



MediWound Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Company Update

March 21, 2024

*\$19 million revenue in 2023; \$24 million projected revenue in 2024
NexoBrid® commercially launched in U.S., Japan, India
Potential blockbuster EscharEx® to begin Phase III in the second half of 2024
\$42 million cash runway through profitability*

Conference call today, March 21 at 8:30am Eastern Time

YAVNE, Israel, March 21, 2024 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq: MDWD), the global leader in next-generation enzymatic therapeutics for tissue repair, today announced financial results for the fourth quarter and full year ended December 31, 2023, and provided a corporate update.

"2023 was an exceptional year for NexoBrid driven by new market launches, expanded indications, substantial new governmental grants, and increased global demand. Additionally, this lifesaving treatment was successfully battle-tested in real-life burn mass casualty incidents (BMCI) during the war in Israel. Furthermore, the full capacity of our new manufacturing facility in 2025 will enable us to meet the soaring demand of NexoBrid," said Ofer Gonen, CEO of MediWound. "Recent clinical data further validates our pipeline product, EscharEx, demonstrating that it significantly outperformed SANTYL® in a head-to-head comparative analysis. The product has attracted research collaborations with industry leaders 3M, Mölnlycke and MIMEDX and the Phase III study is set to begin in the second half of 2024. We strongly believe in the exciting future ahead for MediWound."

2023 Highlights and Recent Developments:

NexoBrid®

- Expanded commercial availability to U.S., Japan, and India, leading to \$19 million revenue in 2023, and a surge of orders for 2024, with \$24 million projected revenue.
- Construction of a new GMP-compliant state-of-the-art manufacturing facility is on track for mid-2024 completion. It is projected to achieve a 6-fold manufacturing capacity increase in 2025.
- Commercial Activities:
 - Launched in the U.S. by Vericel Corp, with more than 50 burn centers submitting packages to Pharmacy and Therapeutics (P&T) committees and more than 25 already approved. Furthermore, the Centers for Medicare & Medicaid Services (CMS) awarded NexoBrid a permanent J code and granted it transitional pass-through payment status, enhancing its accessibility and reimbursement potential.
 - Launched in Japan through Kaken Pharmaceuticals, and in India through Bharat Serums and Vaccines (BSV).
 - Expanded European market presence by establishing a collaboration with PolyMedics Innovations (PMI) for the promotion of NexoBrid in Germany, Austria, Belgium, the Netherlands, and Luxembourg.
 - Successfully fulfilled emergency demand in Israel to treat mass burn casualties resulting from the war, consuming all available non-U.S. inventory.
- Government Funding:
 - Awarded \$13.0 million R&D funding by U.S. Department of Defense (DoD) to develop and produce a new NexoBrid temperature stable formulation for use as a non-surgical solution for field-care burn treatment for the U.S. Army.
 - Awarded \$10.1 million in additional funding from the Biomedical Advanced Research and Development Authority (BARDA) for emergency preparedness product replenishment and R&D activities.
- Pediatric label expansion:
 - Gained European Commission approval for the removal of eschar in deep partial- and full-thickness thermal burns for all ages.
 - Supplemental BLA for pediatric indication accepted for review by the U.S. Food and Drug Administration (FDA). Decision expected in the second half of 2024.

EscharEx®

- Aligned the Phase III study protocol with the European Medicine Agency (EMA) and the FDA, and expected to submit a final protocol in the first half of 2024. 216 patients will be treated globally across 40 sites with either EscharEx or a gel vehicle placebo, with an interim assessment to be performed once 67% of participants complete the study. Study initiation is expected in the second half of 2024.
- Established research collaborations with 3M, Mölnlycke and MIMEDX to support the EscharEx Phase III clinical study.
- Conducted head-to-head comparative analysis of EscharEx vs SANTYL®. Data from a Phase II randomized controlled study demonstrated significant superiority of EscharEx over SANTYL in multiple clinical outcome measures: incidence of complete debridement; median time to achieve complete debridement; incidence of achieving wound bed preparation (WBP); median time to achieve WBP; and time to wound closure. The [data](#) is scheduled for oral 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).

MW005

- Reported positive results of the Phase I/II study to evaluate the safety and efficacy of MW005 in the treatment of low-risk Basal Cell Carcinoma (BCC). The data showed MW005 to be safe and well-tolerated, with patients achieving complete clinical and histological clearance of their target lesions.

Fourth Quarter 2023 Financial Highlights

- **Revenue:** Revenue for the fourth quarter 2023 was \$5.3 million, compared to \$11.6 million in the fourth quarter of 2022. The decrease is primarily attributed to the BLA approval milestone payment from Vericel.
- **Gross Profit:** Gross profit in the fourth quarter 2023 was \$0.7 million, representing 13.5% of the total revenue in the fourth quarter of 2023, compared to \$8.2 million, representing 70.2% of total revenue in the fourth quarter of 2022. The decrease is primarily attributed to the BLA approval milestone payment from Vericel in the fourth quarter of 2022.
- **Expenditures:**
 - Research and development expenses in the fourth quarter 2023 were \$1.8 million compared to \$2.7 million in the fourth quarter of 2022. This change is primarily attributed to the completion of EscharEx phase II study in 2022.
 - Selling, general, and administrative expenses in the fourth quarter 2023 were \$2.8 million, compared to \$3.0 million in the fourth quarter of 2022.
- **Operating Results:** Operating loss in the fourth quarter of 2023 was \$3.9 million, compared to an operating profit of \$2.1 million in the fourth quarter of 2022.
- **Net Loss:** Net loss in the fourth quarter of 2023 was \$1.7 million or \$0.19 per share, compared to the net loss of \$7.5 million, or \$1.18 per share in the fourth quarter of 2022. The decrease is primarily attributed to a favorable adjustment from the revaluation of warrants.
- **Non-GAAP Adjusted EBITDA:** Adjusted EBITDA in the fourth quarter of 2023 was a loss of \$3.2 million, compared to a profit of \$3.4 million in the fourth quarter of 2022.

Full Year 2023 Financial Highlights

- **Revenue:** Revenue for the year ended December 31, 2023, was \$18.7 million, compared to \$26.5 million for the year ended December 31, 2022. The decrease is primarily attributed to the BLA approval milestone payment from Vericel.
- **Gross Profit:** Gross profit for the year ended December 31, 2023, was \$3.6 million with a gross margin of 19.1%, compared to \$13.2 million with a gross margin of 49.7% in the prior year period. The decrease is primarily attributed to the BLA approval milestone payment from Vericel.
- **Expenditures:**
 - Research and development expenses for the year ended December 31, 2023, were \$7.5 million compared to \$10.2 million in the prior year.
 - Selling, general, and administrative expenses for the year ended December 31, 2023, were \$11.6 million, compared to \$10.6 million in the prior year.
- **Operating Results:** Operating loss for the year ended December 31, 2023, was \$15.3 million, compared to an \$8.3 million loss in the year ended December 31, 2022.
- **Net Loss:** Net loss in the year ended December 31, 2023 was \$6.7 million or \$0.75 per share, compared to the net loss of \$19.6 million, or \$3.93 per share for the year ended December 31, 2022.
- **Non-GAAP Adjusted EBITDA:** Adjusted EBITDA for the year ended December 31, 2023 was a loss of \$12.3 million,

compared to a loss of \$4.4 million for the year ended December 31, 2022.

Balance Sheet Highlights

As of December 31, 2023, the Company's cash, restricted cash, and investments were \$42.1 million, compared to \$34.1 million reported on December 31, 2022. In the first quarter of 2023, the Company raised a gross amount of \$27.5 million through a registered direct offering. The company used \$17.1 million to fund its activities. The existing cash and restricted cash, and investments will provide sufficient funds through profitability.

Conference Call

MediWound management will host a conference call for investors on Thursday, March 21, 2024, beginning at 8:30 a.m., Eastern Time to discuss these results and answer questions. Shareholders and other interested parties may participate in the conference call by dialing 1-833-630-1956 (in the U.S.), 1-80-921-2373 (Israel), or 1-412-317-1837 (outside the U.S. & Israel). The call will be available via webcast by [clicking HERE](#) or on the [Events & Presentations](#) page of Company's website.

A replay of the call will be available on the Company's website at www.mediwound.com.

Non-IFRS Financial Measures

To supplement consolidated financial statements prepared and presented in accordance with IFRS, the Company has provided a supplementary non-IFRS measure to consider in evaluating the Company's performance. Management uses Adjusted EBITDA, which it defines as earnings before interest, taxes, depreciation and amortization, impairment, one-time expenses, restructuring and share-based compensation expenses.

Although Adjusted EBITDA is not a measure of performance or liquidity calculated in accordance with IFRS, we believe the non-IFRS financial measures we present provide meaningful supplemental information regarding our operating results primarily because they exclude certain non-cash charges or items that we do not believe are reflective of our ongoing operating results when budgeting, planning and forecasting and determining compensation, and when assessing the performance of our business with our senior management.

However, investors should not consider these measures in isolation or as substitutes for operating income, cash flows from operating activities or any other measure for determining the Company's operating performance or liquidity that is calculated in accordance with IFRS. In addition, because Adjusted EBITDA is not calculated in accordance with IFRS, it may not necessarily be comparable to similarly titled measures employed by other companies. The non-IFRS measures included in this press release have been reconciled to the IFRS results in the tables below.

About MediWound

MediWound Ltd. (Nasdaq: MDWD) is the global leader in next-generation enzymatic therapeutics focused on non-surgical tissue repair. The Company specializes in the development, production and commercialization of solutions that seek to improve existing standards of care. MediWound 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 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[®] and NexoBrid[®]. 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; risks related to our contracts with BARDA; 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, 2023, filed with the Securities and Exchange Commission ("SEC") on March 21, 2024 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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MediWound, Ltd.

Audited Condensed Consolidated Statements of Financial Position

U.S. dollars in thousands

	Dec 31,	
	2023	2022
CURRENT ASSETS:		
Cash and cash equivalents and short-term deposits	41,708	33,895
Trade and other receivable	5,141	9,982
Inventories	2,846	1,963
Total current assets	49,695	45,840
Non-current assets		
Other receivables	673	364
Property, plant and equipment, net	9,228	2,366
Right of use assets, net	6,698	1,215
Intangible assets, net	165	231
Total non-current assets	16,764	4,176
Total assets	66,459	50,016
CURRENT LIABILITIES:		
Current maturities of long-term liabilities	1,410	2,242
Trade payables and accrued expenses	5,528	5,656
Other payables	3,891	4,159
Total current liabilities	10,829	12,057
Warrants, net	7,296	15,606
Liabilities in respect of IIA grants	7,677	7,445
Liability in respect of TEVA	2,256	2,788
Lease liabilities	6,350	846
Severance pay liability, net	456	360
Total non-current liabilities	24,035	27,045
Shareholders' equity	31,595	10,914
Total liabilities & equity	66,459	50,016

MediWound, Ltd.

Audited Condensed Consolidated Statements of Profit or Loss and Other Comprehensive Income or Loss

U.S. dollars in thousands (except of share and per share data)

	Twelve months ended Dec 31,		Three months ended Dec 31,	
	2023	2022	2023	2022
Total Revenues	18,686	26,496	5,338	11,618
Cost of revenues	15,108	13,331	4,619	3,460
Gross profit	3,578	13,165	719	8,158
Research and development	7,467	10,181	1,808	2,699
Selling and Marketing	4,844	3,725	1,209	692
General and administrative	6,768	6,920	1,583	2,269
Other (Income) expenses	(211)	684	13	375
Operating loss	(15,290)	(8,345)	(3,894)	2,123
Financial income (expenses), net	8,759	(11,176)	2,271	(9,515)
Taxes on income	(185)	(78)	(120)	(65)
Net loss	(6,716)	(19,599)	(1,743)	(7,457)
Foreign currency translation adjustments	(13)	14	(11)	(20)
Total comprehensive loss	(6,729)	(19,585)	(1,754)	(7,477)
<u>Basic and diluted loss per share:</u>				
Net loss per share	(0.75)	(3.93)	(0.19)	(1.18)
Weighted average number of ordinary shares	9,013,144	4,987,069	9,219,923	6,332,981

MediWound, Ltd.

Audited Condensed Consolidated Statements of Cash Flows

U.S. dollars in thousands

	Twelve months ended Dec 31,		Three months ended Dec 31,	
	2023	2022	2023	2022
	Audited		Unaudited	
<u>Cash Flows from Operating Activities:</u>				
Net Loss	(6,716)	(19,599)	(1,743)	(7,457)
Adjustments to reconcile net loss to net cash used in operating activities:				
Adjustments to profit and loss items:				
Depreciation and amortization	1,303	1,272	346	284
Share-based compensation	1,940	1,946	298	642
Revaluation of warrants accounted at fair value	(8,310)	8,977	(1,603)	8,977
Issuance expenses of warrants through profit and loss	-	1,911	-	1,523
Revaluation of liabilities in respect of IIA grants	427	(132)	(282)	(944)
Revaluation of liabilities in respect of TEVA	468	533	111	129
Financing income and exchange differences of lease liability	257	(109)	463	37
Increase in severance liability, net	83	109	3	45
Other income	(211)	-	13	-
Financial income, net	(2,231)	(74)	(836)	(408)
Un-realized foreign currency loss (gain)	189	525	(347)	60
	(6,085)	14,958	(1,834)	10,345
Changes in asset and liability items:				
Decrease (increase) in trade receivables	5,658	(7,582)	(528)	(5,137)
Decrease (increase) in inventories	(906)	(721)	782	(113)
Decrease (increase) in other receivables	(894)	364	(696)	221
Increase (decrease) in trade payables and accrued expenses	(594)	414	1,093	784
Increase (decrease) in other payables	(928)	281	311	2,107
	2,336	(7,244)	962	(2,138)

Net cash used in operating activities	<u>(10,465)</u>	<u>(11,885)</u>	<u>(2,615)</u>	<u>750</u>
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MediWound, Ltd.

Audited Condensed Consolidated Statements of Cash Flows

U.S. dollars in thousands

Cash Flows from Investing Activities:

Purchase of property and equipment	(6,464)	(555)	(2,209)	(174)
Interest received	1,947	74	722	71
Proceeds from (Investment in) short term bank deposits, net	(29,804)	-	6,515	2,499
Net cash used in investing activities	<u>(34,321)</u>	<u>(481)</u>	<u>5,028</u>	<u>2,396</u>

Cash Flows from Financing Activities:

Repayment of lease liabilities	(778)	(701)	(204)	(170)
Proceeds from issuance of shares and warrants, net	24,909	38,390	-	16,475
Repayments of IIA grants, net	(380)	(258)	-	-
Repayment of liabilities in respect of TEVA	(834)	(1,667)	-	(417)
Net cash provided by (used in) financing activities	<u>22,917</u>	<u>35,764</u>	<u>(204)</u>	<u>15,588</u>

Exchange rate differences on cash and cash equivalent balances	(160)	(549)	378	(44)
Increase (decrease) in cash and cash equivalents	(22,029)	22,849	2,587	18,990
Balance of cash and cash equivalents at the beginning of the period	33,895	11,046	9,279	14,905
Balance of cash and cash equivalents at the end of the period	<u>11,866</u>	<u>33,895</u>	<u>11,866</u>	<u>33,895</u>

MediWound, Ltd.

Adjusted EBITDA

U.S. dollars in thousands

	<u>Twelve months ended</u>		<u>Three months ended</u>	
	<u>Dec 31,</u>	<u>Dec 31,</u>	<u>Dec 31,</u>	<u>Dec 31,</u>
	<u>2023</u>	<u>2022</u>	<u>2023</u>	<u>2022</u>
Net loss	<u>(6,716)</u>	<u>(19,599)</u>	<u>(1,743)</u>	<u>(7,457)</u>
<i>Adjustments:</i>				
Financial income (expenses), net	8,759	(11,176)	2,271	(9,515)
Other (Income) expenses, net	211	(684)	(13)	(375)
Taxes on income	(185)	(78)	(120)	(65)
Depreciation and amortization	(1,303)	(1,272)	(346)	(284)
Share-based compensation expenses	(1,940)	(1,946)	(298)	(642)
Total adjustments	5,542	(15,156)	1,494	(10,881)
Adjusted EBITDA	<u>(12,258)</u>	<u>(4,443)</u>	<u>(3,237)</u>	<u>3,424</u>