**SECURITIES AND EXCHANGE COMMISSION**

**Washington, D.C. 20549**

# FORM 6-K

**REPORT OF FOREIGN PRIVATE ISSUER**

**Pursuant to Rule 13a-16 or 15d-16 of the**
**Securities Exchange Act of 1934**

**For the month of August 2024**

**Commission File Number: 001-36349**

# MediWound Ltd.

(Translation of registrant's name into English)

**42 Hayarkon Street**
**Yavne, 8122745 Israel**
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): __

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): __

**CONTENTS**

On August 14, 2024, MediWound Ltd. (the "Company") published a presentation on its website, highlighting its commercial product, its clinical products as well as certain estimates and projections as to expected future financial results and information. The presentation can be accessed on the Company's website at www.mediwound.com and is also furnished as Exhibit 99.1 to this Report of Foreign Private Issuer on Form 6-K (this "Form 6-K"). The contents of the foregoing website are not a part of this Form 6-K.

The information contained in the presentation is provided as of August 14, 2024. The Company does not assume any obligation to update the presentation in the future or revise any forward-looking statements to reflect actual future events or developments. The furnishing of the materials related to the presentation is not an admission as to the materiality of any information contained in those materials.

The content of the presentation is incorporated by reference into MediWound's Registration Statements on Form S-8, filed with the SEC on April 28, 2014, March 24, 2016, March 19, 2018, March 25, 2019, February 25, 2020, May 15, 2021, August 9, 2022 and August 15, 2023 (Registration Nos. No. 333-195517, 333-210375, 333-223767, 333-230487, 333-236635, 333-255784, 333-266697 and 333-273997, respectively) and on Form F-3, filed with the SEC on May 25, 2022 (Registration No. 333-265203).

**SIGNATURE**

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, thereunto duly authorized.

MEDIWOUND LTD.

Date: August 14, 2024

By: /s/ Hani Luxenburg
Name: Hani Luxenburg
Title: Chief Financial Officer

**EXHIBIT INDEX**

The following exhibit is filed as part of this Form 6-K:

| Exhibit | Description |
| --- | --- |
| 99.1 | Corporate Presentation of MediWound Ltd. dated August 2024. |


MediWound
Next-Generation Enzymatic Therapeutics
for Non-Surgical Tissue Repair
August 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



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.

# **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**
**EscharEx®** - Targets a **$2B U.S. market**[2]
Challenges a $360M+ dominant product

### Strategic global collaborations

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

### Solid balance sheet with strong investor base

**Cash of $51M**[3]
Runway through profitability

### cGMP certified sterile manufacturing facility

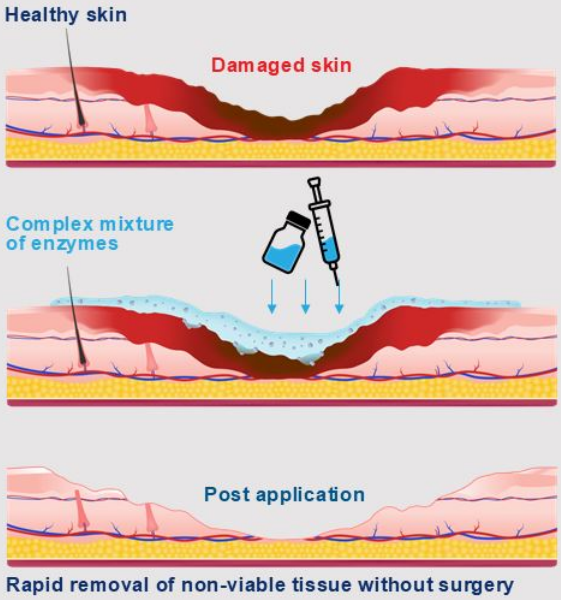
**6x manufacturing capacity** planned for 2025, supporting global demand

**1**. Investigational drug **2.** Oliver Wyman (OW) primary research.
**3.** As of June 30, 2024, including proceeds from the PIPE transaction dated July 15, 2024. This does not reflect the EIC grant

# **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 of deep partial and full thickness burns

**Classification:** Orphan biological drug

**Target users:** Hospitalized patients

**Development status:** FDA/EU/JP approved

**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

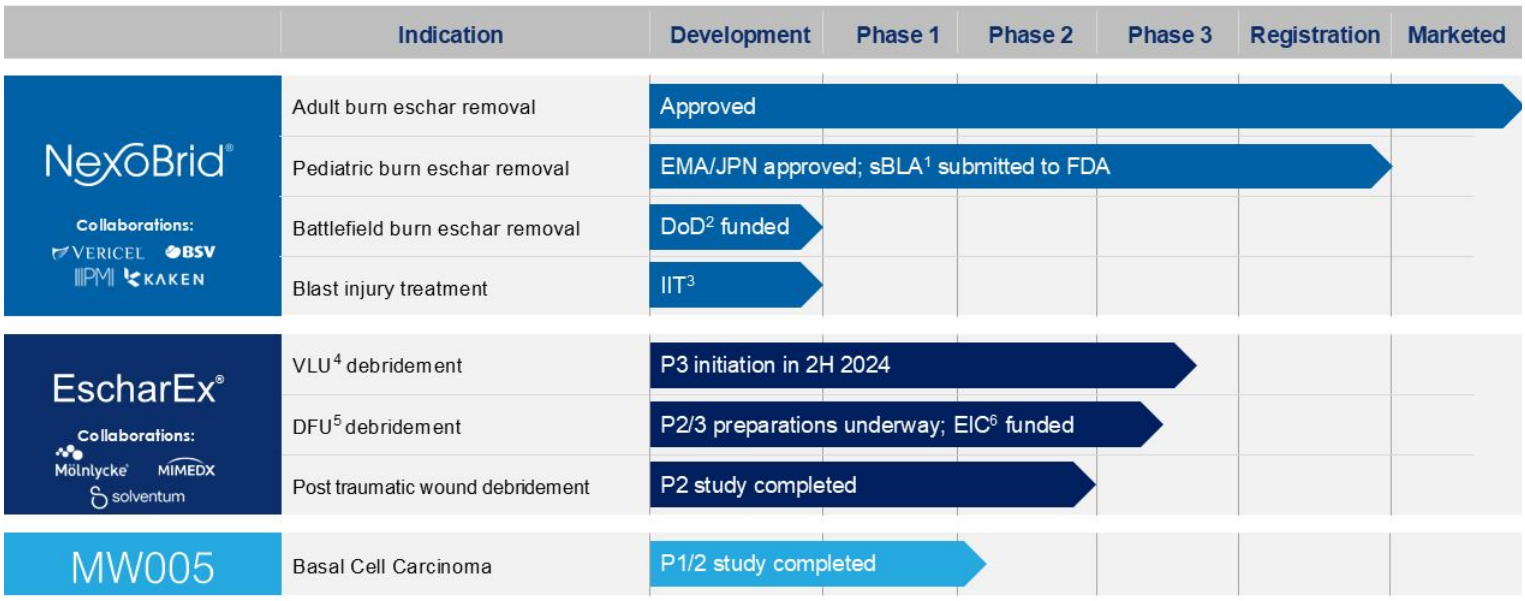
**Target users:** Patients in all wound care settings

**Development status:** Three successful Phase 2 studies
Phase 3 for VLU 2H 2024
Preparations for DFU Phase 2/3 are currently underway

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

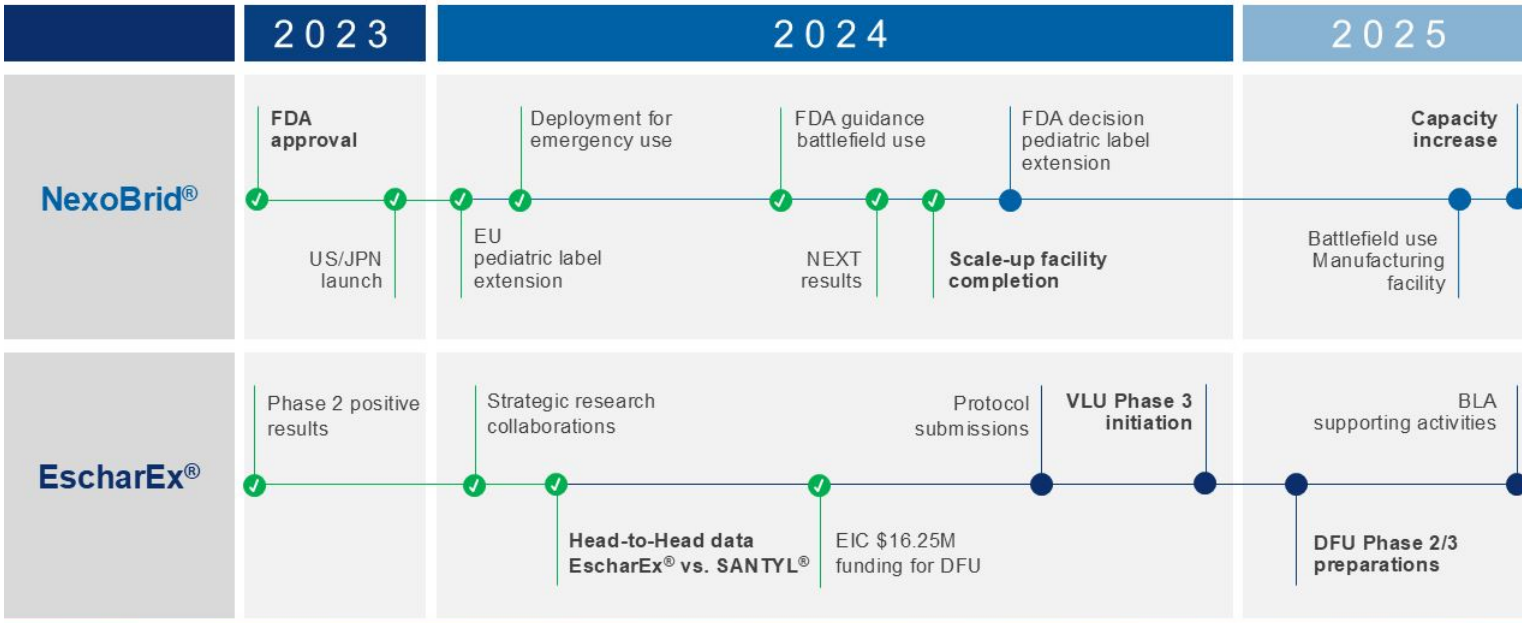
**1.** Investigational drug **2.** ~90% of eligible patients require eschar removal; assumes NexoBrid average price of ~$9,000 per patient
**3.** TAM - targeted addressable market; Oliver Wyman market research

# Product Pipeline




1. Supplemental BLA 2. U.S. Department of Defense 3. Investigator-Initiated Trial 4. Venous Leg Ulcers 5. Diabetic Foot Ulcers 6. European Innovation Council

# Value Creating Milestones



# Financial Highlights

## BALANCE SHEET

**$51M in cash**[1]

No debt

## REVENUE

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

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

**$110M+** received from BARDA
**$15M** funded by DoD

**€16.25M** to be funded by EIC

## EQUITY

Outstanding shares: ~10.8M
Fully diluted: ~15.1M

Nasdaq | MDWD

**ANALYSTS:**

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

**1.** As of June 30, 2024, including proceeds from the PIPE transaction dated July 15, 2024. This does not reflect the EIC grant

NexoBrid®
(8.8% concentration)

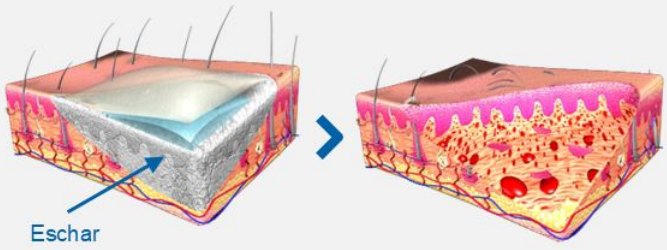
Early, effective and selective non-surgical eschar removal for severe burns

| | |
|---|---|
| Validated & commercialized | Approved in 40+ countries including US, EU, JP; 12,000+ patients to date |

MediWound

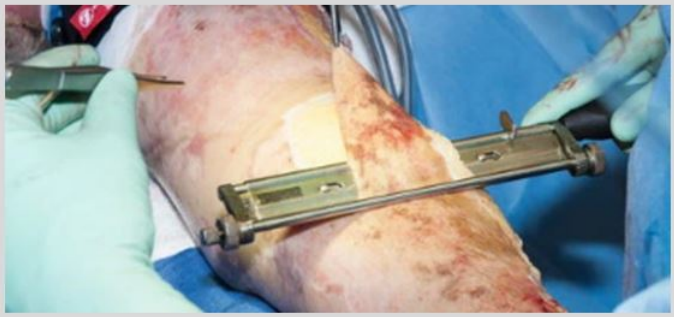
# First Step in Burn Care - **Eschar Removal**

## 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]



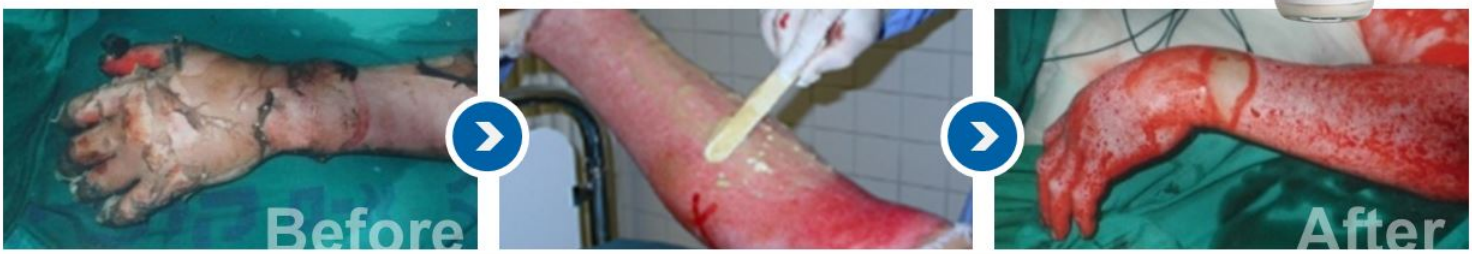
| Loss of healthy tissue and blood | Challenging in delicate areas | Requires surgical team, operating room |
|---|---|---|

# 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), and India (BSV)

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

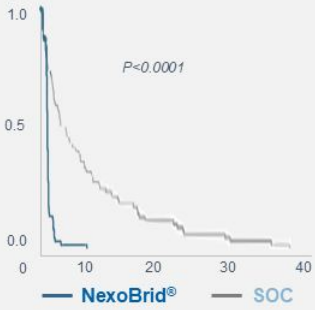

- Easy-to-use
- Topical application at patient's bedside
- Removes eschar within 4 hours
- Preserves viable tissue
- Enables visual medical assessment
- Significantly reduces need for surgery
- Reduces blood loss
- Improves patient outcomes (scar quality and function)

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

### Incidence of complete eschar removal

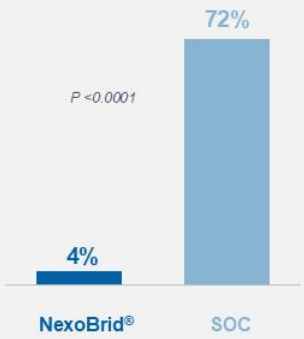

[N=100 (75,25)]

### Time to complete eschar removal (days)



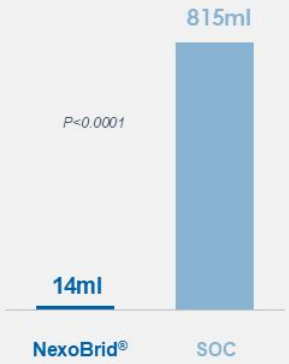

[N=150 (75,75)]

### Incidence of surgical eschar removal




[N=150 (75,75)]

### Blood loss

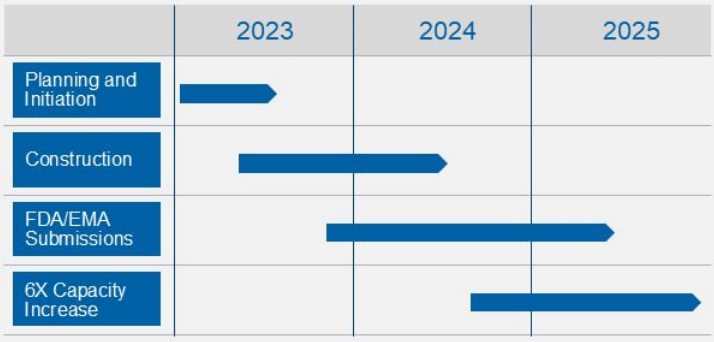



[N=150 (75,75)]

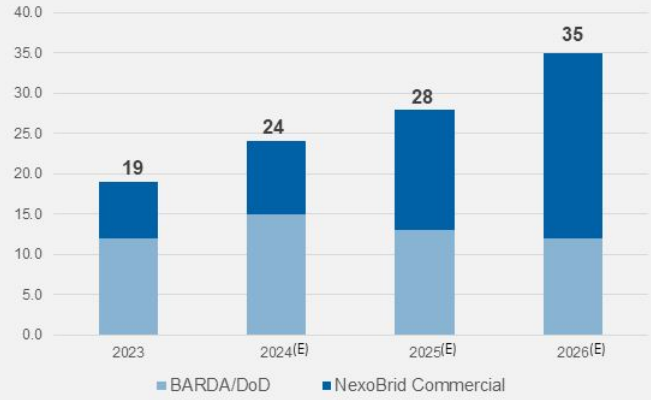
Safe and well-tolerated | Improved scarring and comparable wound closure | Consistent across various studies[2] and post-marketing data[3]

# Growth Supported by **Facility Scale-Up**

## Full manufacturing capacity anticipated in 2025




## NexoBrid® target revenue ($M)




NexoBrid® Global demand exceeds our current manufacturing capability 3-fold

# EscharEx®

(5% concentration)

Next-Generation Enzymatic Debridement Candidate for Chronic Wounds

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

MediWound

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

## **VLU** Venous Leg Ulcers

**Underlying pathology** - Chronic venous insufficiency

**Affects** - Lower leg or ankle

**Ulcer characteristics** - Larger, shallower ulcers; moderate/severe pain

**Prevalence** – 2% of population age 65+
600K -1M 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** - Smaller, deeper ulcers; varying pain levels

**Prevalence** - 25-34% of diabetics develop DFU in their lifetime
1.6M+ new cases annually (US) [1]

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

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

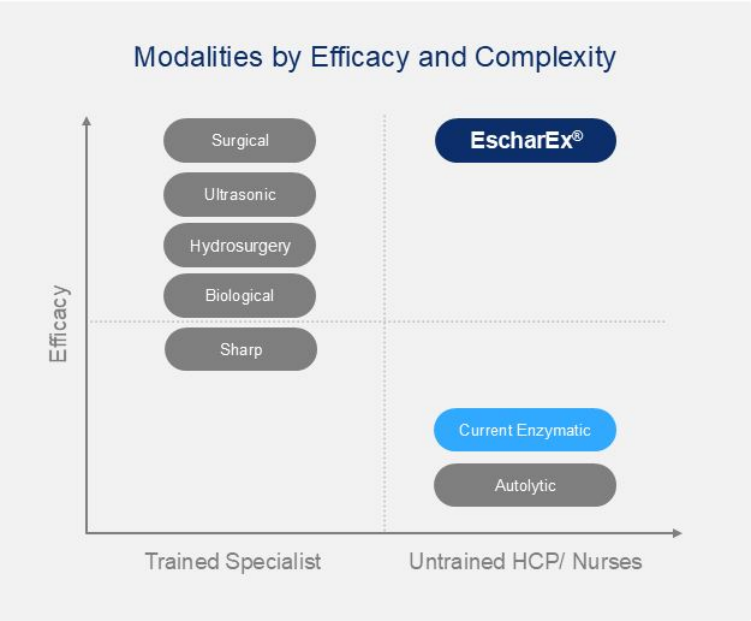
**Management** - Debridement, wound bed preparation, offload pressure, control inflammation and infection, promote healing

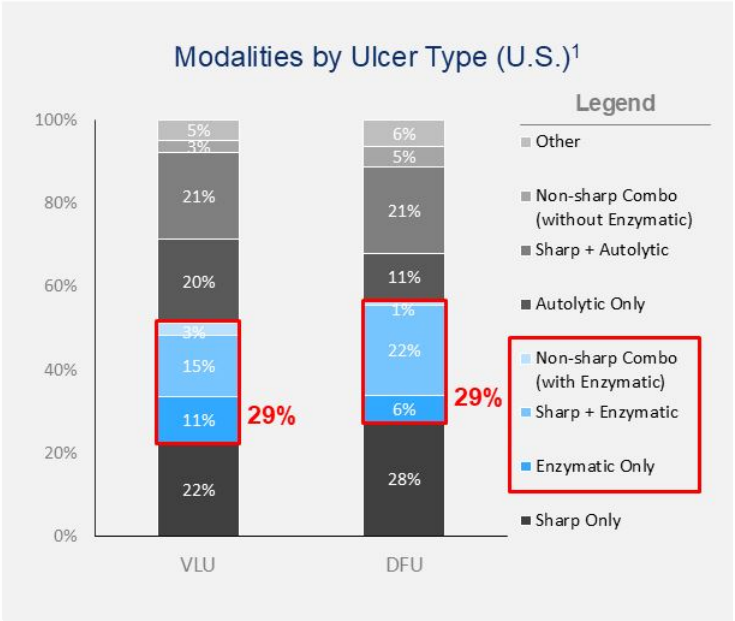
**1.** Oliver Wyman (OW) primary research



Debridement is a critical first step towards healing in both VLU and DFU

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





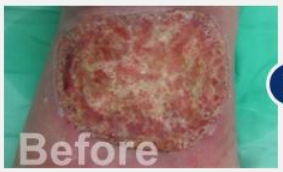

1. Oliver Wyman Primary Research

EscharEx®


**Status**: Investigational drug

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

# Enzymatic Debridement **within Days**




**VLU**
Venous Leg Ulcers

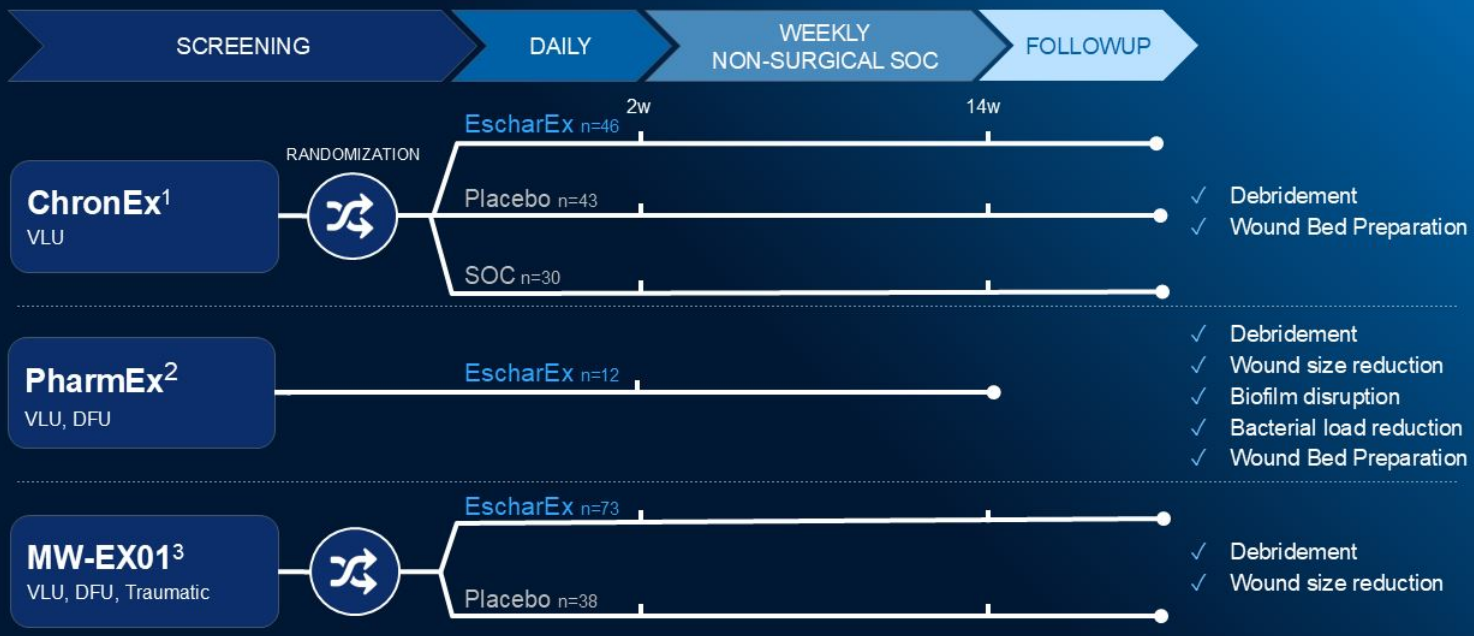

**DFU**
Diabetic Foot Ulcers

- Easy to use daily topical application designed for all patient settings
- Debrides chronic ulcers within 4-8 daily applications
- Promotes granulation tissue
- Reduces bacteria & biofilm
- In-line with current treatment workflows and reimbursement landscape



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

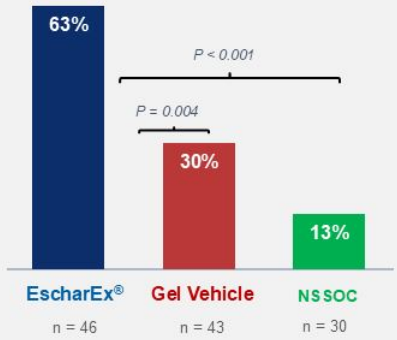
# Successfully Evaluated in **Three Phase 2 Studies**




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

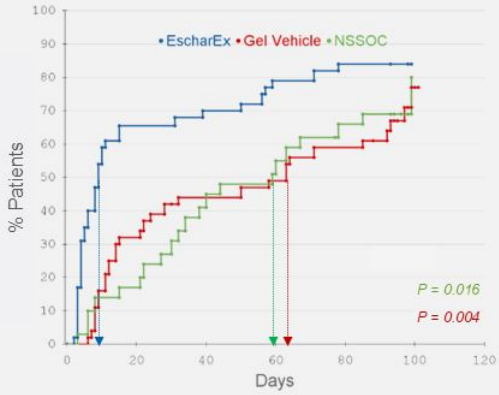
# Phase 2 Study[1] - **Endpoints Significantly Met**

## Complete debridement within 2 weeks (primary endpoint)




**EscharEx is superior to Gel Vehicle and Non-surgical SOC (NSSOC)**

## Time to complete debridement




**EscharEx: 9 days vs. NSSOC: 59 days**

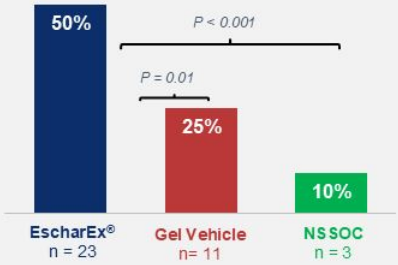
No safety issues observed; efficacy results consistent with previous Phase 2 studies[2]



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

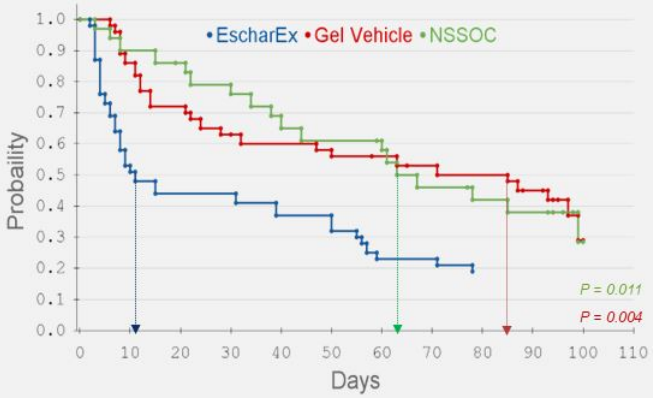
# Phase 2 Study[1] - **Rapid Wound Bed Preparation (WBP) Achieved**

## Incidence of WBP




**EscharEx is superior to Gel Vehicle and NSSOC**

## Time to WBP




**EscharEx 11 days vs. Gel Vehicle 85 days**

## WBP & Healing

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

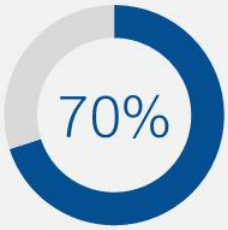
Significant correlation of WBP vs. time to wound closure. HR[2] of 11.96 ($p < 0.0001$)

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

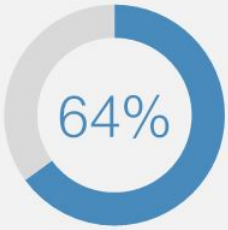


1. Shoham et al. 2024; eClinicalMedicine
2. Hazard Ratio

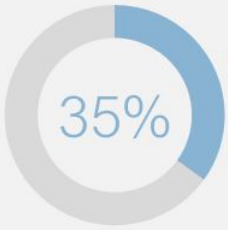
# Phase 2 Pharmacology Study[1] - **Beyond Traditional Debridement**[2]




**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

# EscharEx® 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 be safe and 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]

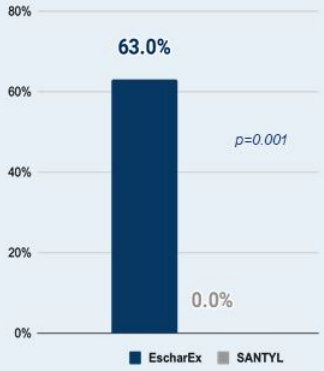
*"There is a **lack of RCTs** with adequate methodological quality"*[4]

Demonstrated to be safe and well-tolerated

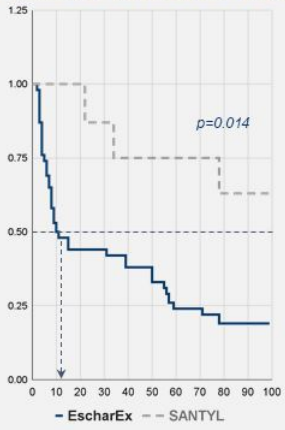
EscharEx®
**1.** The comparison presented represent cross-trial comparison **2.** OW Primary Research **3.** Lantis JC and Gordon I., 2017; Wounds **4.** Patry et al., 2017
**5.** Snyder et al., 2023; Wounds **6.** SOC in the Phase 2 trial included SANTYL® **7.** Based on the data to date **8.** SANTYL®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

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

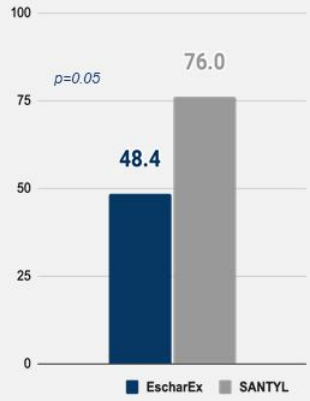
## Incidence of complete debridement in 2 weeks



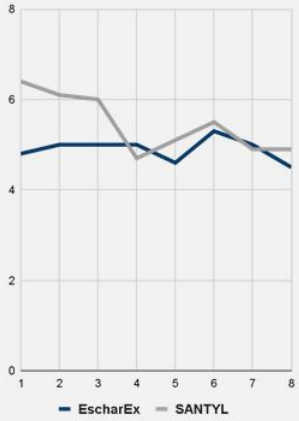

## Time to achieve WBP




## Time to wound closure




## Patient reported pain[2]



# EscharEx® Planned **Phase 3 Study in VLU Patients**

## STUDY OBJECTIVES

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

## STUDY DESIGN

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

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

**Sample size:** 216 VLU patients

**Study design:**

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

# 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 period - up to 8 applications (2 weeks) followed by standardized wound management treatment for 10 weeks
- 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

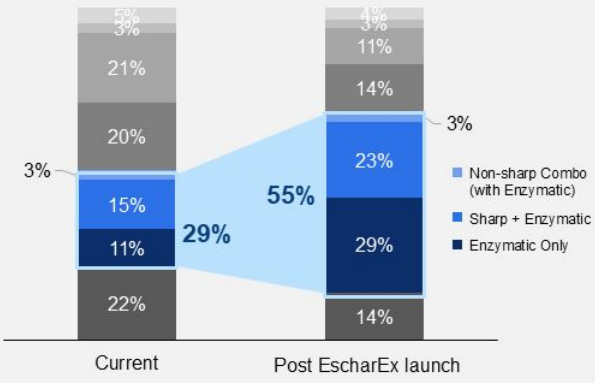
Change in wound area

**Safety:**

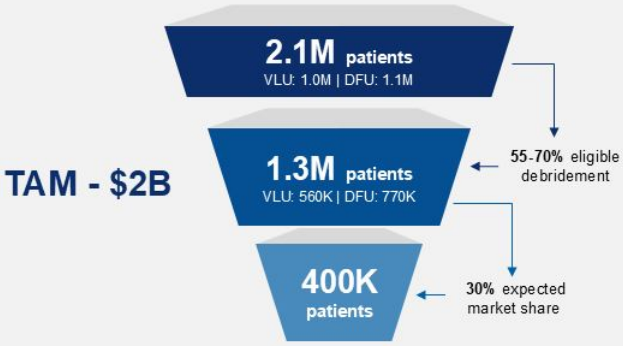
Safety & tolerability | ECG | Change in pain | Wound infection rates | Immunogenicity

# EscharEx® Combined VLU/DFU **U.S. Market Opportunity**[1]

## Market Potential Growth




## Epidemiology Estimate




Non-surgical debridement has an **existing reimbursement code**

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



1. Oliver Wyman Primary research

# Highly Experienced Leadership Team

**Nachum (Homi) Shamir**
Chairman

Luminex
GLEN 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