
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 February 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):

EXPLANATORY NOTE

On February 12, 2024, MediWound Ltd. (the "Company") issued a press release entitled "MediWound Announces Positive Results in Head-to-Head Comparison of EscharEx® vs. SANTYL® within the ChronEx Phase II Randomized Controlled Study". A copy of this press release is attached to this Report of Foreign Private Issuer on Form 6-K (this "Form 6-K") as Exhibit 99.1.

Additionally, a presentation entitled ChronEx Phase II Study Data: A Head-to-Head Comparison of EscharEx® vs. SANTYL® is available on the Company's website at www.mediwound.com and are furnished as Exhibit 99.2 to this Form 6-K. The contents of the foregoing website are not a part of this Form 6-K.

The content of this report on Form 6-K (including the information contained in Exhibit 99.1, but excluding quotes of senior management of the Company and Exhibit 99.2), is hereby incorporated by reference into the Company'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 and March 31, 2023 (Registration Nos. 333-265203 and 333-268297, respectively).

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: February 12, 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:

<u>Exhibit</u>	<u>Description</u>
99.1	Press release dated February 12, 2024 entitled "MediWound Announces Positive Results in Head-to-Head Comparison of EscharEx® vs. SANTYL® within the ChronEx Phase II Randomized Controlled Study."
99.2	A presentation entitled "ChronEx Phase II Study Data: A Head-to-Head Comparison of EscharEx® vs. SANTYL®" dated February 2024.



MediWound Announces Positive Results in Head-to-Head Comparison of EscharEx® vs. SANTYL® within the ChronEx Phase II Randomized Controlled Study

Results demonstrate superiority of EscharEx®, a bromelain-based gel vs. SANTYL®, a collagenase ointment, in wound debridement, promotion of granulation tissue, and time to wound closure in patients with chronic venous leg ulcers (VLU)

YAVNE, Israel, February 12, 2024 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq: MDWD), the global leader in next-generation enzymatic therapeutics for tissue repair today announced the results of head-to-head comparison analyses of EscharEx, the Company's lead asset in development for chronic wounds, to collagenase SANTYL ointment, approved by the FDA for debriding chronic dermal ulcers. SANTYL is currently the market-leading enzymatic debridement product, with more than \$360 million in estimated annual sales in the United States.

Results from the previously disclosed Phase II study (ChronEx) which evaluated the safety and efficacy of EscharEx, demonstrated the superiority of EscharEx vs. a gel vehicle (placebo) and non-surgical standard of care (NSSOC), in achieving complete debridement of non-viable tissue and promotion of granulation tissue (healthy, highly vascularized tissue). The secondary analyses announced today assessed the incidence and time to complete debridement, complete granulation, and wound closure in patients treated with EscharEx (n=46) compared to a sub-group of patients who were treated with SANTYL (n=8).

Ofer Gonen, CEO of MediWound said, "These head-to-head results position EscharEx to become the market leader in enzymatic agents for the treatment of chronic wounds. Data from clinical studies show that EscharEx provides a multimodal mechanism of action for debridement and promotion of granulation tissue, as well as reduction of biofilm and bioburden. All are achieved within a short time frame to facilitate early wound closure, a major benefit for patients suffering from chronic non-healing wounds. With such promising Phase II data, we look forward to the upcoming Phase III trial, set to begin in the second half of 2024, as planned."

Results highlights ([EscharEx vs SANTYL](#))

- Baseline characteristics (age, gender, wound age, wound size) were comparable in both groups.
- The incidence of complete debridement during the *daily treatment period* (the first two weeks of the study) was 63.0% (95% CI=47.5-76.8) for EscharEx vs. 0% for SANTYL; p=0.001.
- The estimated median time to achieve complete debridement during the study was 9 days (95% CI=5-15 days) for EscharEx vs. not achieved for SANTYL (95% CI=22-Not Applicable); p=0.023.
- The incidence of achieving complete debridement and complete cover of the wound bed with granulation tissue (i.e., wound bed preparation, WBP) during the daily treatment period was 50.0% (95% CI = 34.9%-65.1%) for EscharEx vs. 0% for SANTYL; p=0.015.
- The incidence of achieving WBP throughout the study was 78.3% (95% CI = 63.6-89.1) for EscharEx vs. 37.5% for SANTYL (95% CI=8.5-75.5); p=0.03.

- The estimated median time to achieve WBP was 11 days (95% CI =7-50 days) for EscharEx vs. not achieved for SANTYL (95% CI=22-Not Applicable); p=0.014.
- 15 of the 46 patients (32.6%) treated with EscharEx completely closed their wounds during the study, compared to 2 out of 8 patients (25%) treated with SANTYL (NSS). In those patients who achieved complete wound closure, the average time to wound closure was 48.4 days (SD=23.5) for EscharEx vs. 76.0 days (SD=2.8) for SANTYL; p=0.05.
- Patient reported applicational pain was comparable in both groups.
- The safety profile and overall incidence of adverse wound reactions were comparable between arms.

Dr. Robert J. Snyder, Chief Medical Officer of MediWound added, "Complete debridement and complete granulation are key components of wound bed preparation, a critical step in the transition of a chronic wound from an abnormal, disrupted healing process to a normal healing process. These results further support the potential superiority of EscharEx compared with SANTYL in both the percentage of wounds achieving these critical steps, as well as the timeframe in which they are achieved. These significant differences could have a profound impact on wound healing, prevention of complications, and reduction in disease burden."

The data is scheduled for presentation in May 2024 at three leading annual congresses dedicated to advanced wound care: The Wound Healing Society (WHS), the Symposium on Advanced Wound Care (SAWC), and the European Wound Management Association (EWMA).

About the ChronEx study

The ChronEx study was a Phase II multicenter, prospective, randomized, placebo controlled, adaptive design study that evaluated the safety and efficacy of a bromelain-based enzymatic debridement agent in debridement of Venous Leg Ulcers (VLUs).

In the ChronEx study, patients with chronic VLU were randomized (3:3:2 ratio) to daily treatment with EscharEx, placebo, or non-surgical standard of care (SOC), respectively, for up to 2 weeks or until reaching complete debridement and then treated with non-surgical SOC for 12 weeks. The non-surgical SOC arm included SANTYL[®], hydrogels, medical grade honey, and non-active dressings.

About EscharEx

EscharEx is a bioactive, multimodal debridement therapy for the treatment of chronic and other hard-to-heal wounds, currently in the advanced stages of clinical development. It is a concentrate of proteolytic enzymes enriched in bromelain for topical, easy to use daily applications. In several Phase II trials, EscharEx was shown to be safe, well-tolerated, and demonstrated its efficacy in debridement and promotion of granulation tissue in various hard-to-heal wounds, with only a few daily applications. EscharEx's mechanism of action is mediated by proteolytic enzymes that cleave to and remove the necrotic tissue preparing the wound bed for healing. Phase III study in patients with VLU, is planned to start in the second half of 2024.

About MediWound

MediWound Ltd. (Nasdaq: MDWD) is the global leader in next-generation enzymatic therapeutics focused on non-surgical tissue repair. MediWound specializes in the development, production and commercialization of solutions that seek to improve existing standards of care. The Company is committed to providing rapid and effective biologics that improve patient experiences and outcomes, while reducing costs and unnecessary surgeries.

MediWound's first drug, NexoBrid®, is an FDA-approved orphan biologic for eschar removal in severe burns that can replace surgical interventions and minimize associated costs and complications. Utilizing the same core biotherapeutic enzymatic platform technology, MediWound has developed a strong R&D pipeline including the Company's lead drug under development, EscharEx®. EscharEx is a Phase III-ready biologic for debridement of chronic wounds with significant potential advantages over the \$360 million dominant product and an opportunity to expand the market. MediWound's pipeline also includes MW005, a topical therapeutic for the treatment of basal cell carcinoma that has demonstrated positive results in a recently completed Phase I/II study.

For more information visit www.mediwound.com and follow the Company on [LinkedIn](#) and [X](#).

Cautionary Note Regarding Forward-Looking Statements

MediWound cautions you that all statements other than statements of historical fact included in this press release that address activities, events, or developments that we expect, believe, or anticipate will or may occur in the future are forward-looking statements. Although we believe that we have a reasonable basis for the forward-looking statements contained herein, they are based on current expectations about future events affecting us and are subject to risks, assumptions, uncertainties, and factors, all of which are difficult to predict and many of which are beyond our control. Actual results may differ materially from those expressed or implied by the forward-looking statements in this press release. These statements are often, but are not always, made through the use of words or phrases such as "anticipates," "intends," "estimates," "plans," "expects," "continues," "believe," "guidance," "outlook," "target," "future," "potential," "goals" and similar words or phrases, or future or conditional verbs such as "will," "would," "should," "could," "may," or similar expressions.

Specifically, this press release contains forward-looking statements concerning the anticipated progress, development, study design, expected data timing, objectives anticipated timelines, expectations and commercial potential of our products and product candidates, including EscharEx®. Among the factors that may cause results to be materially different from those stated herein are the inherent uncertainties associated with the uncertain, lengthy and expensive nature of the product development process; the timing and conduct of our studies of our products and product candidates, including the timing, progress and results of current and future clinical studies, and our research and development programs; the approval of regulatory submission by the FDA, the European Medicines Agency or by any other regulatory authority, our ability to obtain marketing approval of our products and product candidates in the U.S. or other markets; the clinical utility, potential advantages and timing or likelihood of regulatory filings and approvals of our products and products; our expectations regarding future growth, including our ability to develop new products; market acceptance of our products and product candidates; our ability to maintain adequate protection of our intellectual property; competition risks; the need for additional financing; the impact of government laws and regulations and the impact of the current global macroeconomic climate on our ability to source supplies for our operations or our ability or capacity to manufacture, sell and support the use of our products and product candidates in the future.

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, 2022, filed with the Securities and Exchange Commission ("SEC") on March 16, 2023 and Quarterly Reports on Form 6-K 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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Next-Generation Enzymatic Therapeutics
for Non-Surgical Tissue Repair

ChronEx Phase II Study Data: A Head-to-Head Comparison of EscharEx[®] vs. SANTYL[®]

February 2024 | 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 runway. 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. Specifically, this press release contains forward-looking statements concerning the anticipated progress, development, study design, expected data timing, objectives anticipated timelines, expectations and commercial potential of our products and product candidates, including EscharEx®. Among the factors that may cause results to be materially different from those stated herein are the inherent uncertainties associated with the uncertain, lengthy and expensive nature of the product development process; the timing and conduct of our studies of our products and product candidates, including the timing, progress and results of current and future clinical studies, and our research and development programs; the approval of regulatory submission by the FDA, the European Medicines Agency or by any other regulatory authority, our ability to obtain marketing approval of our products and product candidates in the U.S. or other markets; the clinical utility, potential advantages and timing or likelihood of regulatory filings and approvals of our products and products; our expectations regarding future growth, including our ability to develop new products; market acceptance of our products and product candidates; our ability to maintain adequate protection of our intellectual property; competition risks; the need for additional financing; the impact of government laws and regulations and the impact of the current global macroeconomic climate on our ability to source supplies for our operations or our ability or capacity to manufacture, sell and support the use of our products and product candidates in the future. These and other significant factors are discussed in greater detail in MedWound’s annual report on Form 20-F for the year ended December 31, 2022, filed with the Securities and Exchange Commission (“SEC”) on March 16, 2023, and other filings with the SEC from time-to-time. These forward-looking statements reflect MedWound’s current views as of the date hereof and MedWound 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.

Certain studies and data presented herein have been conducted for us by other entities as indicated where relevant. Intellectual property, including patents, copyrights or trade secret displayed in this presentation, whether registered or unregistered, are the intellectual property rights of MedWound. MedWound’s name and logo and other MedWound product names, slogans and logos referenced in this presentation are trademarks of MedWound Ltd. and/or its subsidiaries, registered in the U.S.A., EU member states and Israel.

Comparison to Enzymatic Standard of Care

EscharEx[®]



Investigational drug - Phase 3 in 2H 2024

Mixture of enzymes; **Multiple** targets of action

Debridement, promotion of granulation, reduction of biofilm & bacteria^{4,6}

1-2 weeks, daily; Monotherapy

Controlled Phase 2 trials; **Significant superiority** over hydrogel & SOC⁵

Demonstrated to be **safe** and well-tolerated⁶

SANTYL[®]



Approved in the 1960s; \$360M+ annual revenues (2022)
Existing reimbursement code¹

Collagenase; **Single** target of action (collagen)

Debridement⁷

4-8+ weeks, daily; Typically coupled with sharp debridement²

*"There is a **lack of RCTs** with adequate methodological quality"*³

Demonstrated to be safe and well-tolerated

¹ OW Primary Research

² Lantis JC and Gordon I., 2017; Wounds

³ Patry et al., 2017

⁴ Snyder et al., 2023; Wounds

⁵ SOC in the Phase 2 trial included SANTYL[®]

⁶ Based on the data to date

⁷ SANTYL[®] PI

ChronEx – Multicenter, Randomized, Controlled Phase II Study



¹ A standardized selection of non-active dressings to be applied according to their approved label or investigator discretion. Compression wraps were mandatory

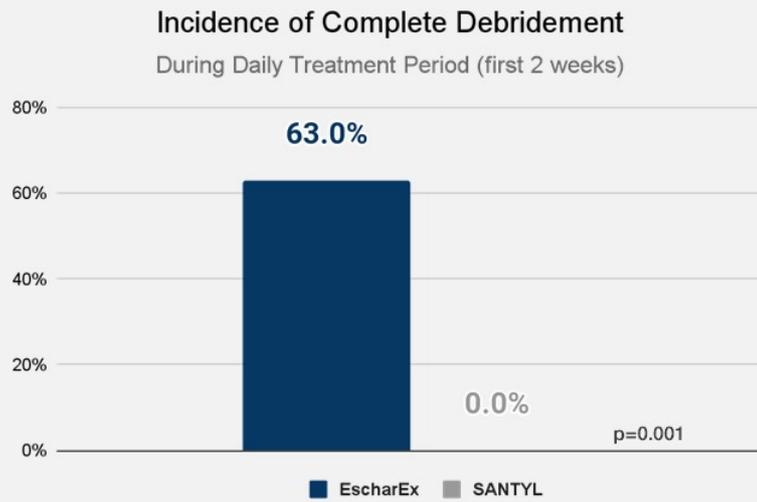
² Non-Surgical Standard of Care - a standardized selection of non-active dressings or enzymatic debridement product to be applied according to their approved label or investigator discretion. Compression wraps were mandatory

³ The data in this presentation is a sub-group analysis comparing EscharEx to SANTYL

Comparable Baseline Characteristics

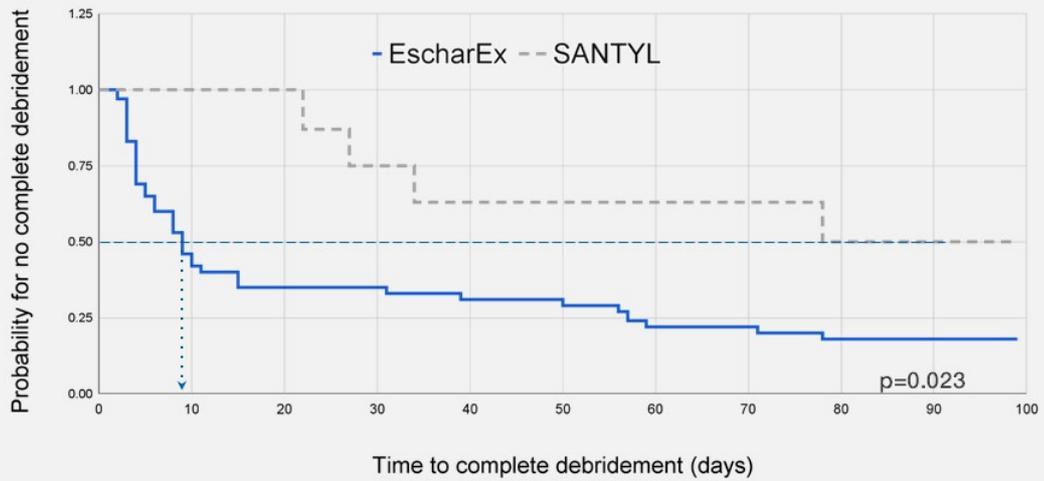
Parameter	EscharEx (n=46)	SANTYL (n=8)
Age (years) - Mean (SD)	65.5 (12.2)	59.9 (11.7)
Female Gender - n (%)	20 (43.5%)	4 (50.0%)
Wound Age (weeks) - Mean (SD)	26.8 (20.5)	29.1 (27.9)
Wound Size (cm ²) - Mean (SD)	13.3 (20.4)	10.3 (5.7)
Non-Viable Tissue (%) - Mean (SD)	72.2 (13.7)	78.1 (15.8)

EscharEx Showed Superiority in Incidence of Complete Debridement



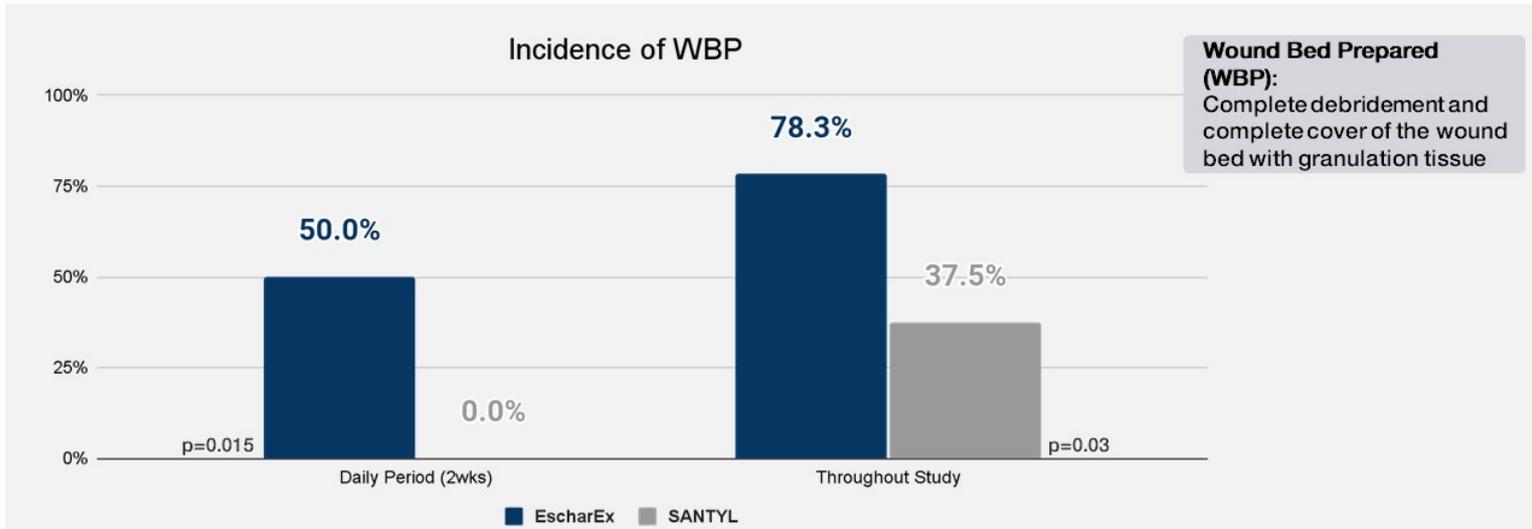
Incidence of complete debridement was 63.0% (95% CI=47.5-76.8) for EscharEx vs. 0% for SANTYL; p=0.001

EscharEx Achieved Complete Debridement Significantly Faster



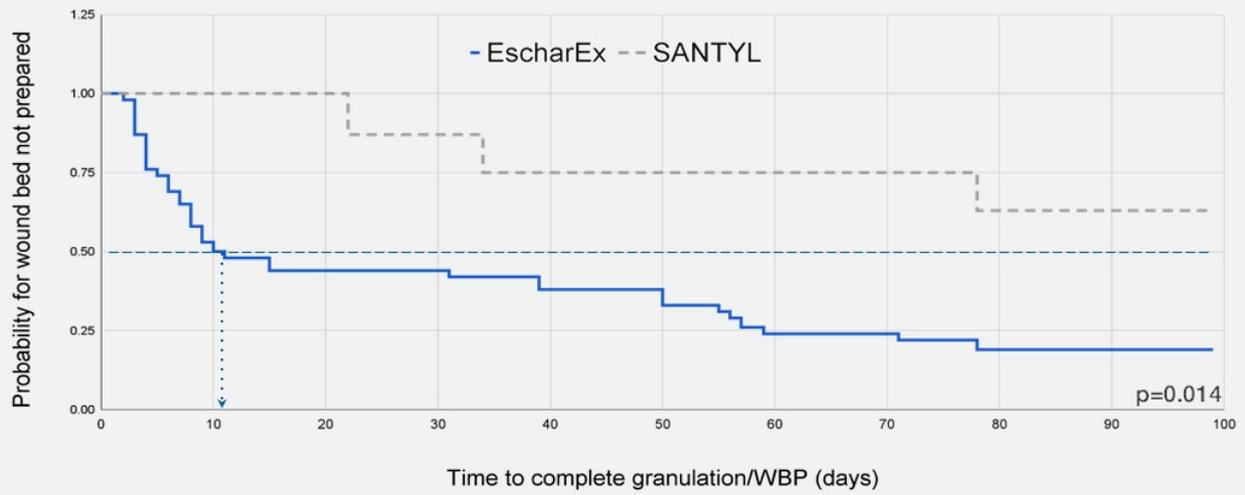
Estimated median time to achieve complete debridement was 9 days (95% CI=5-15 days) for EscharEx vs. not achieved for SANTYL (95% CI=22-Not Applicable); $p=0.023$

EscharEx Showed Superiority in the Incidence of Wound Bed Prepared



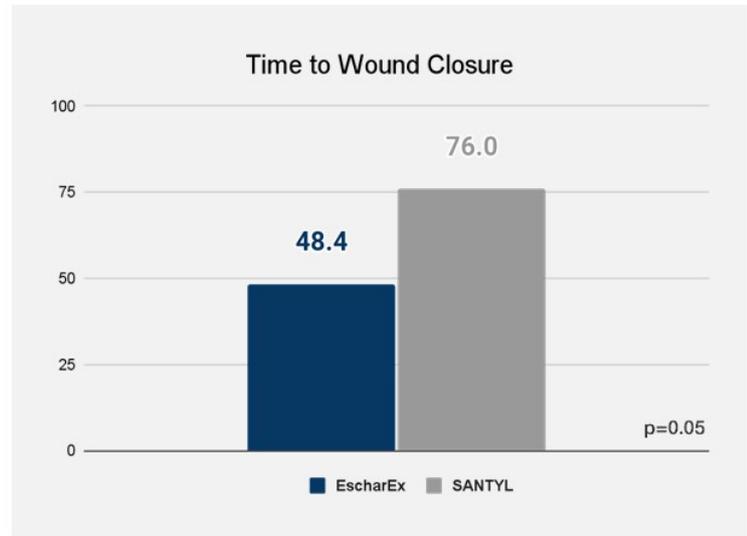
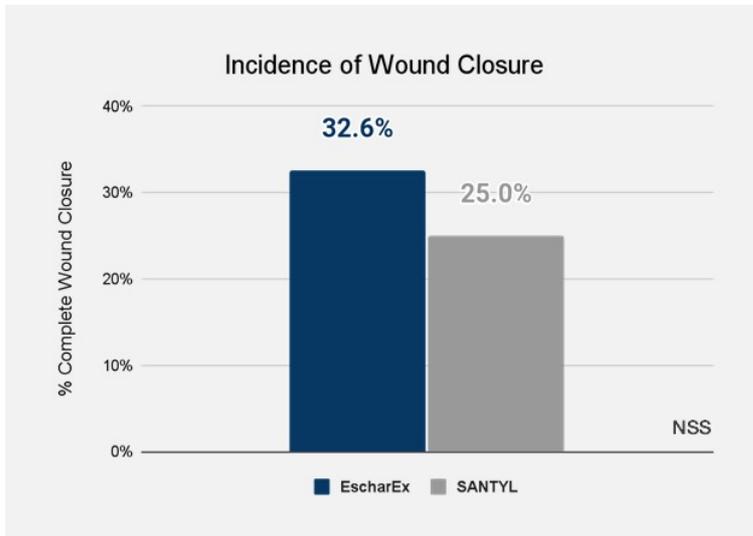
Incidence of WBP in Daily Period was 50% (95% CI = 34.9-65.1) for EscharEx and 0% for SANTYL; p=0.015
Throughout study, EscharEx achieved 78.3% (95% CI = 63.6-89.1) vs. 37.5% for SANTYL (95% CI=8.5-75.5); p=0.03

EscharEx Achieved Significantly Shorter Time to Wound Bed Prepared



Estimated median time to achieve WBP was 11 days (95% CI =7-50 days) for EscharEx vs. not achieved for SANTYL (95% CI=22-Not Applicable); $p=0.014$

Data Suggests EscharEx Advantage in Wound Closure

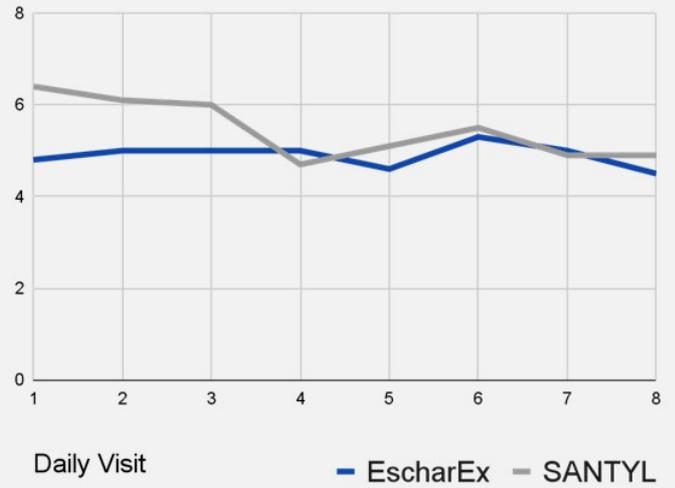


32.6% treated with EscharEx achieved complete wound closure vs. 25% treated with SANTYL (NSS). Average time to wound closure was 48.4 days (SD=23.5) on EscharEx vs. 76.0 days (SD=2.8) on SANTYL; p=0.05

Comparable Safety Profile and Patient Reported Pain

Adverse Event	EscharEx (n=46)	SANTYL (n=8)
Target wound AEs Skin exfoliation, skin maceration, wound infection, cellulitis	20 (43.5%)	3 (37.5%)
Applicational pain AEs	1 (2.2%)	1 (12.5%)

Mean Reported Pain Levels



Summary of Results

Parameter	EscharEx (n=46)	SANTYL (n=8)	p-value
Incidence of complete debridement	63%	0%	0.001
Median time for complete debridement	9 days	Not achieved	0.023
Incidence of WBP (daily treatment period)	50.0%	0%	0.015
Incidence of WBP (throughout study)	78.3%	37.5%	0.03
Estimated median time to achieve WBP	11 days	Not achieved	0.014
Incidence of complete wound closure	32.6%	25.0%	NSS
Average time to wound closure	48.4 days	76 days	0.05
Patient reported applicational pain	Comparable		N/A
Incidence of adverse wound reactions	Comparable		N/A