MediWound

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

April 2024 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 (HHS); Administration for Strategic Preparedness and Response (ASPR); Biomedical Advanced Research and Development Authority (BARDA), part of the Administration for Strategic Preparedness and Response within the U.S. Department of Health and Human Services, 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) in the U.S. 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.

# 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 growth potential

**NexoBrid® - 2023 revenue of $19M**
Launched in U.S. by Vericel
**EscharEx®** - Targets a $2B U.S. market[2]
Challenges a **$360M+** dominant product

## Strategic global collaborations

Vericel, Kaken, Solventum, Mölnlycke, MIMEDX, BARDA, DoD, PolyMedics, BSV

## Solid balance sheet with strong investor base

**Cash of $42M[3]**
Runway through profitability


## cGMP certified sterile manufacturing facility

Scale up program to provide
6X manufacturing capacity by 2025
Supports growing global demand

[1] Investigational drug
[2] Oliver Wyman (OW) primary research
[3] As of December 31, 2023; cash and cash equivalents, short-term and restricted bank deposits

# Core Platform - Enzymatic Technology

## Proprietary IP protected manufacturing process

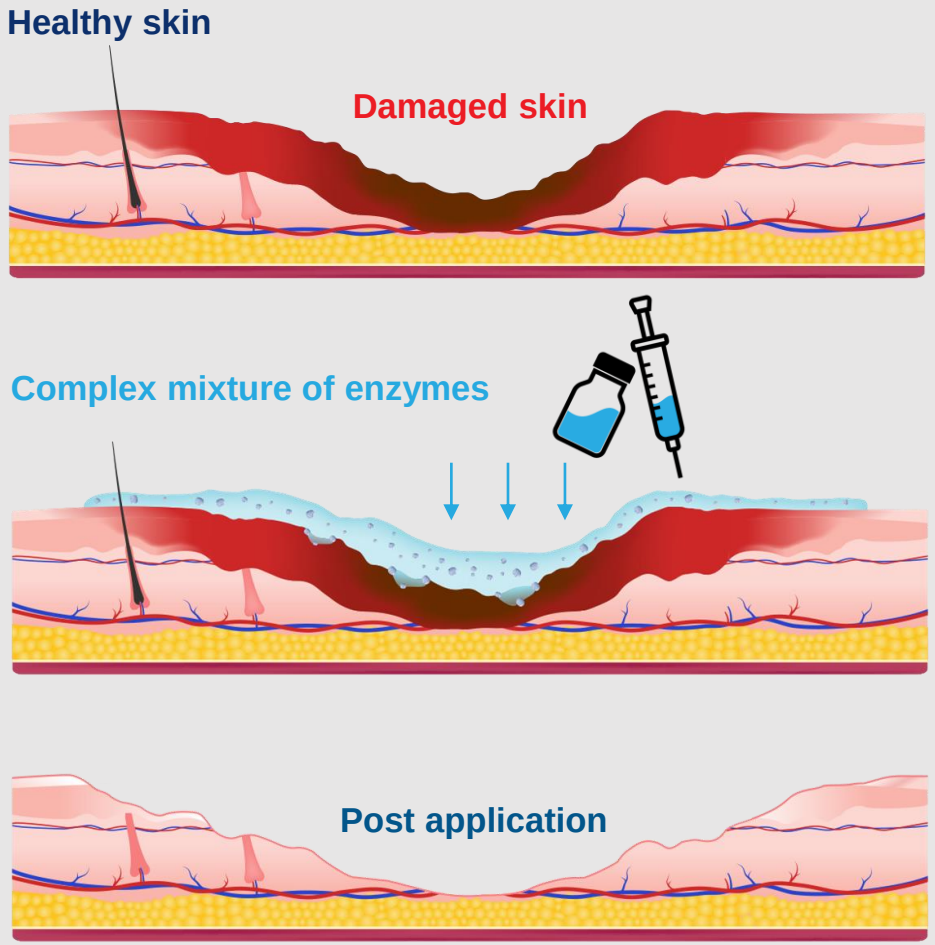
1
Pineapple stem harvest

2
Protein extraction

3
Purification, enrichment, stabilization

4
Complex mixture of proteolytic enzymes

Images modified from Labster theory and bioinfo




**Non-viable tissue is rapidly removed avoiding surgery; healing begins**

# Multi-Billion Dollar Portfolio

## Commercial

### NexoBrid®

Disruptive therapy for burn care

**Indication:** Eschar removal of deep partial and full thickness burns

**Classification:** Orphan biological drug

**Target users:** Hospitalized patients

**Development status:** FDA/EU/JP approved; supplemental BLA for pediatric indication under review by the FDA

**TAM[2,3] (U.S.):** **>$300M**

## Pipeline

### EscharEx®

Next-gen enzymatic therapy for wound care[1]


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

**Classification:** Biological drug

**Target users:** Patients in any wound care setting

**Development status:** Phase 3 initiation expected in 2H 2024

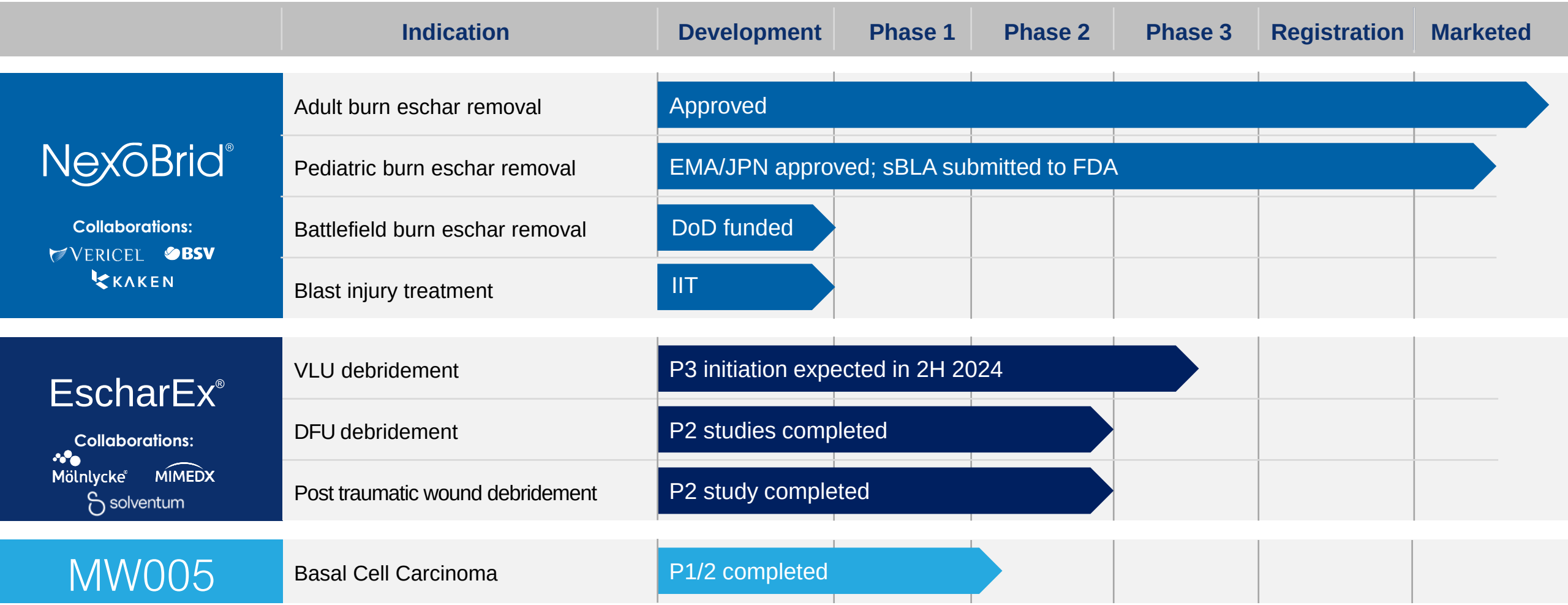
**TAM (U.S.):** **>$2B**

[1] Investigational drug

[2] ~90% of eligible patients require eschar removal; Assumes NexoBrid average price of ~$9,000 per patient

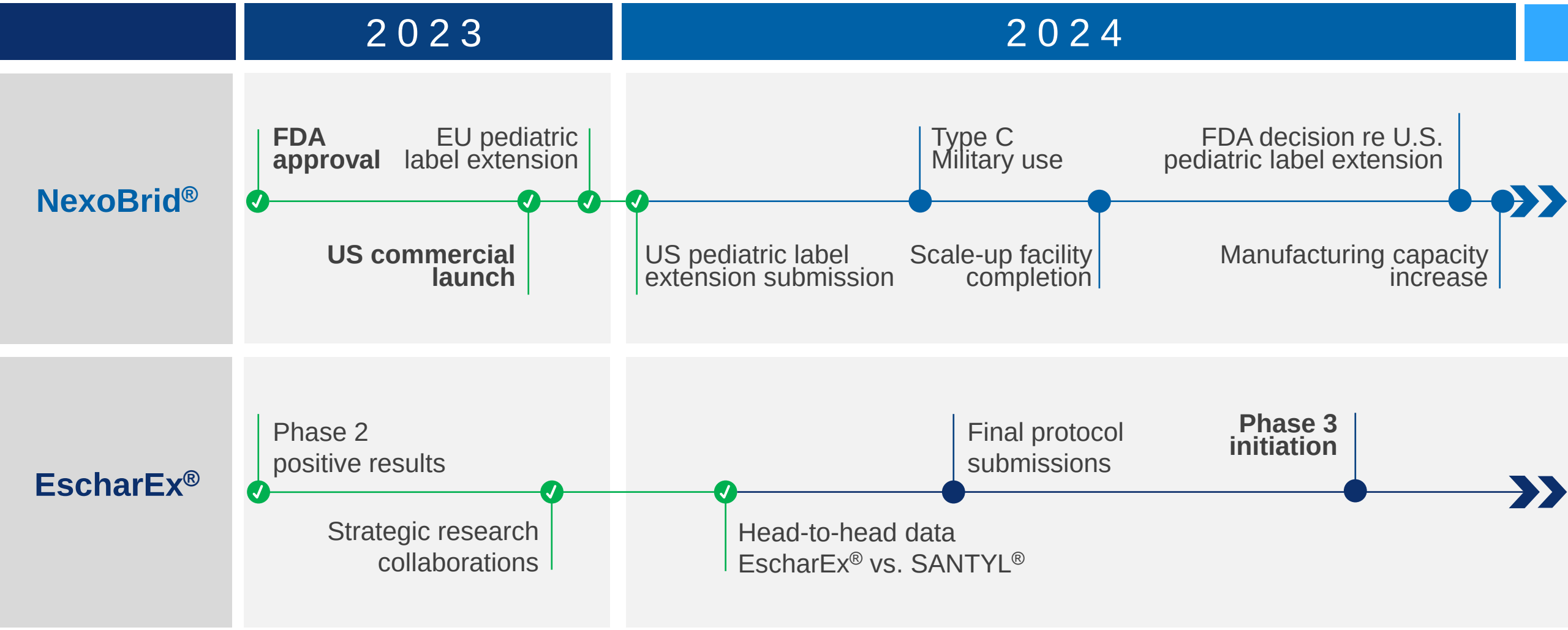
[3] TAM - targeted addressable market; Oliver Wyman market research

# Product Pipeline




DFU=diabetic foot ulcers; DoD=U.S. Department of Defense; IIT=investigator-initiated trial; sBLA=supplemental BLA; VLU=venous leg ulcers

# Value Creating Milestones



# Financial Highlights

## BALANCE SHEET

**~$42M in cash**[1]

No debt

**Cash runway through profitability**

## REVENUE

2023 revenue of ~**$19M**
NexoBrid is profitable

2024 product revenue expected **>40% growth**

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

>**$100M** received from BARDA
>**$13M** received from DoD

## EQUITY

Outstanding shares: ~9.2M
Fully diluted: ~13.7M

Nasdaq | MDWD

**ANALYSTS:**

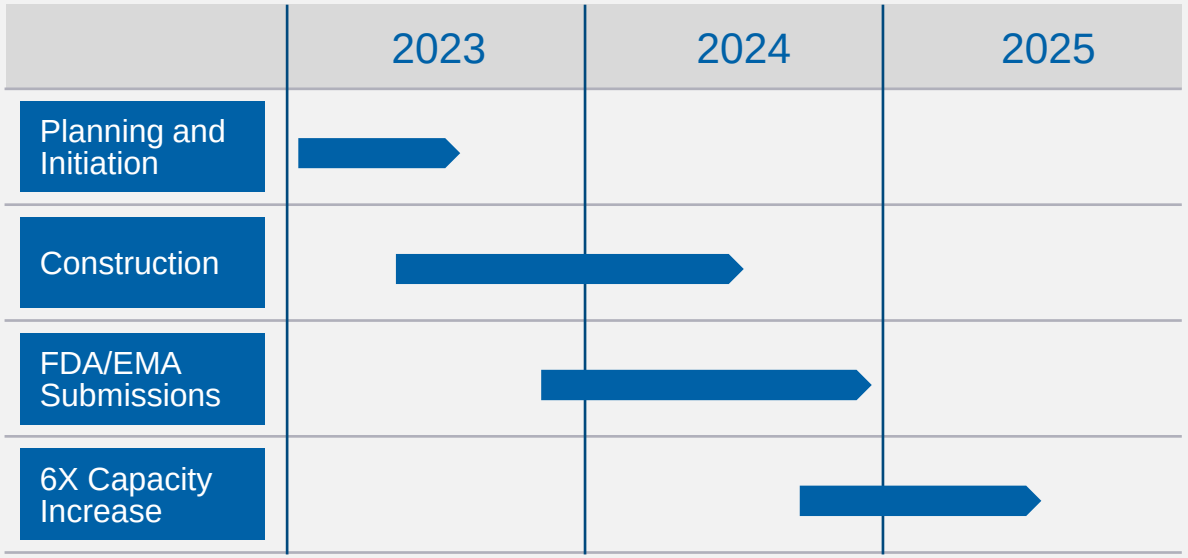
- Josh Jennings, MD - Cowen
- Francois Brisebois - Oppenheimer
- Jason McCarthy, PhD - Maxim
- Swayampakula Ramakanth, PhD - HCW
- David Bouchey - Aegis

**Avg. Price Target - $28.50**

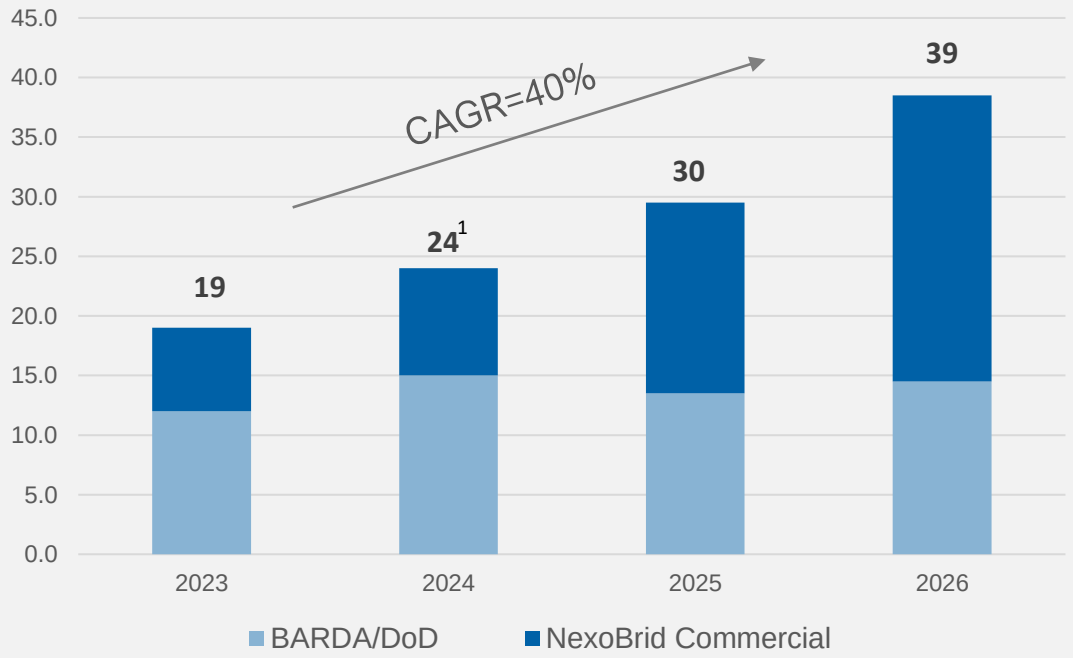
[1] Cash, cash equivalents and short-term and restricted bank deposits as of December 31, 2023

# NexoBrid® Growth Supported by Facility Scale-Up

## Full manufacturing capacity anticipated in 2025




## NexoBrid revenue forecast ($M)




**Global demand surpasses our current manufacturing capability 3-fold**

[1] Includes binding order received from Vericel for the full year of 2024

# NexoBrid®

(10% concentration)

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

| | |
|---|---|
| Validated & commercialized | Approved for use in adults in the U.S., EU, JP; 12,000 patients treated globally |

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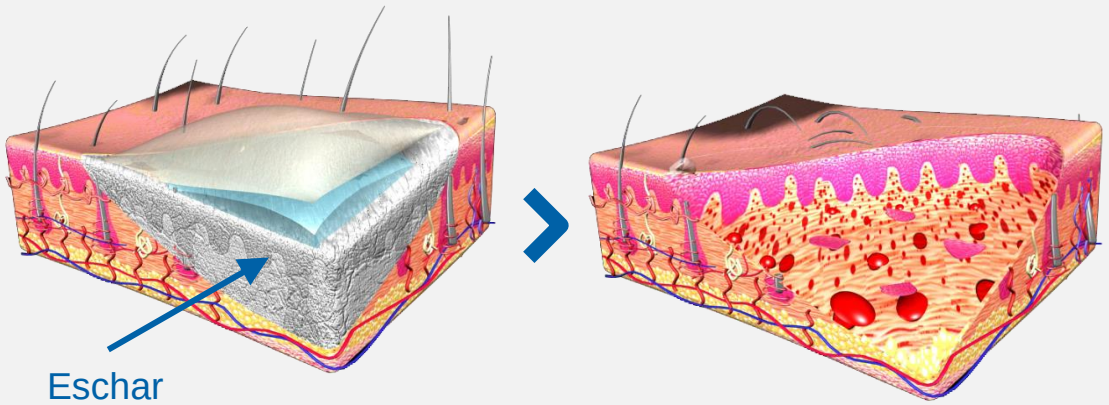
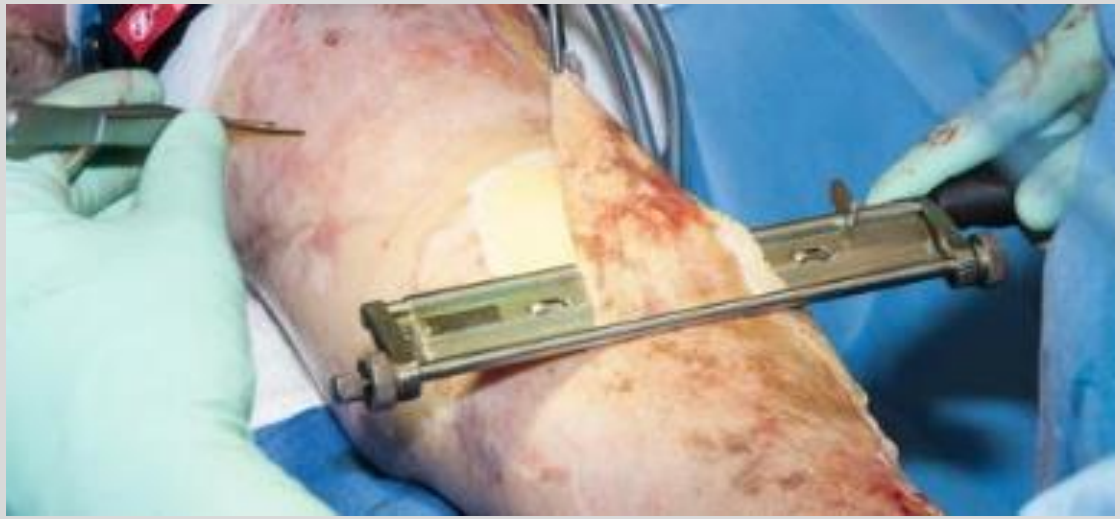
# First Step in Burn Care - **Eschar Removal**

## 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®

[1] Edmondson et al., 2018; Burns | [2] Gurfinkel et al., 2010; Can J Plast Surg

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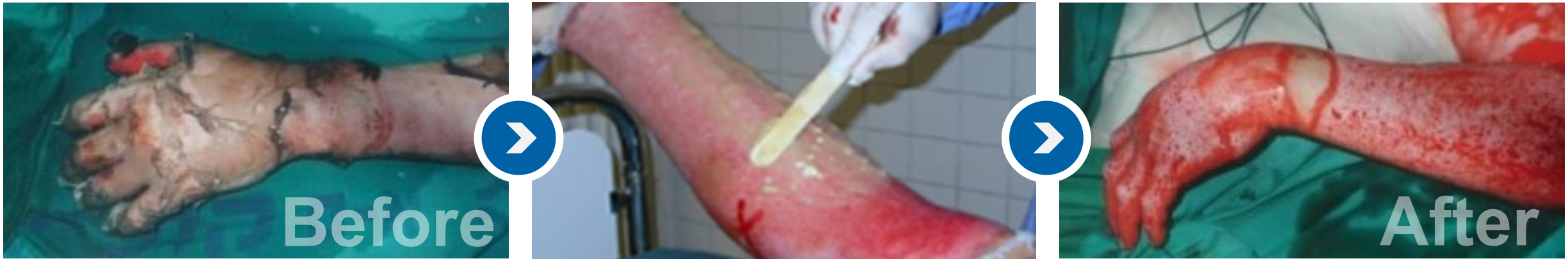
# NexoBrid® Simple, Selective, Effective

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

**Clinical benefit:** Significantly reduces need for surgery & improves patient outcomes

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

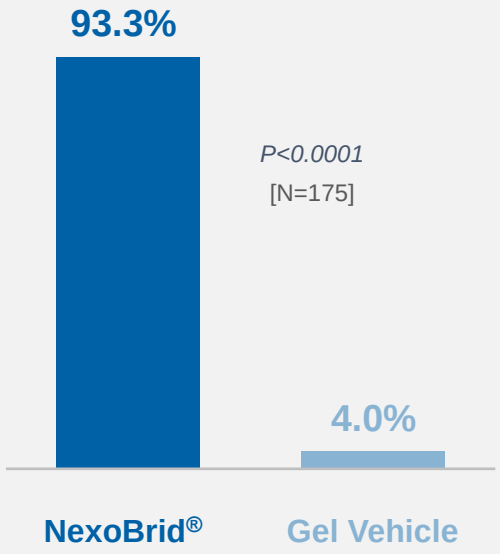
**Government support:** Up to $200M BARDA & DoD Contracts


- Easy-to-use
- Topical application at patient's bedside
- Removes eschar within 4 hours
- Preserves viable tissue
- Reduces blood loss
- Enables visual medical assessment.

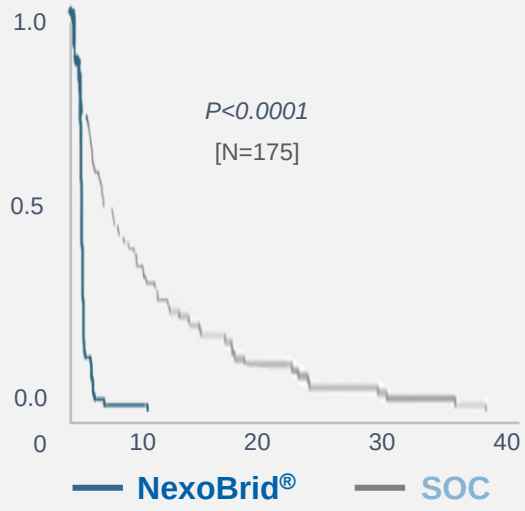
# NexoBrid® - Phase 3 Studies Demonstrate Superiority[1]

## Incidence of complete eschar removal

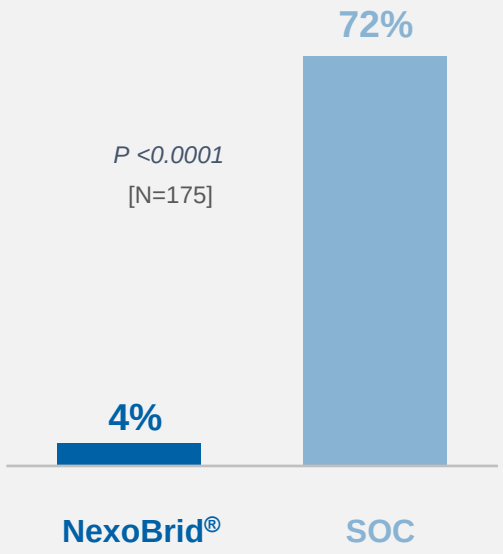



## Time to complete eschar removal

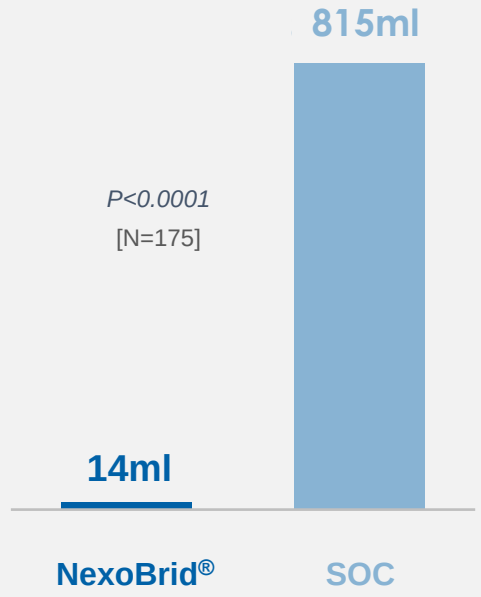
(days)




## Incidence of surgical eschar removal




## Blood loss




Safe and well-tolerated | Improved scarring and comparable wound closure | Consistent results in pediatric Phase 3 study, EU Phase 3 study and post-marketing data[2]



[1] Shoham et al. 2023; Journal of Burn care & Research | [2] Shoham et al. 2023; IWJ

# EscharEx®

(5% concentration)

Next-Generation Enzymatic Debridement Candidate for Chronic Wounds

| | | |
|---|---|---|
| Potentially superior to SOC - May set a new bar for efficacy | Targets **$2B TAM opportunity** | De-risked: Based on a validated technology & successful Phase 2 trials |

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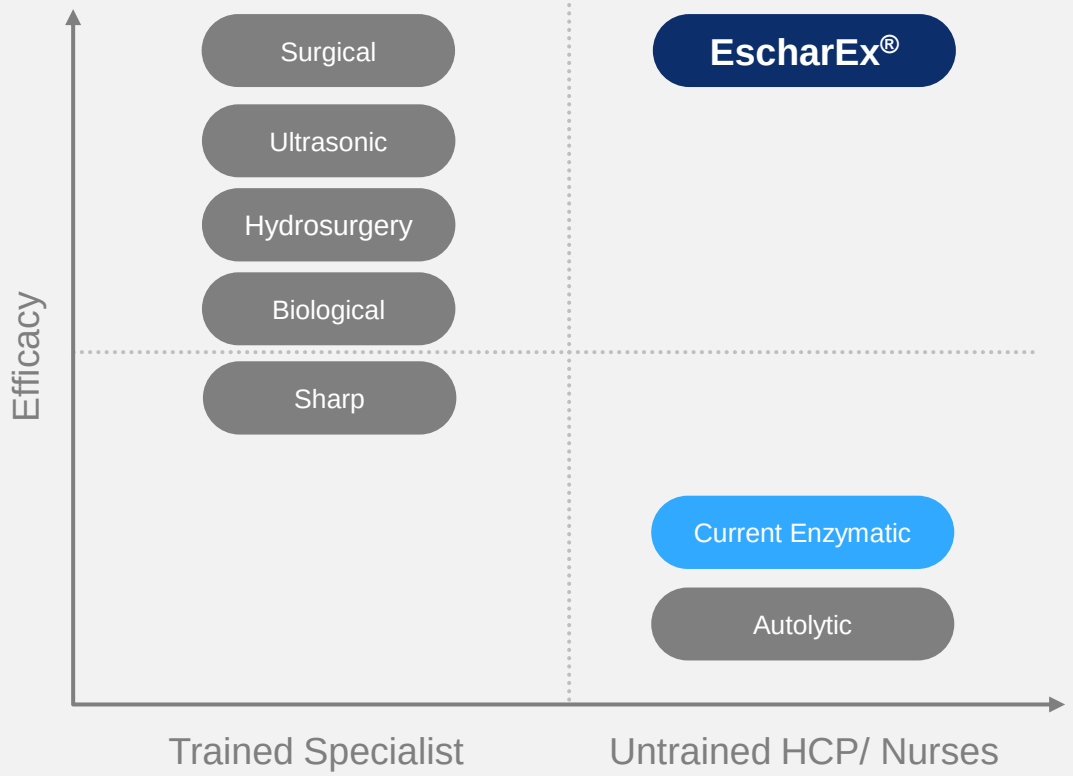
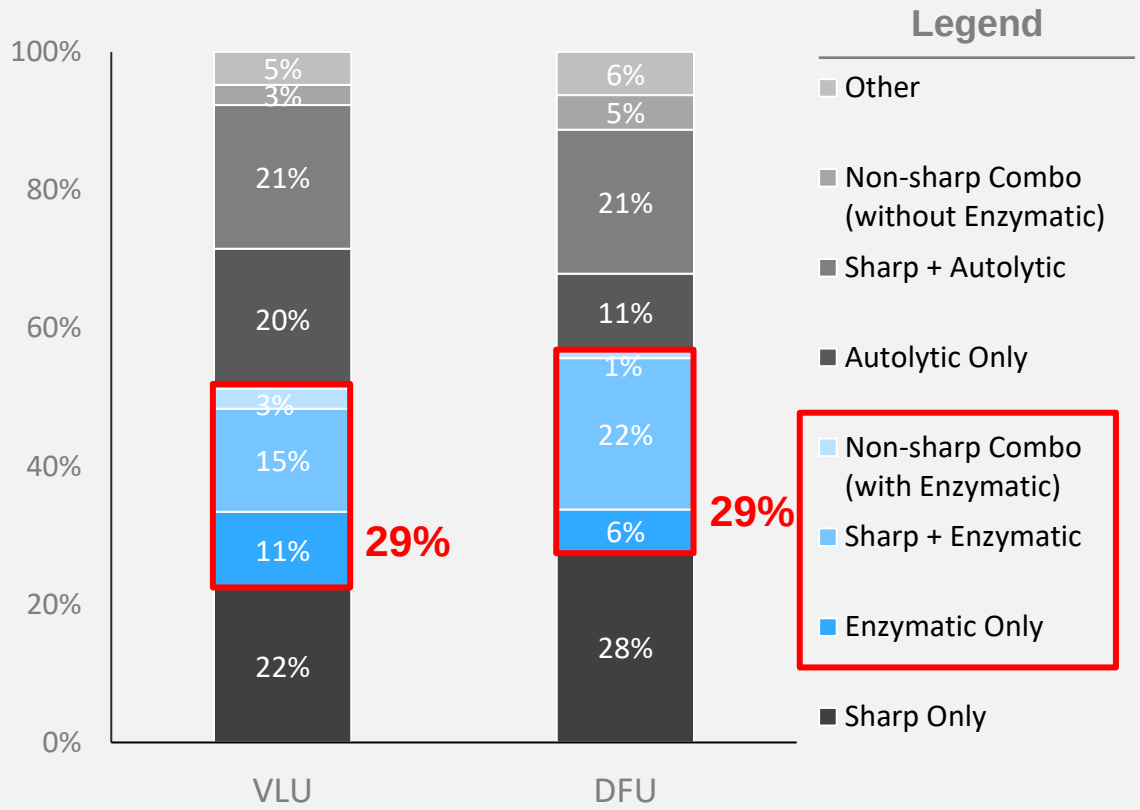
# Chronic Wound Debridement - Current Alternatives are Sub-Optimal

## Modalities by Efficacy and Complexity[1]




## Modalities by Wound Type (U.S.)[2]






[1] The comparison is based on independent real-world data (not cross-trial comparisons; not head-to-head data)

[2] OW Primary Research

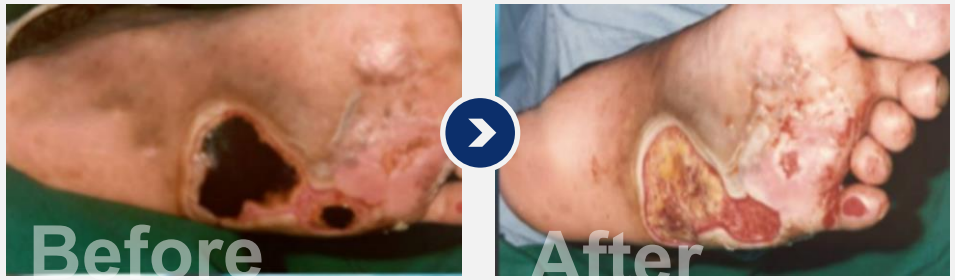
# EscharEx®

# Enzymatic Debridement **within Days**


**Status**: Investigational drug containing sterile mixture of proteolytic enzymes

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


**VLU**
Venous Leg Ulcers



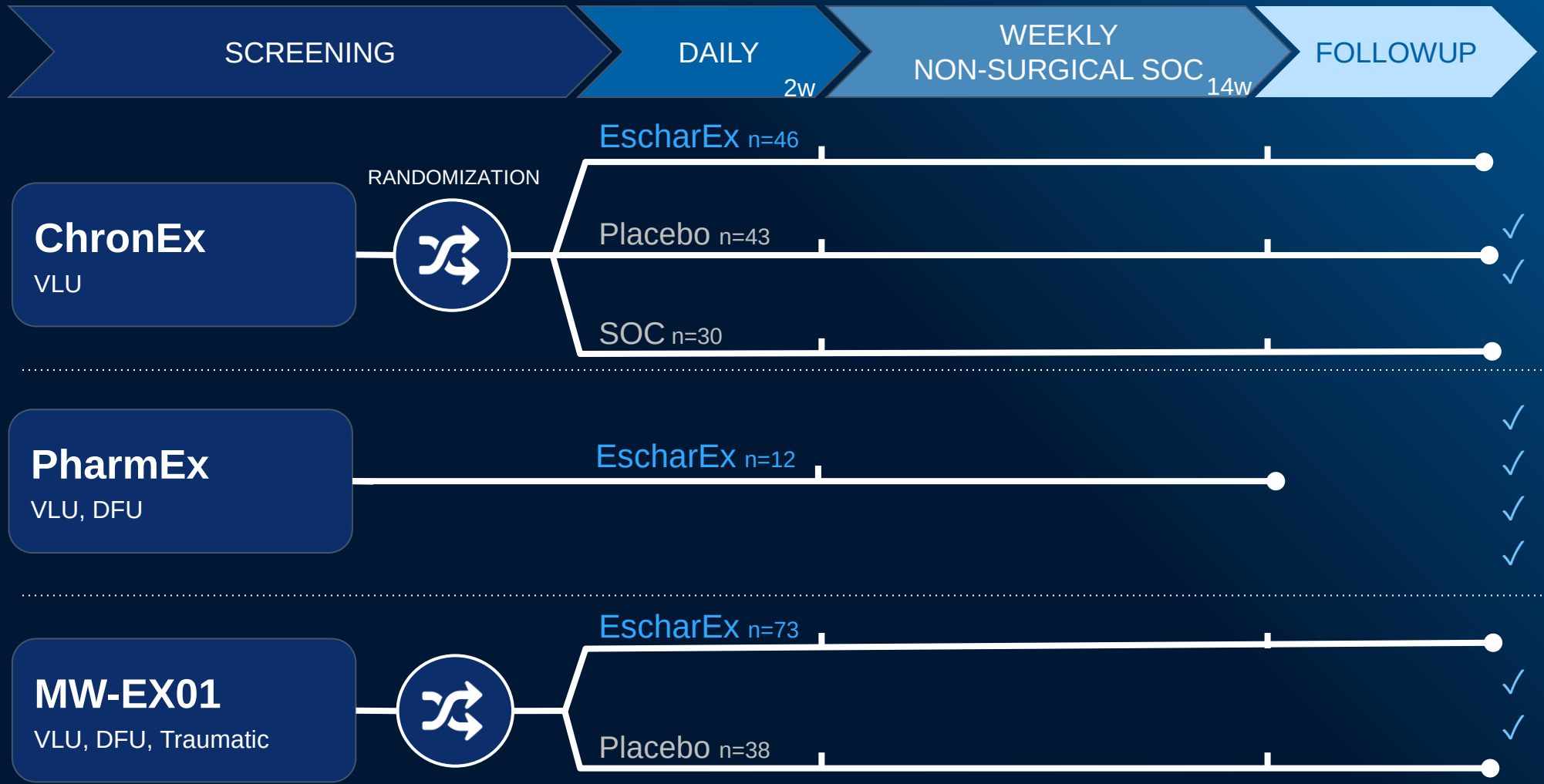

**DFU**
Diabetic Foot Ulcers

- Designed to debride chronic wounds in 4-8 daily applications
- Designed to promote granulation tissue
- Designed to reduce biofilm & bacteria
- In-line with current treatment workflows and reimbursement landscape
- Easy to use daily topical application designed for outpatient setting



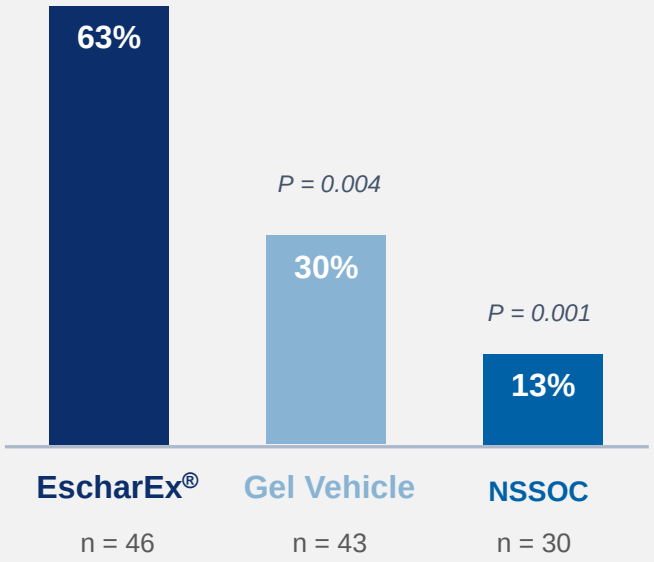
[1] Wound bed preparation (WBP) = complete debridement + complete granulation

# Evaluated in **Three Successful Phase 2 Studies**



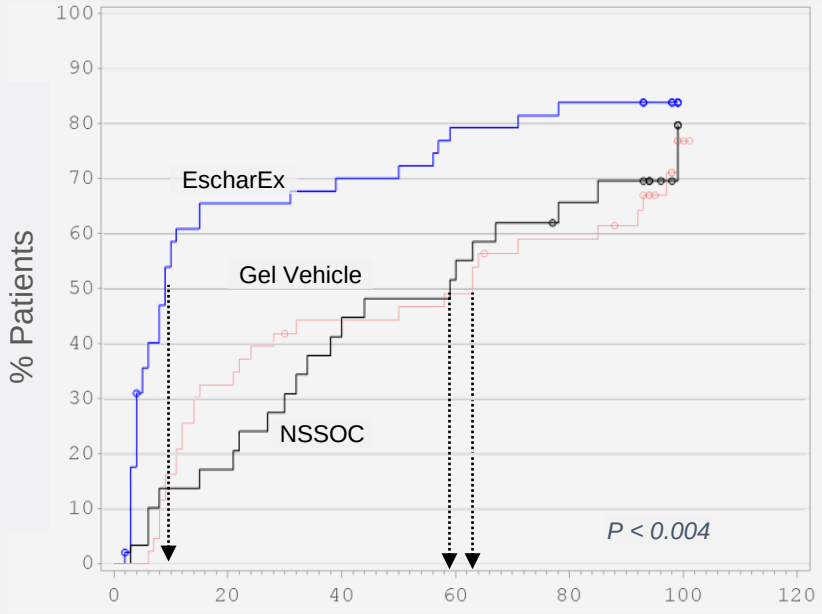
# EscharEx® Phase 2 Study - **Endpoints Significantly Met**

## Primary Endpoint




Incidence of complete debridement
**EscharEx: 63% vs NSSOC: 13%**

## Secondary Endpoint

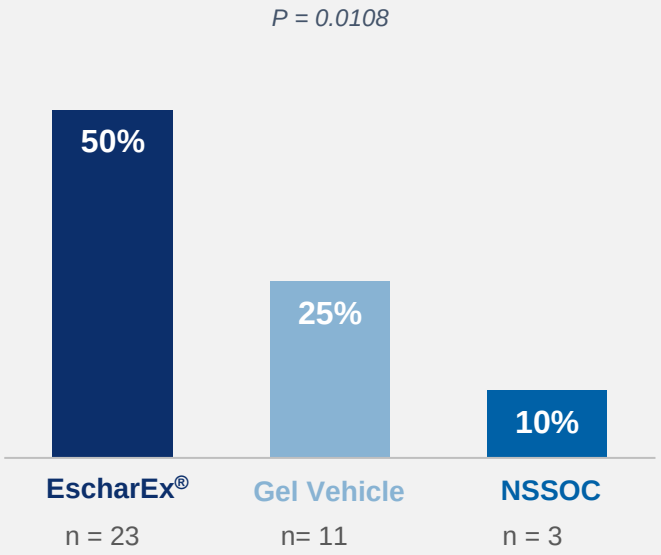



Time to complete debridement:
**EscharEx: 9 days vs NSSOC: 59 days**

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

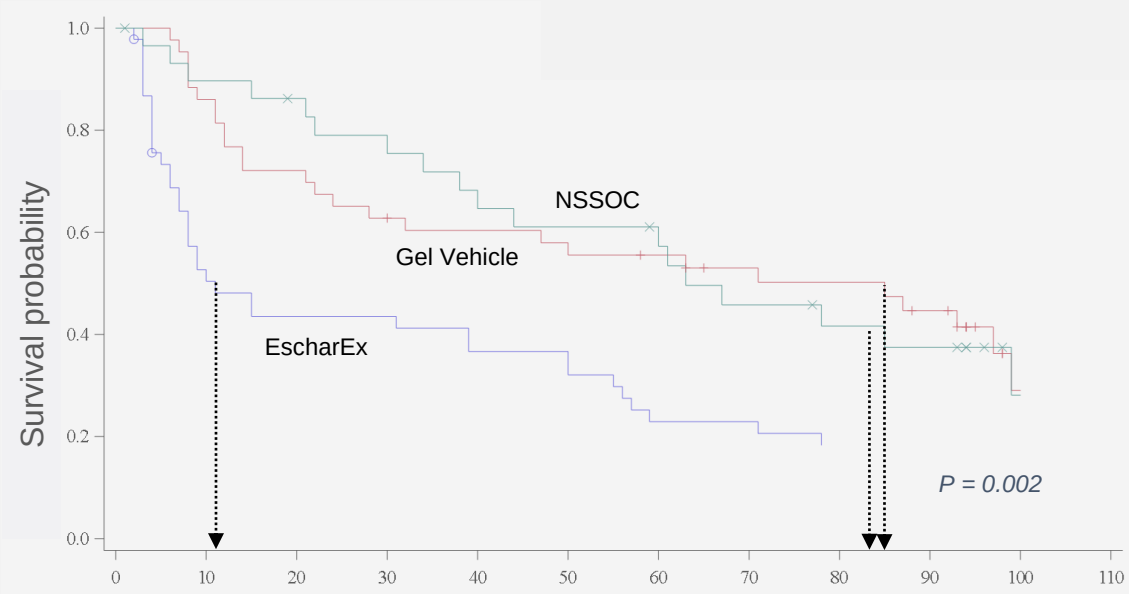
# EscharEx® Phase 2 Study - **Rapid Wound Bed Preparation**

## Incidence of WBP




Incidence of WBP
**EscharEx 50% vs. Gel Vehicle 25%**

## Time to WBP



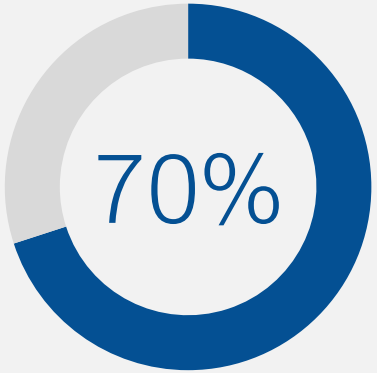

Length of treatment
**EscharEx 11 days vs. Gel Vehicle 85 days**

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

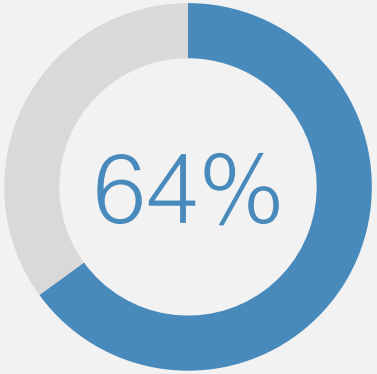
Significant correlation - WBP vs. time to wound closure. HR of 11.96 (p < 0.0001)

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

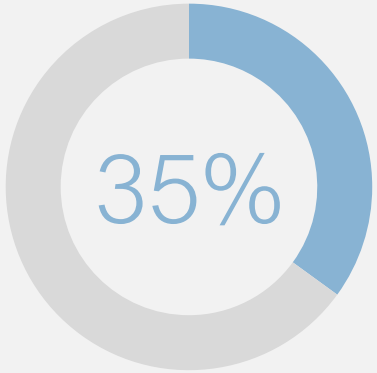
# EscharEx® Phase 2 Pharmacology - **Beyond Traditional Debridement**




**Complete debridement achieved**
within 8 applications
(avg 3.9 applications)




**Bioburden reduced**
by end of treatment




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


**Biofilm substantially reduced**
for all patients positive for biofilm
at baseline

**Results showed reduction in wound size, biofilm and bacterial burden**


[1] Snyder et al., 2023; Wounds Journal

# EscharEx® Planned Phase 3 Study in VLU Patients

## STUDY OBJECTIVES

To assess safety and efficacy of EscharEx compared to placebo in VLUs

## STUDY DESIGN

A global (USA, EU, ROW)[1], randomized, double blind, adaptive design study in patients with VLUs

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

**Sample size:** 216 VLU patients across 40 sites

**Treatment:** up to 8 applications of 24 hours each

**Study Duration:** 12 weeks + 3 months (to monitor durability of wound closure)

**Pre-defined interim assessment:** 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



[1] Research collaborations with Solventum, Mölnlycke and MIMEDX

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

## EscharEx®


**Investigational drug - Phase 3 expected to begin in 2H 2024**

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 have been well-tolerated[7]

## SANTYL®


**Approved in the 1960s; $360M+ annual revenues (2022)**
**Existing reimbursement code[2]**

Collagenase; **single** target of action

Debridement[8]

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

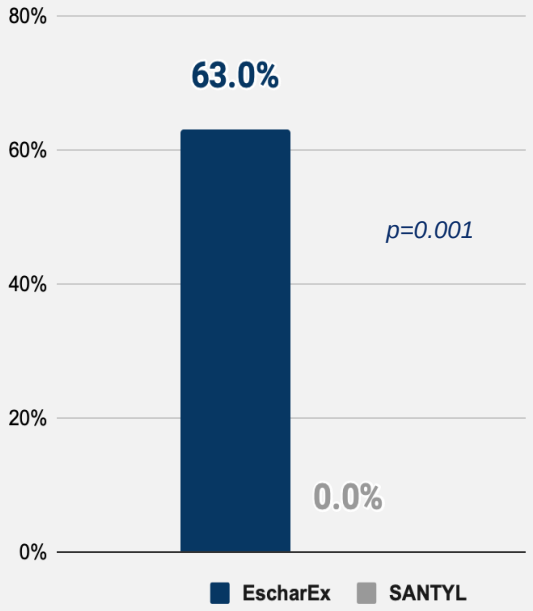
*"There is a **lack of RCTs** with adequate methodological quality"*[4]

Demonstrated to be safe and well-tolerated

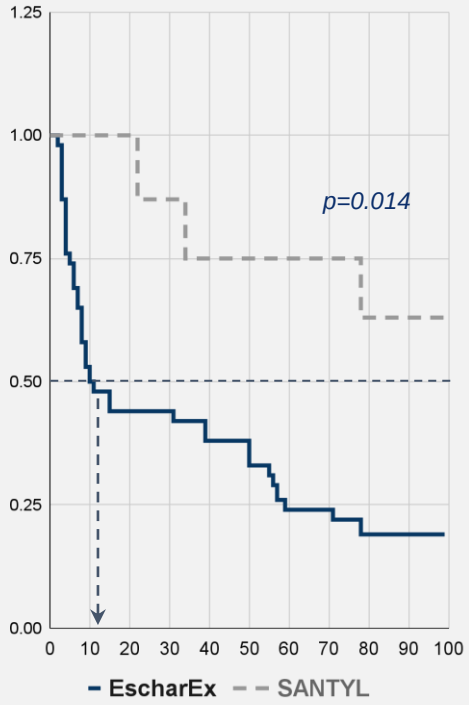
[1] The comparison presented represent cross-trial comparison and does not involve data from a head-to-head trial [2] OW Primary Research [3] Lantis JC and Gordon I., 2017; Wounds
[4] Patry et al., 2017 [5] Snyder et al., 2023; Wounds [6] SOC in the Phase 2 trial included SANTYL® [7] Based on the data to date [8] SANTYL® PI

# **Summary** of Head-to-Head Data[1]

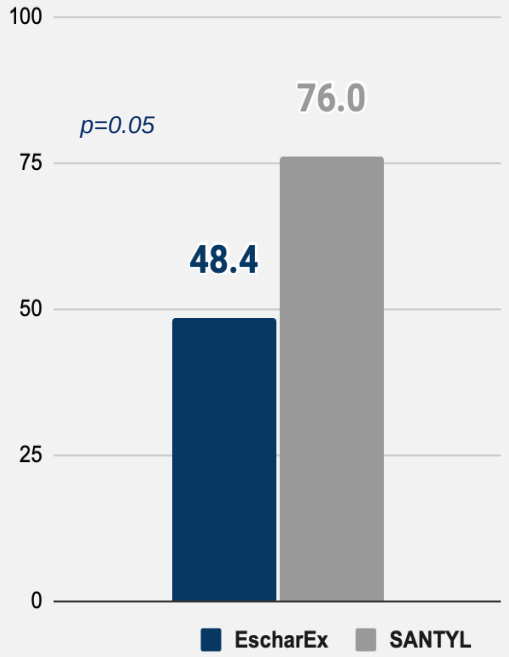
## Incidence of complete debridement in 2 weeks



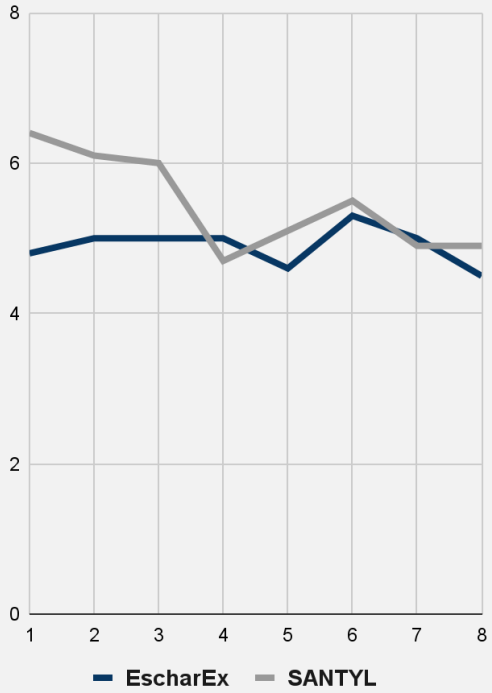

## Time to achieve WBP




## Time to wound closure




## Patient reported pain

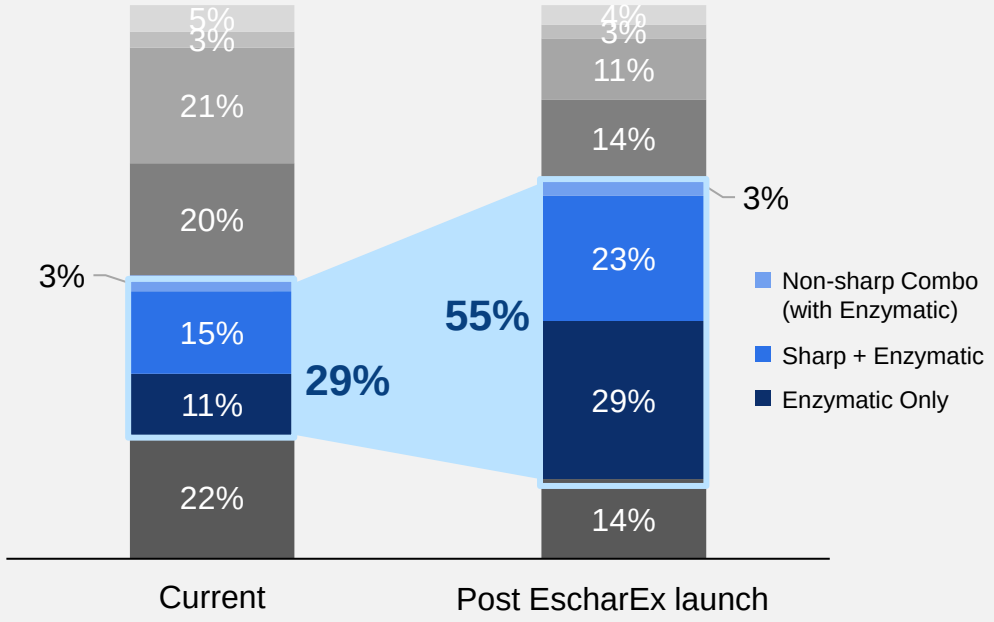



Comparable incidence of adverse wound reactions identified

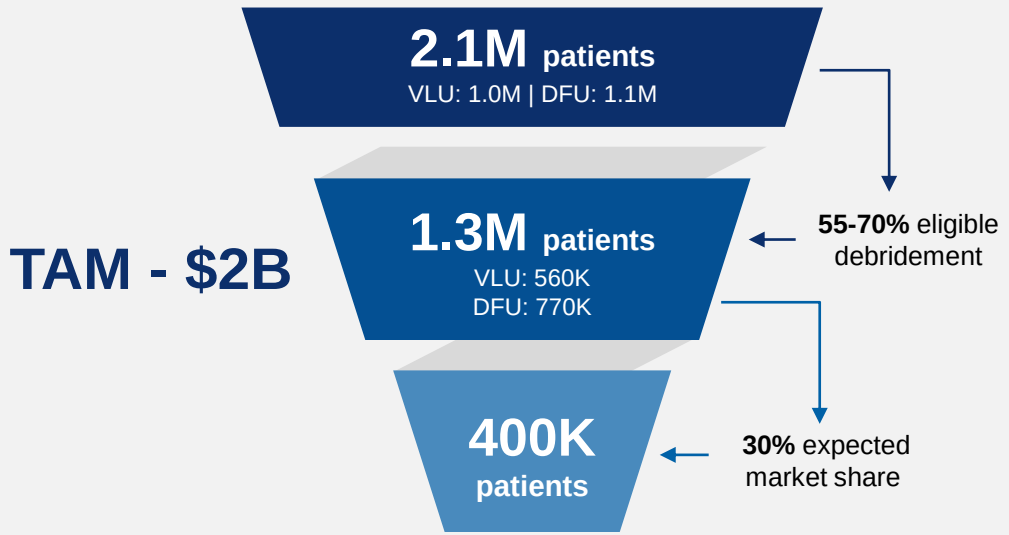
[1]Post-hoc data from the CHRONEX Phase 2 study

# EscharEx® U.S. Market Opportunity[1]

## Market potential growth




## Epidemiology Estimate




**Existing reimbursement codes for enzymatic debridement**
**Current enzymatic debridement cost of treatment: $1,600-$2,000**

EscharEx® anticipated to draw market share from all other debridement modalities


[1] OW Primary Research

# Leadership Team

**Nachum (Homi) Shamir**
Chairman

Luminex
GIVEN IMAGING
Kodak

**Ofer Gonen**
CEO

gamida cell
CACTUS
CBI

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

DERMASCIENCES
A TISSUE REGENERATION COMPANY
ANDERSEN CONSULTING
Bristol Myers Squibb

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

teva
PROTEO LOGICS
TEL AVIV UNIVERSITY

**Dr. Shmulik Hess**
COO & CCO

ENLIVEX
TABBY THERAPEUTICS
Valin Technologies

**Hani Luxenburg**
CFO

AstraZeneca
BIRD AEROSYSTEMS
EY

**Dr. Robert J. Snyder**
CMO

Systagenix
3M
Johnson & Johnson

# Strategic Timeline