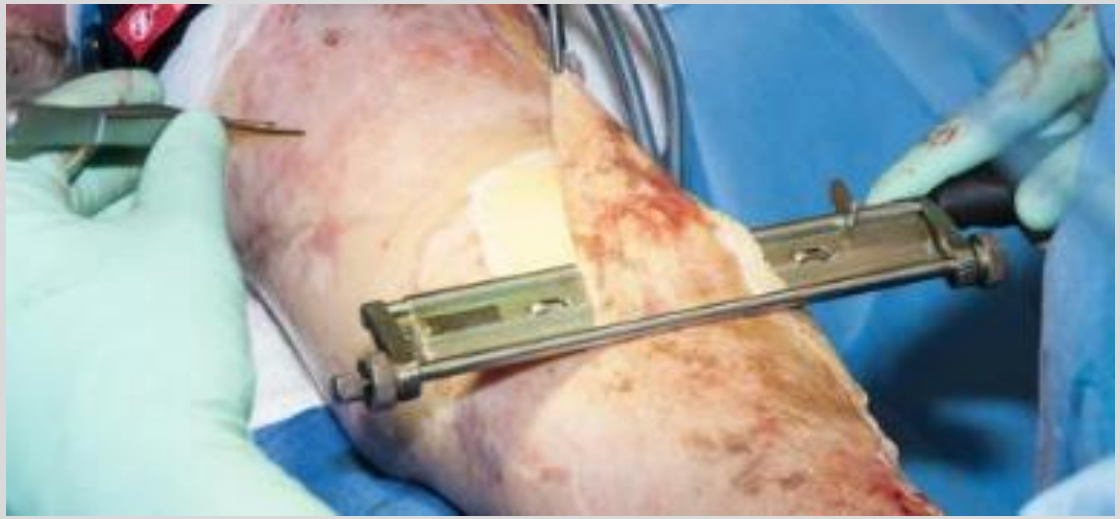
# First Step in Burn Care - **Eschar Removal**

## Removal of non-viable tissue is critical for **wound healing**




**Prevents infection and sepsis** | **Stops deterioration and scarring** | **Reveals tissue for medical evaluation**

## Surgical removal of eschar is **traumatic & non-selective**[1,2]



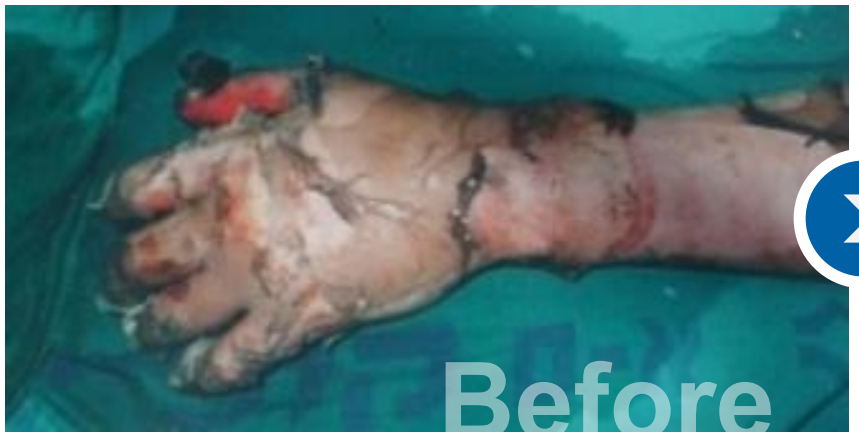
**Loss of healthy tissue and blood** | **Challenging in delicate areas** | **Requires surgical team, operating room**

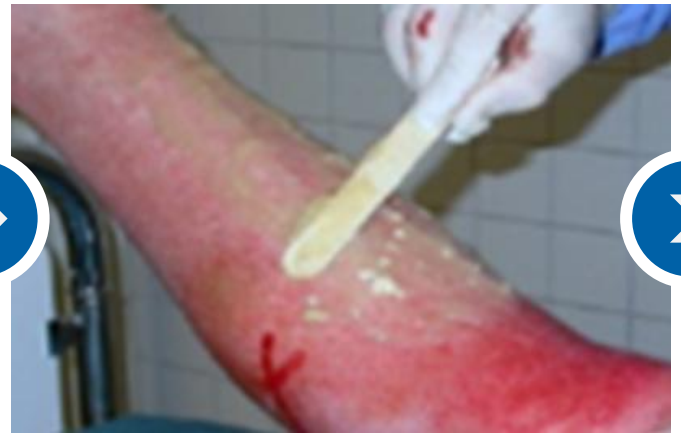
# NexoBrid® Non-Surgical, Simple, Selective, Effective

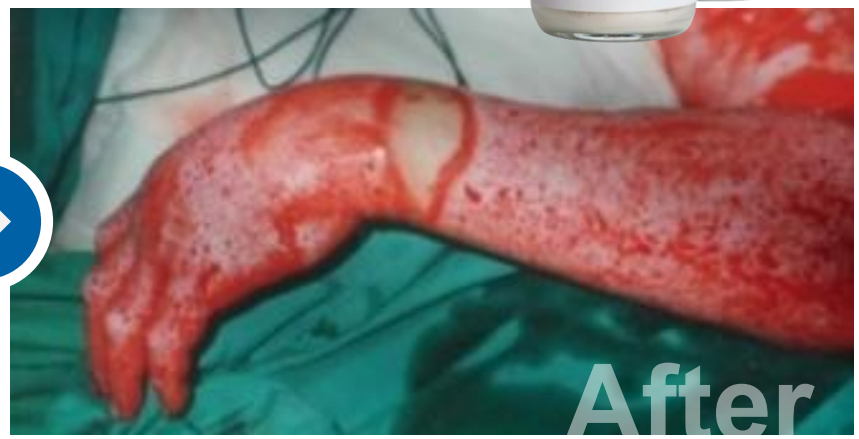
**Indication:** Eschar removal of deep partial-thickness and/or full-thickness thermal burns

**Commercial availability**: US (Vericel), Japan (Kaken), Europe (direct, and PMI), India (Mankind)

**Government support:** $115M+ received from BARDA & DoD Contracts

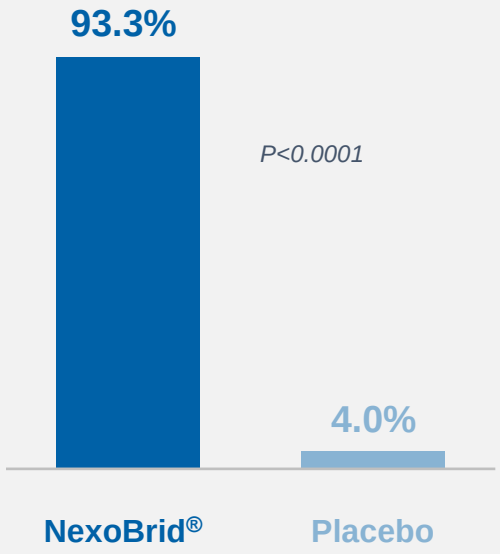






- Easy-to-use
- Topical application at patient's bedside
- Removes eschar within 4 hours
- Preserves viable tissue
- Enables visual medical assessment
- Reduces need for surgery
- Reduces blood loss
- Improves patient outcomes (scar quality and function)

# **Phase 3 Studies** Demonstrate Superiority[1]

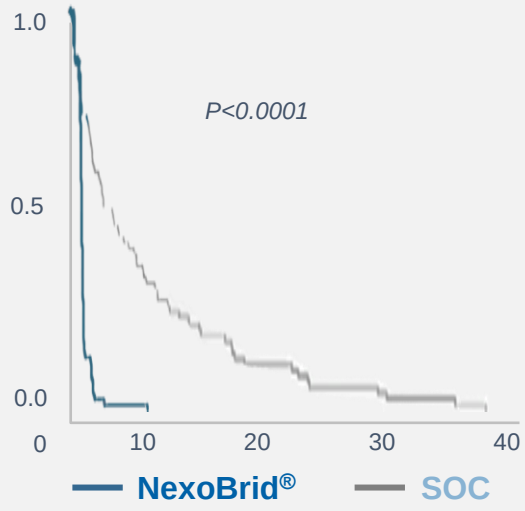
## Incidence of complete eschar removal




[N=100 (75,25)]

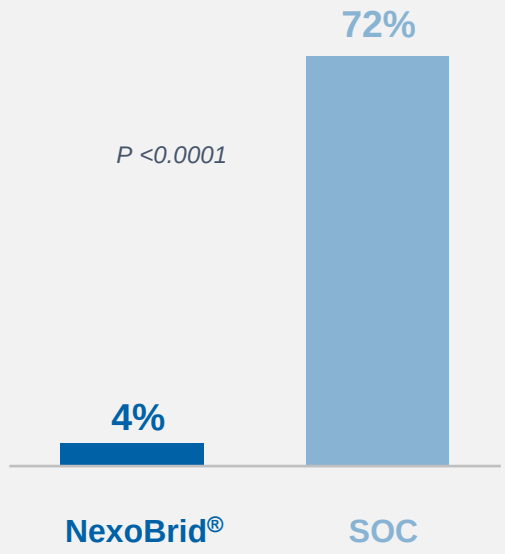
## Time to complete eschar removal

(days)



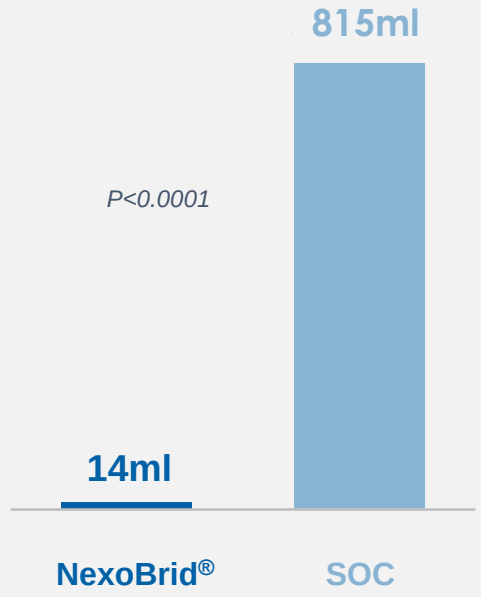

[N=150 (75,75)]

## Incidence of surgical eschar removal




[N=150 (75,75)]

## Blood loss

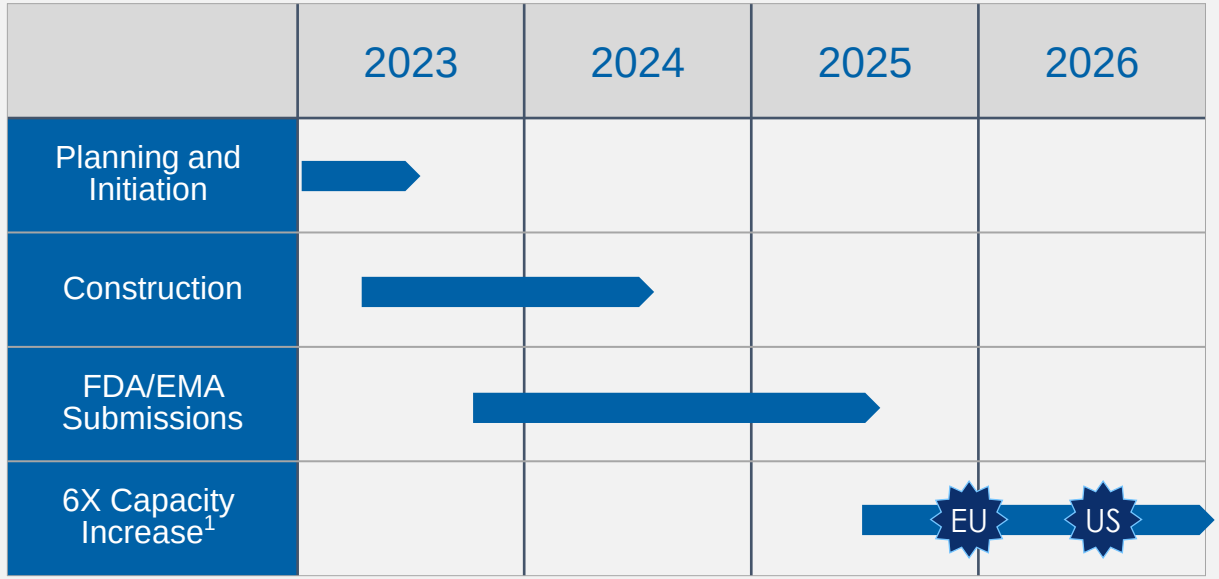



[N=150 (75,75)]

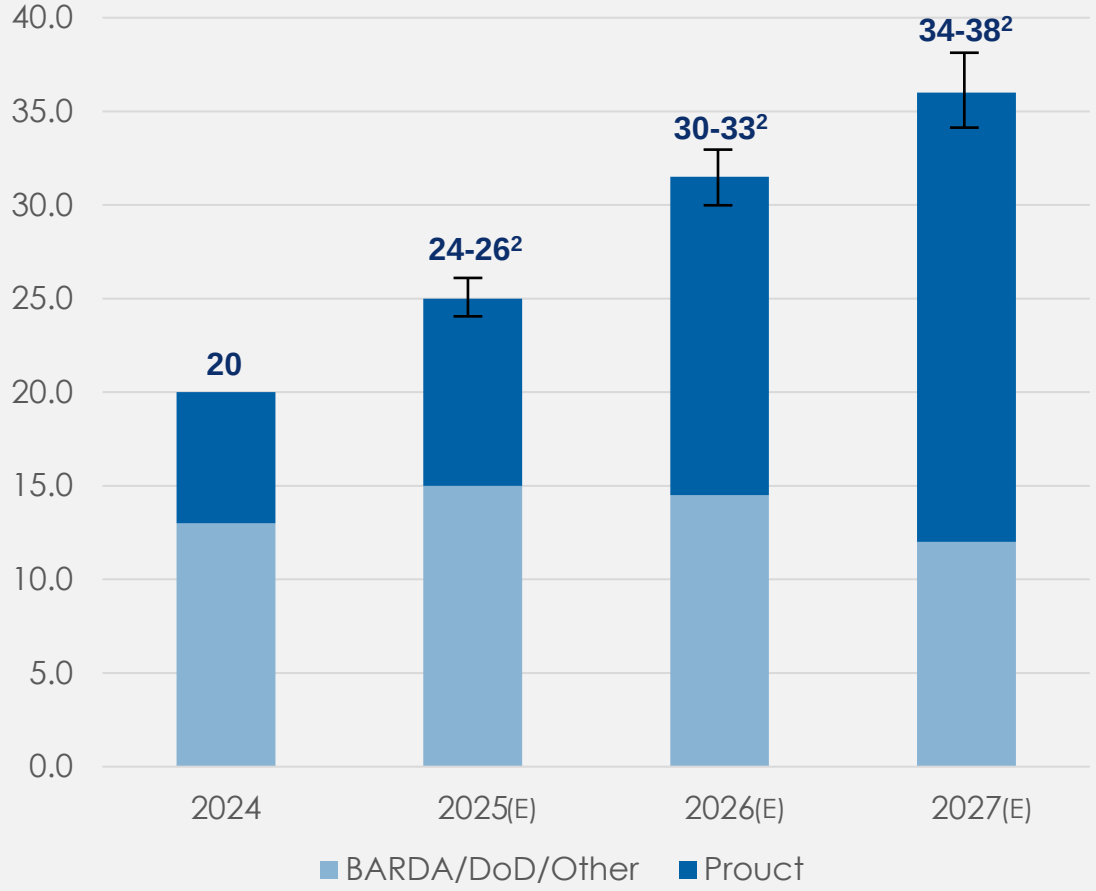
Safe and well-tolerated | Improved scarring and comparable wound closure | Consistent across various studies[2] and post-marketing data[3]

# Growth Supported by **Facility Scale-Up**[1]

## Full manufacturing capacity anticipated in 2025/6




## NexoBrid® target revenue ($M)




**1.** Global demand exceeds current manufacturing capability 3X **2.** Subject to regulatory approvals **3.** Variability driven by development services revenue

# EscharEx®

(5% concentration)

Next-Generation Enzymatic Debridement Candidate for Chronic Wounds

| | | |
|---|---|---|
| Superior to SOC - aims to set a new bar for efficacy | $2.5B TAM opportunity | De-risked - validated technology and successful Phase 2 trials |

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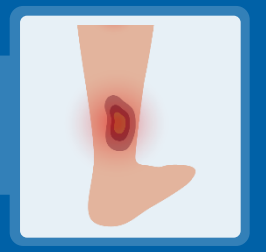
# EscharEx® Targets **Lower Extremity Chronic Ulcers**

## **VLU** Venous Leg Ulcers



**Underlying pathology** - Chronic venous insufficiency

**Affects** - Lower leg or ankle

**Ulcer characteristics** - Large, shallow ulcers; moderate/severe pain

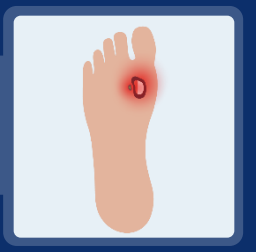
**Prevalence** – 2% of population age 65+
1.5M+ new cases annually (US)[1]

**Complications** - Infection, pain, disability

**Societal impact** - Substantial healthcare burden, low QoL

**Management** - Debridement, wound bed preparation, compression therapy, control inflammation and infection, promote healing

## **DFU** Diabetic Foot Ulcers



**Underlying pathology** - Diabetes (Type I/II)

**Affects** - Mostly bottom of the foot

**Ulcer characteristics** - Small, deep ulcers; varying pain levels

**Prevalence** - 25-34% of diabetics develop DFU in their lifetime
2.2M+ new cases annually (US)[1]

**Complications** - Infection, sepsis, amputation, death

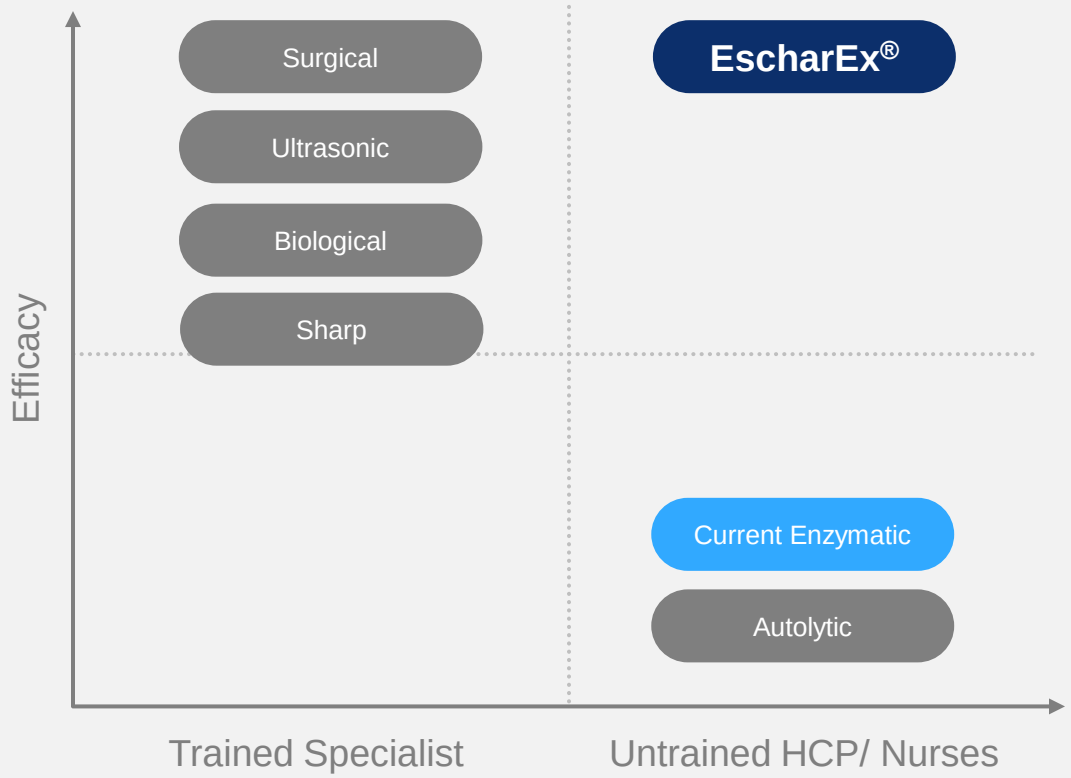
**Societal impact** - Substantial healthcare burden, low QoL

**Management** - Debridement, wound bed preparation, offload pressure, moist wound healing, control inflammation and infection, promote healing

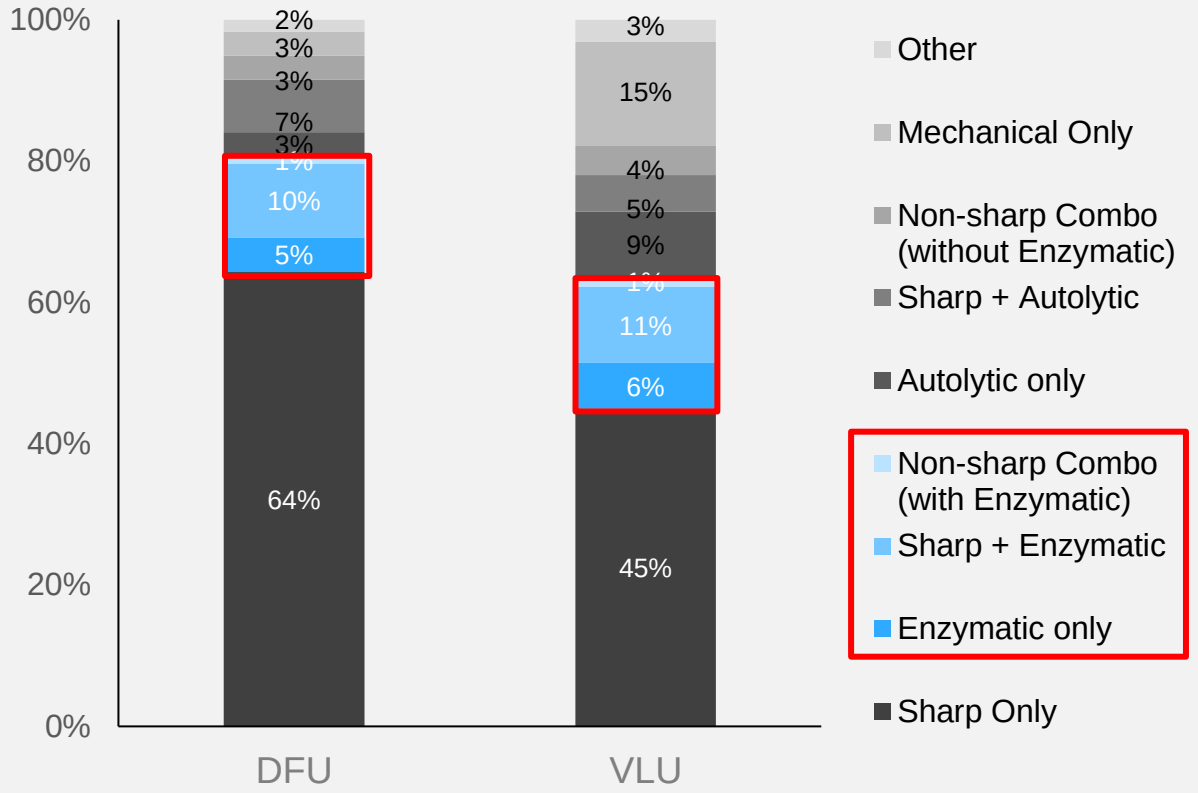
**1.** Primary Research, Alira Health analysis (2025)

# Chronic Ulcers: **Current Debridement Treatments are Sub-Optimal**

## Modalities by efficacy and complexity




## Modalities by ulcer type (U.S.)[1]






**1.** Primary Research, Alira Health analysis (2025)

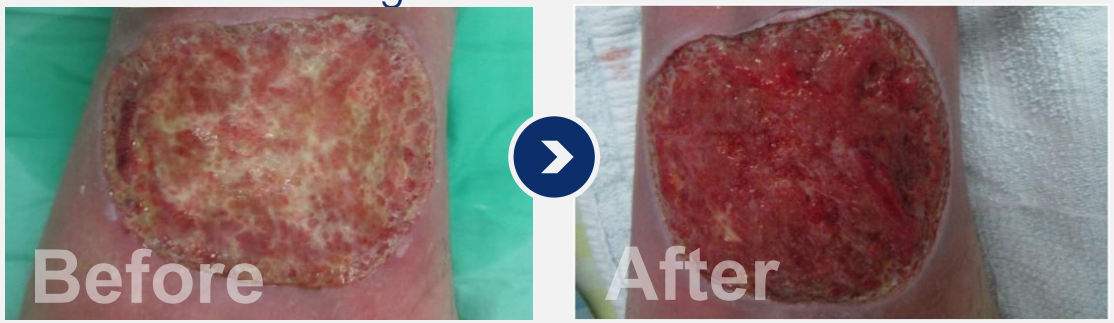
# EscharEx® Enzymatic Debridement within Days


**Indication:** Rapid debridement and promotion of healthy granulation tissue (WBP) in chronic and hard-to-heal wounds[1,2]

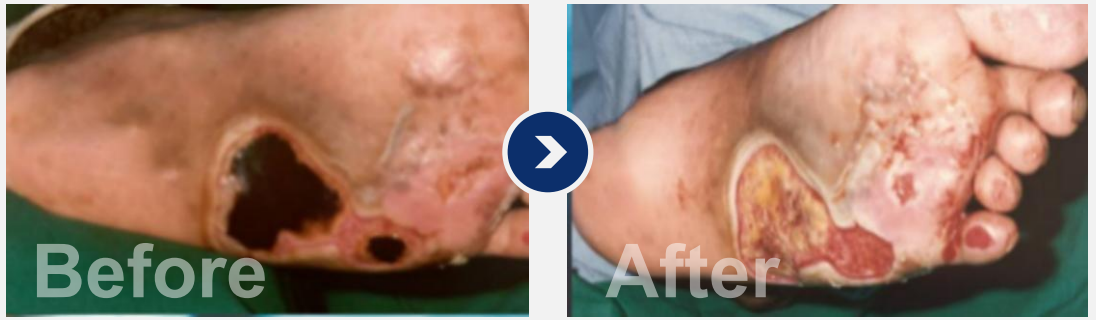
**Status**: Investigational drug

- Debrides chronic ulcers within 4-8 daily administrations
- Easy-to-use topical application
- Designed for all patient settings
- Reduces bacteria and biofilm
- Promotes granulation tissue
- Aligns with treatment workflows & reimbursement landscape

## VLU Venous Leg Ulcers




## DFU Diabetic Foot Ulcer

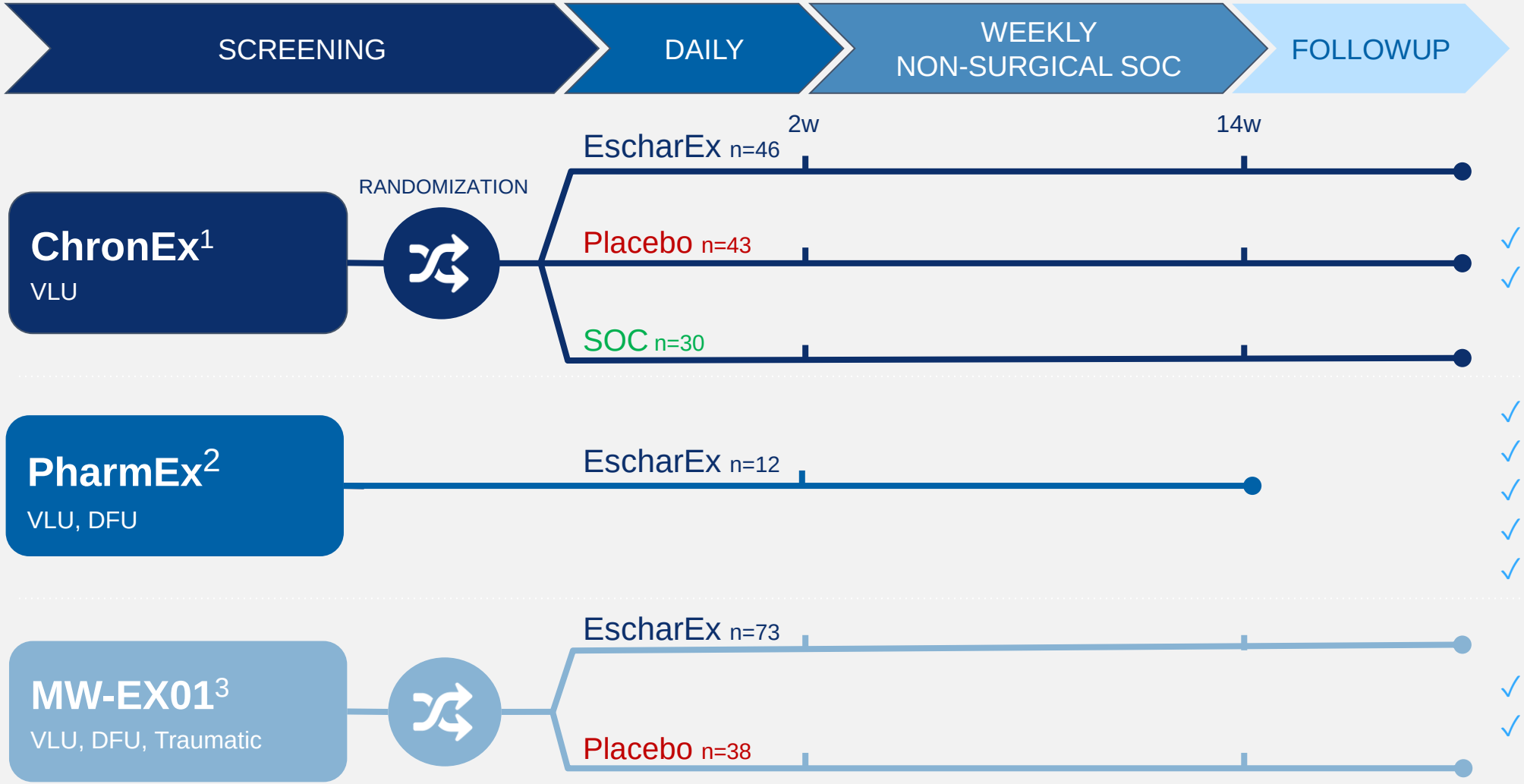





1. Wound bed preparation (WBP) = complete debridement + complete granulation

2. Snyder et al. 2025; Wounds Journal

# **Robust and Consistent Results** in Three Phase 2 Studies

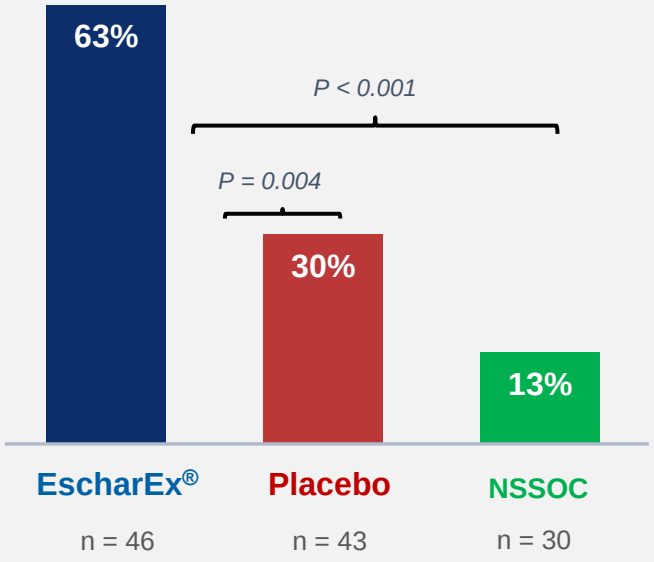





1. Shoham et al. 2024; LANCET's eClinicalMedicine
2. Snyder et al. 2023; Wounds Journal
3. Shoham et al. 2021; Wound Rep Reg

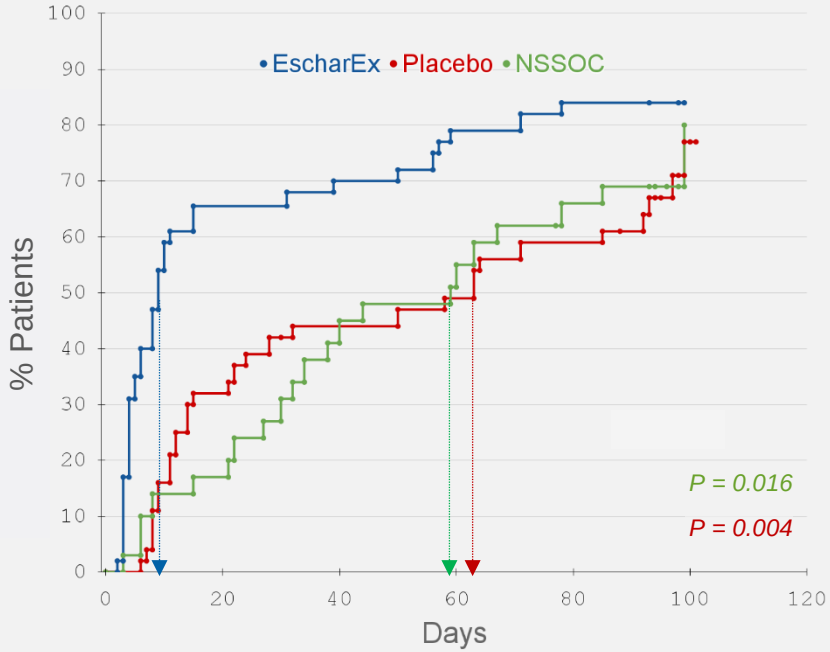
# ChronEx Phase 2 Study[1] - **Endpoints Significantly Met**

## Complete debridement within 2 weeks (primary endpoint)




**EscharEx is superior to placebo and non-surgical SOC (NSSOC)**

## Time to complete debridement




**EscharEx: 9 days vs. NSSOC/placebo: 59/63 days**

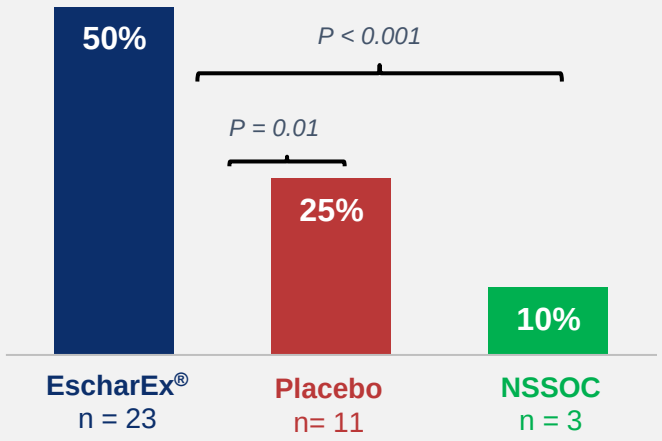
No safety issues observed; efficacy results consistent with previous Phase 2 studies[2]



1. Shoham et al. 2024; LANCET's eClinicalMedicine
2. Snyder et al. 2023; Wounds Journal; Shoham et al. 2021; Wound Rep Reg

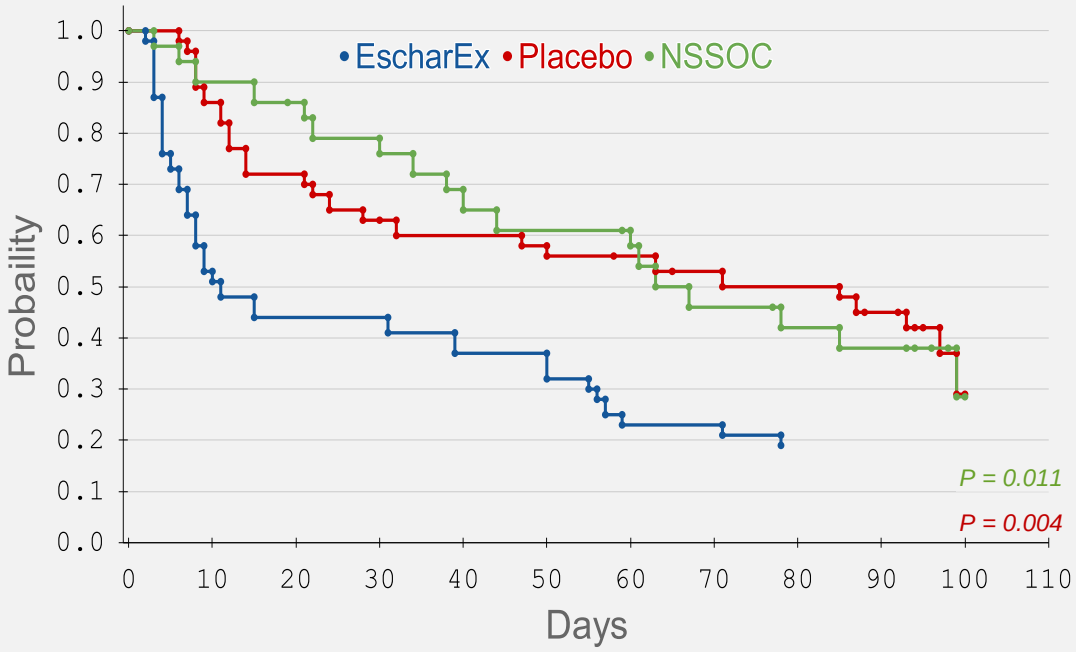
# ChronEx Phase 2 Study[1] - **Rapid Wound Bed Preparation Achieved**

## Incidence of WBP




**EscharEx is superior to placebo and NSSOC**

## Time to WBP




**EscharEx 11 days vs. placebo 85 days**

## WBP & Healing

Subjects reaching WBP are 4.1X more likely to achieve wound closure (p = 0.0004)

Significant correlation of WBP vs. time to wound closure. HR[2] of 11.96 (p < 0.0001)

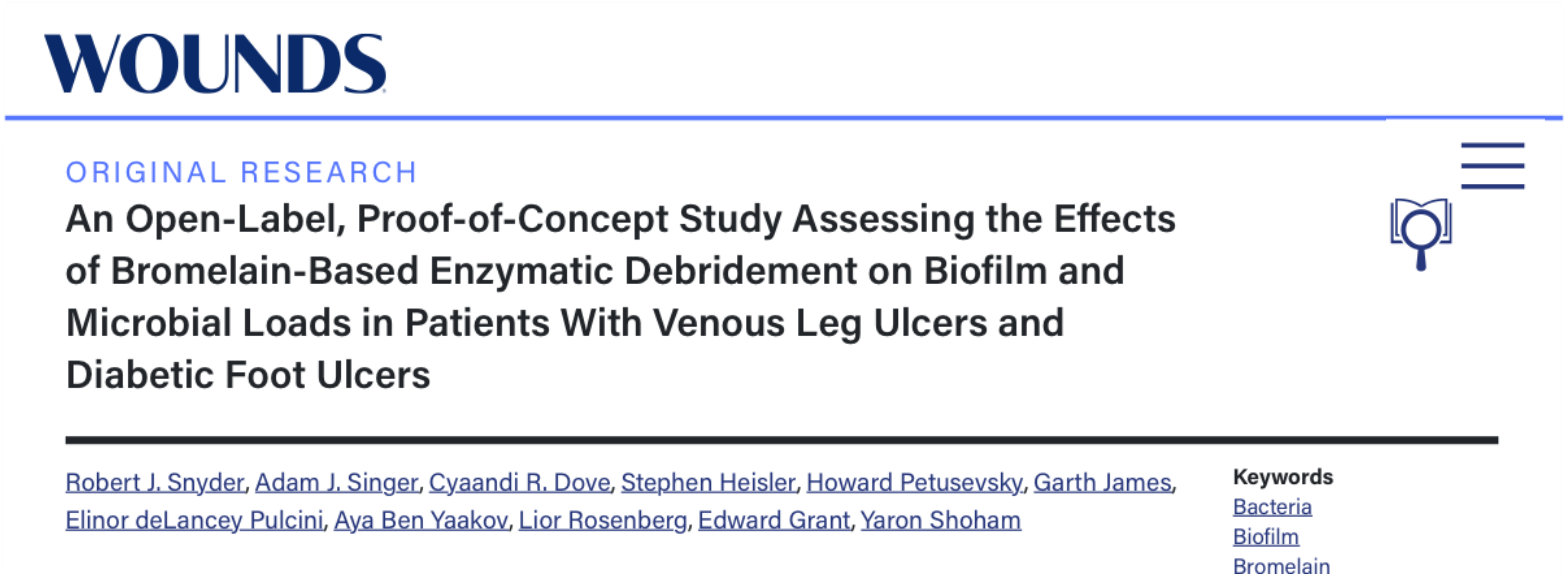
Study suggests that faster wound bed preparation increases the probability of wound closure



1. Shoham et al. 2024; LANCET's eClinicalMedicine

2. Hazard Ratio

# PharmEx Phase 2 Study - **Surpassing Traditional Debridement**



WOUNDS

ORIGINAL RESEARCH

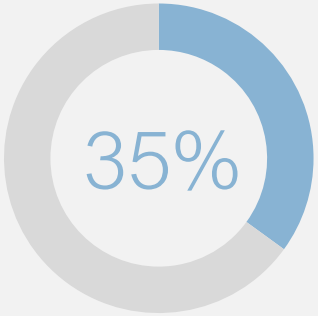
**An Open-Label, Proof-of-Concept Study Assessing the Effects of Bromelain-Based Enzymatic Debridement on Biofilm and Microbial Loads in Patients With Venous Leg Ulcers and Diabetic Foot Ulcers**

Robert J. Snyder, Adam J. Singer, Cyaandi R. Dove, Stephen Heisler, Howard Petusevsky, Garth James, Elinor deLancey Pulcini, Aya Ben Yaakov, Lior Rosenberg, Edward Grant, Yaron Shoham

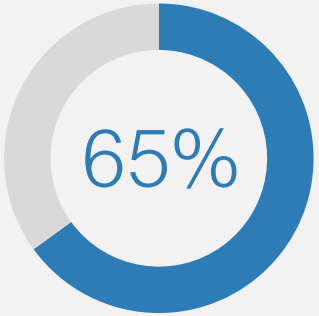
**Keywords**
Bacteria
Biofilm
Bromelain

## Results[1]

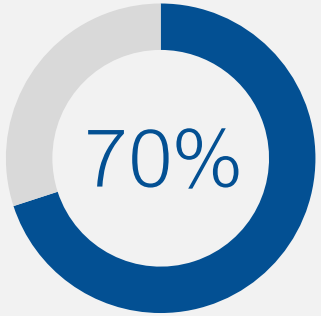
Reduction in wound size, biofilm and bacterial burden[2]




Wound size reduced by end of two-week follow-up




Bioburden reduction by end of treatment




Complete debridement within 8 applications


Biofilm reduced for patients positive at baseline



**1.** Snyder et al., 2023; Wounds Journal **2.** The PharmEx trial included VLU and DFU patients

# EscharEx® Well-Positioned to Become **Market Leader**[1]

## EscharEx®


**Investigational drug - Phase 3 expected to begin in 1Q 2025**

Mixture of enzymes; **multiple** targets of action

Debridement, promotion of granulation, reduction of biofilm & bacteria[5,7]

**1-2 weeks**, daily; Monotherapy

Controlled Phase 2 trials; **significant superiority** over hydrogel & SOC[6]

Demonstrated to be safe and well-tolerated[7]

## SANTYL®


**Approved in the 1960s; $375M+ annual revenues (2023)**
**Existing reimbursement code[2]**

Collagenase; **single** target of action

Debridement[8]

**4-8+ weeks**, daily; typically coupled with sharp debridement[3]

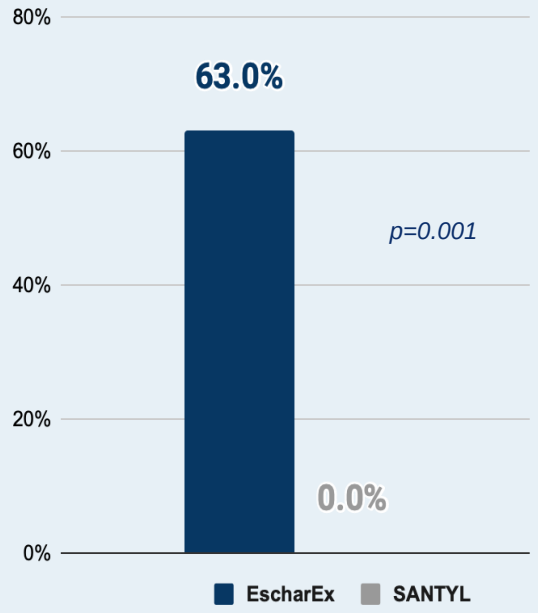
*"There is a **lack of RCTs** with adequate methodological quality"*[4]

Demonstrated to be safe and well-tolerated

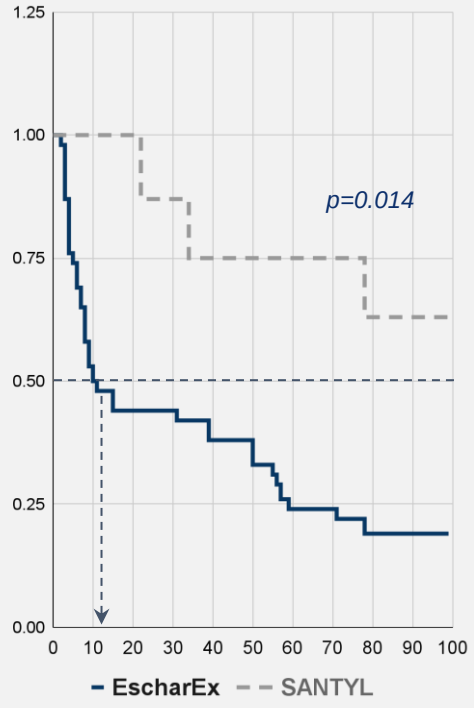

**1.** The comparison presented represent cross-trial comparison **2.** OW Primary Research **3.** Lantis JC and Gordon I., 2017; Wounds **4.** Patry et al., 2017
**5.** Snyder et al., 2023; Wounds **6.** SOC in the Phase 2 trial included SANTYL® **7.** Based on the data to date **8.** SANTYL® PI

# EscharEx® vs. SANTYL® **Head-to-Head Data**[1]

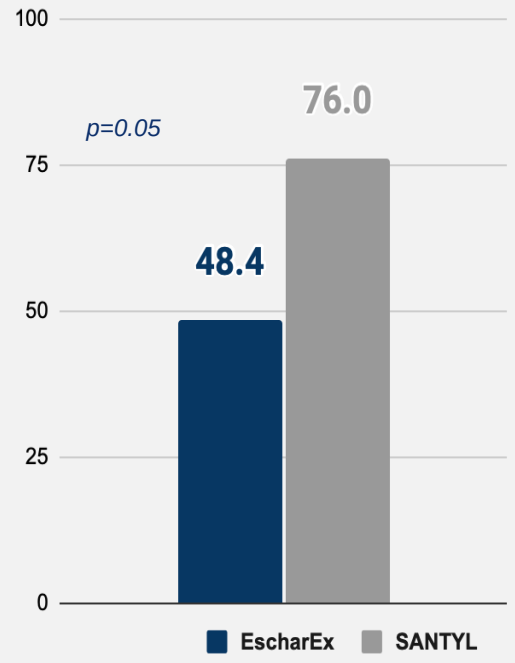
## Incidence of complete debridement in 2 weeks



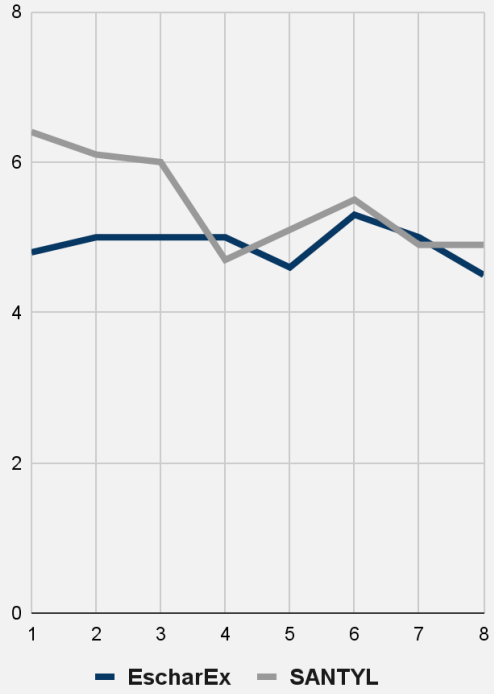

## Time to achieve WBP




## Time to wound closure




## Patient-reported pain[2]






**1.** Post-hoc data from the ChronEx Phase 2 study **2.** Comparable incidence of adverse wound reactions identified

# EscharEx® VALUE Phase 3 Study in VLU Patients

## STUDY OBJECTIVES

To assess safety and efficacy of EscharEx compared to placebo in VLU patients

## STUDY DESIGN

A global (US, EU, ROW), randomized, double blind, adaptive design study in VLU patients

**Two arms:** EscharEx vs. placebo, 1:1 ratio

**Sample size:** 216 VLU patients

**Study design:**

- Daily treatment: Up to 8 applications over 2 weeks, followed by 10 weeks of standardized wound management
- Active wound closure (CTP/ autograft) for patients reaching WBP
- 12 weeks durability follow-up for patients that reached wound closure

**Pre-defined interim assessment:** Conducted after 67% of patients completed the initial 12-week period

## ENDPOINTS

### Co-primary:

**Incidence of complete debridement**

**Incidence of complete wound closure**

### Secondary:

Incidence of 100% granulation tissue

Time to complete debridement

Time to complete wound closure

Change in wound area

### Safety:

Safety & tolerability | ECG | Change in pain | Wound infection rates | Immunogenicity

# EscharEx® Planned **Phase 2/3 Study in DFU Patients**

## STUDY OBJECTIVES[1]

To assess safety and efficacy of EscharEx compared to placebo in patients with DFU

1. Subject to agreements with FDA/EMA

## STUDY DESIGN

A global (US, EU, ROW), randomized, double blind, adaptive design study in patients with DFUs

**Three arms:** EscharEx, placebo and SOC (SOC will be dropped early in the study)

**Sample size:** 240 DFU patients

**Study design:**

- Daily treatment: Up to 8 applications over 2 weeks, followed by 10 weeks of standardized wound management
- Active wound closure (CTP/ autograft) for patients reaching WBP
- 12 weeks durability follow-up for patients reaching wound closure

**Pre-defined interim assessment**

## ENDPOINTS

### Co-primary:

**Incidence of complete debridement**

**Incidence of complete wound closure**

### Secondary:

Incidence of 100% granulation tissue

Time to complete debridement

Time to complete wound closure

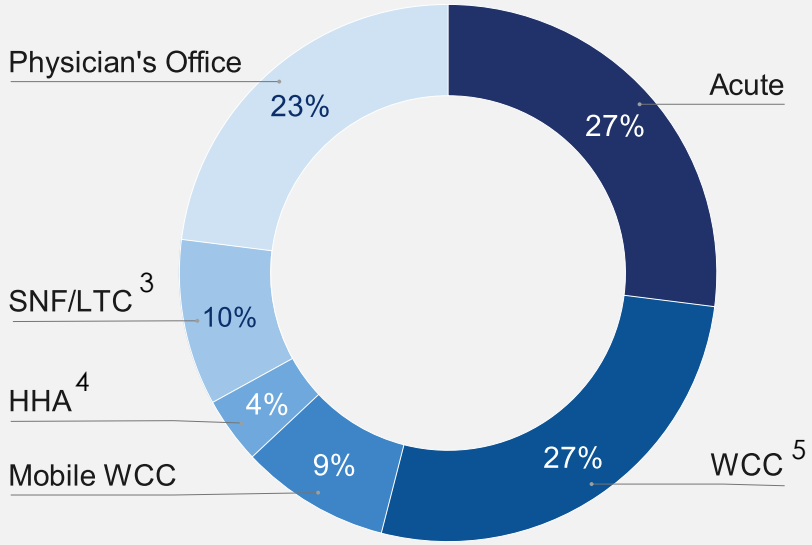
Change in wound area

### Safety:

Safety & tolerability | ECG | Change in pain | Wound infection rates | Immunogenicity

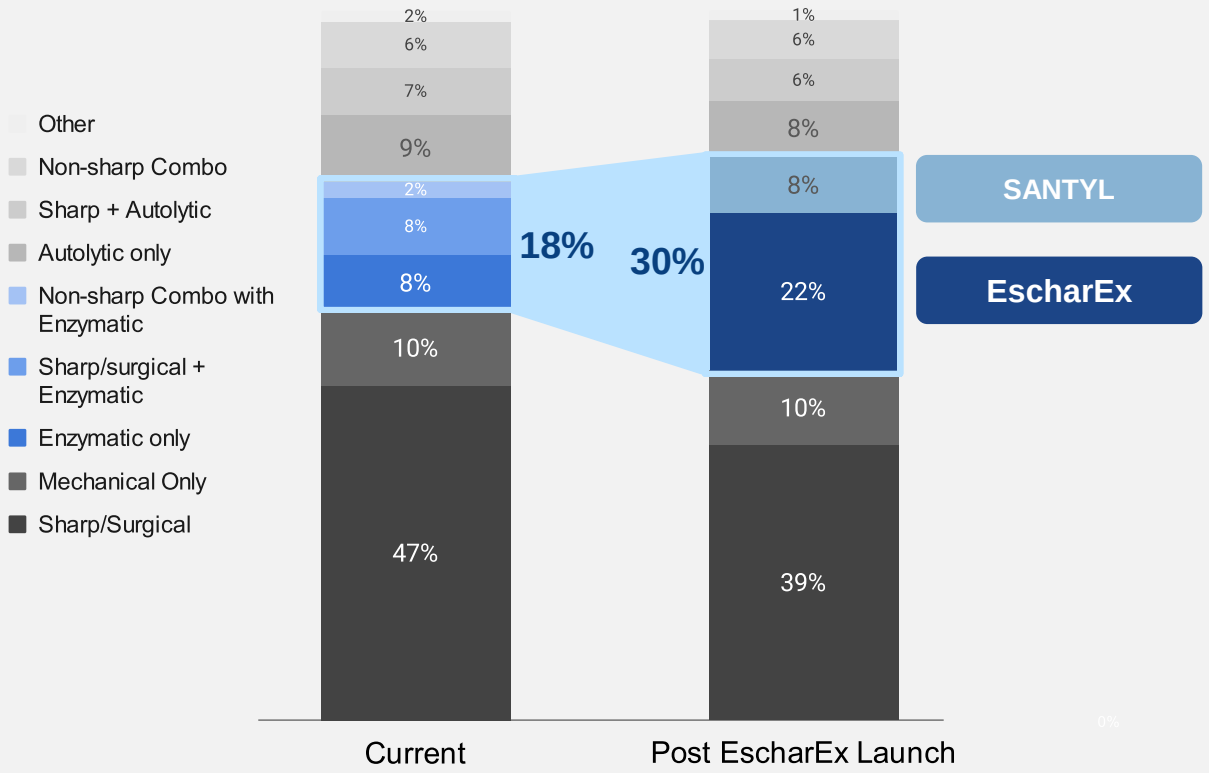
# Primary Research Shows **EscharEx Transforms Market**[1]

## All care settings report[2] strong drivers for adoption




- Ease of use
- Reduced treatment duration
- Reduction readmission risk
- Accelerated wound healing
- Reimbursement maximization
- Accelerated debridement

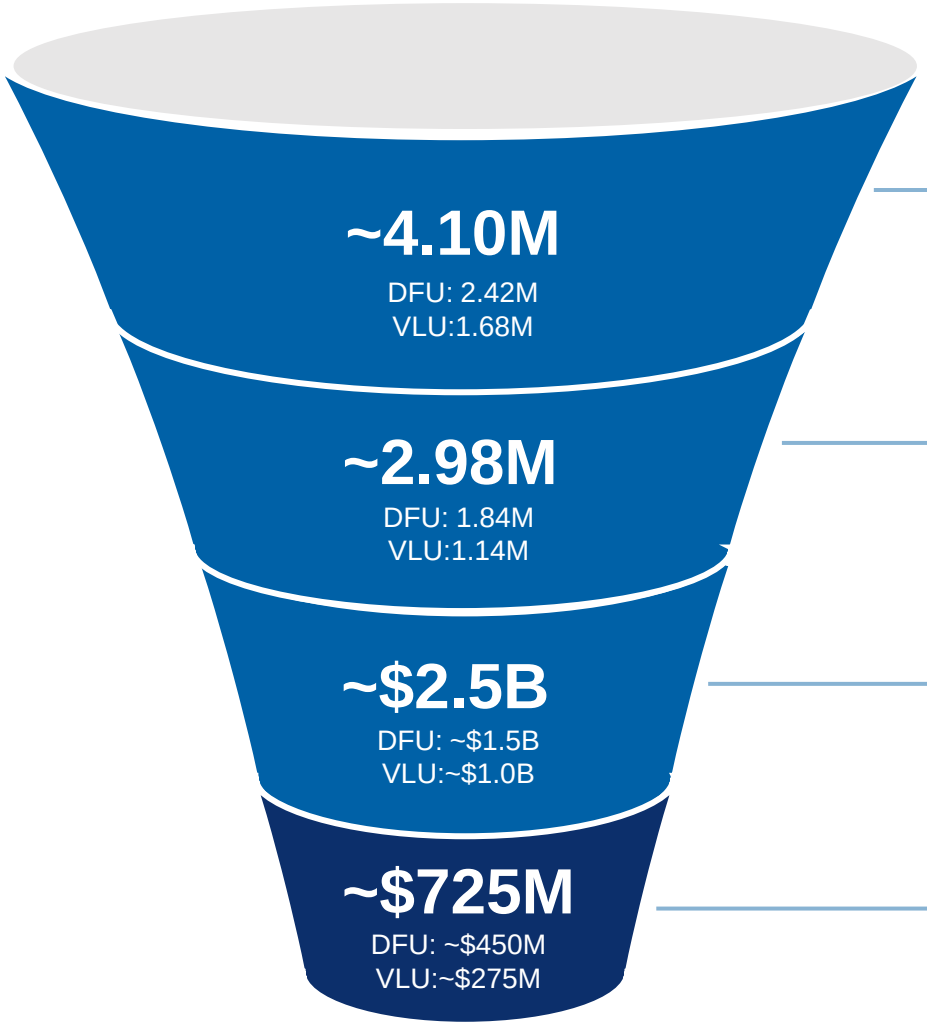
## EscharEx draws share across all debridement modalities[6]






**1.** Alira Health analysis (2025) **2.** Qualitative (N=21), quantitative (N=96) across all care settings, HCPs and payors
**3.** Skilled Nursing Facilities/Long-Term Care **4.** Home Health Agencies **5.** Wound Care Centers **6.** VLUs and DFUs

# **$725M Projected Peak Sales** in $2.5B TAM in U.S.[1]




### *DFU & VLU prevalence*

Estimated 2028 total patient population[2] **2.42M DFU** and **1.68M VLU**, (**4.10M total)**

### *DFU & VLU debridement patients*

Percent of patients undergoing debridement quantified through **survey** and refined via **qualitative interviews: 72%** (76% of DFU, 68% of VLU)

### *2028 Total Addressable Market for Enzymatic Debridement*

Based on **average treatment cost of $851 per patient**, resulting in a **TAM of $2.5B**

### *Estimated Peak Sales of EscharEx*

**Peak projected revenue** for **EscharEx**: **$725M**, based on estimated 22.3% conversion rate across all current debridement techniques.



**1.** Primary research, Alira Health analysis (2025). **2.** Secondary research.

# Highly Experienced Leadership Team

**Nachum (Homi) Shamir**
Chairman

Luminex
GIVEN IMAGING
Kodak

**Ofer Gonen**
CEO

gamida cell
CACTUS
CBI

**Dr. Shmulik Hess**
COO & CCO

ENLIVEX
TABBY THERAPEUTICS
Valin Technologies

**Dr. Ety Klinger**
Chief R&D Officer

teva
PROTEO LOGICS
TEL AVIV UNIVERSITY

**Barry Wolfenson**
EVP Strategy & Corp Dev.

DERMASCIENCES
ANDERSEN CONSULTING
Bristol Myers Squibb

**Hani Luxenburg**
CFO

AstraZeneca
BIRD AEROSYSTEMS
EY

**Dr. Robert J. Snyder**
CMO

Systagenix
3M
Johnson & Johnson

# Strategic Timeline