

# MediWound Reports First Quarter 2024 Financial Results and Provides Company Update

May 29, 2024

NexoBrid<sup>®</sup> interest surges; \$5 million in Q1 2024 revenue, with \$24 million forecast for the year

Manufacturing facility on target for completion by mid-2024

EscharEx® Phase III study to launch 2H 2024

Company set to join Russell 3000® Index

Conference call today, May 29 at 8:30am Eastern Time

YAVNE, Israel, May 29, 2024 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq: MDWD), the global leader in next-generation enzymatic therapeutics for tissue repair, today announced financial results for the first guarter ended March 31, 2024, and provided a corporate update.

"During the first quarter we maintained a laser-focused approach to executing our strategic plan. At the beginning of the year, we set three major goals: accelerate the revenue growth of NexoBrid<sup>®</sup>, complete construction of the new manufacturing facility by mid-year, and initiate the EscharEx<sup>®</sup> Phase III clinical trial in the second half of 2024, for which we have established collaborations with the most prominent wound care companies. I am pleased with our progress, as we are on track to achieve all of our targets," said Ofer Gonen, Chief Executive Officer of MediWound.

#### First Quarter 2024 Highlights, Recent Developments and Upcoming Milestones:

## NexoBrid<sup>®</sup>

- U.S. launch by Vericel continued to progress. More than 60 burn centers completed submissions to Pharmacy and Therapeutics (P&T) committees, approximately 40 centers obtained approval, and more than 30 centers have placed initial product orders. Vericel noted significant increases in the number of patients treated with NexoBrid and the number of NexoBrid orders by both burn centers and hospitals.
- Construction of our new GMP-compliant, state-of-the-art manufacturing facility is on track to be completed by mid-2024, with commissioning set to begin in the third quarter of the year. The facility is expected to be fully operational in 2025, increasing the Company's manufacturing capacity sixfold.
- 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.
- Development of the NexoBrid temperature-stable formulation for use as a non-surgical solution for field-care burn treatment for the U.S. Army is progressing as planned. FDA feedback on the development path is expected in the second half of 2024.
- Enrollment and 12-month follow-up for the Expanded Access Treatment Protocol (NEXT) have been concluded: 239 burn patients have been treated across 29 U.S. centers. Data readout is anticipated in the second half of 2024.

## $\mathsf{EscharEx}^{\circledR}$

- Phase III trial remains on track for final protocol submission in the first half of 2024. The global study aims to enroll 216
  patients across 40 sites to be treated with either EscharEx or a gel vehicle placebo. An interim assessment will be
  performed once 67% of participants complete the trial. The study is expected to commence in the second half of 2024.
- Recent Phase II data, which included comparative analyses demonstrating EscharEx's superiority over SANTYL®, were presented at three prominent annual wound care conferences: the Wound Healing Society (WHS), the Symposium on Advanced Wound Care (SAWC), and the European Wound Management Association (EWMA).

### **Corporate Developments**

• Company included in the preliminary list of the Russell 3000® Index, as part of the 2024 Russell indexes annual reconstitution.

### First Quarter 2024 Financial Highlights

- Revenue: Revenue for the first quarter of 2024 was \$5.0 million, compared to \$3.8 million in the first quarter of 2023. The increase is primarily attributed to revenue from Vericel and new contracts with the U.S. Department of Defense (DoD).
- Gross Profit: Gross profit in the first quarter of 2024 was \$0.6 million, representing 12.2% of total revenue, compared to \$0.8 million, representing 21.7% of total revenue in the first quarter of 2023. The decrease in gross margin is primarily due

to changes in the revenue mix.

#### • Expenditures:

- Research and Development: R&D expenses in the first quarter of 2024 were \$1.5 million, compared to \$2.1 million in the first quarter of 2023. This decrease is primarily due to the completion of the EscharEx Phase II study.
- o Selling, General, and Administrative: SG&A expenses in the first quarter of 2024 were \$2.9 million, compared to \$3.1 million in the first quarter of 2023.
- Operating Results: Operating loss in the first quarter of 2024 was \$3.7 million, compared to an operating loss of \$4.4 million in the first quarter of 2023.
- **Net Loss**: Net loss in the first quarter of 2024 was \$9.7 million, or \$1.05 per share, compared to a net loss of \$3.7 million, or \$0.44 per share, in the first quarter of 2023. The increase in net loss is primarily due to financial expenses from revaluation of warrants, amounting to \$6.1 million, driven by 40% increase in the Company's share price.
- Non-GAAP Adjusted EBITDA: Adjusted EBITDA for the first quarter of 2024 was a loss of \$2.9 million, compared to a loss of \$3.4 million in the first quarter of 2023.

### **Balance Sheet Highlights**

As of March 31, 2024, the Company had cash and cash equivalents, restricted cash, and deposits totaling \$36.0 million, compared to \$42.1 million as of December 31, 2023. During the first quarter of 2024, the Company received \$0.5 million from the exercise of Series A warrants. The Company utilized \$6.5 million to fund its activities in the first quarter of 2024, of which \$2.7 million was invested in CAPEX related to the facility scale-up.

#### **Conference Call**

MediWound management will host a conference call for investors on Wednesday, May 29, 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 <u>clicking HERE</u> or on the <u>Events & Presentations</u> 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 rapid and effective biologics that improve existing standards of care and patient experiences, while reducing costs and unnecessary surgeries.

MediWound's first drug, NexoBrid <sup>®</sup>, 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 <sup>®</sup>. EscharEx is a Phase III-ready biologic for debridement of chronic wounds with significant potential advantages over the \$360 million dominant commercially available product and an opportunity to expand the market.

For more information visit www.mediwound.com and follow the Company on LinkedIn.

## **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<sup>®</sup> and NexoBrid<sup>®</sup>. 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.

# Unaudited Condensed Consolidated Statements of Financial Position U.S. dollars in thousands

	Marc	March 31,	
	2024	2023	2023
CURRENT ASSETS:			
Cash and cash equivalents and short-term deposits	35,568	57,204	41,708
Trade and other receivable	5,317	3,531	5,141
Inventories	3,311	2,536	2,846
Total current assets	44,196	63,271	49,695
Non-current assets			
Trade and other receivables	238	305	233
Long-term restricted bank deposits	446	-	440
Property, plant and equipment, net	10,422	3,724	9,228

Right of use assets, net	6,926	1,151	6,698
Intangible assets, net	149	215	165
Total non-current assets	18,181	5,395	16,764
Total assets	62,377	68,666	66,459
CURRENT LIABILITIES:			
Current maturities of long-term liabilities	1,541	2,139	1,410
Warrants, net	13,065	14,674	7,296
Trade payables and accrued expenses	4,246	3,403	5,528
Other payables	3,486	3,722	3,891
Total current liabilities	22,338	23,938	18,125
Total current liabilities  NON-CURRENT LIABILITIES:	22,338	23,938	18,125
	7,780	7,580	7,677
NON-CURRENT LIABILITIES:			
NON-CURRENT LIABILITIES:  Liabilities in respect of IIA grants	7,780	7,580	7,677
NON-CURRENT LIABILITIES:  Liabilities in respect of IIA grants  Liabilities in respect of TEVA	7,780 2,111	7,580 2,660	7,677 2,256
NON-CURRENT LIABILITIES:  Liabilities in respect of IIA grants  Liabilities in respect of TEVA  Lease liabilities	7,780 2,111 6,467	7,580 2,660 743	7,677 2,256 6,350
NON-CURRENT LIABILITIES:  Liabilities in respect of IIA grants  Liabilities in respect of TEVA  Lease liabilities  Severance pay liability, net	7,780 2,111 6,467 482	7,580 2,660 743 445	7,677 2,256 6,350 456
NON-CURRENT LIABILITIES:  Liabilities in respect of IIA grants  Liabilities in respect of TEVA  Lease liabilities  Severance pay liability, net	7,780 2,111 6,467 482	7,580 2,660 743 445	7,677 2,256 6,350 456

## MediWound, Ltd.

Unaudited 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)

Three months ended March 31,

Year ended December 31,

	2024	2023	2023
Total Revenues	4,964	3,799	18,686
Cost of revenues	4,357	2,973	15,108
Gross profit	607	826	3,578
Research and development	1,470	2,102	7,467
Selling and Marketing	1,179	1,106	4,844
General and administrative	1,692	1,982	6,768
Other Income	-	-	(211)
Operating loss	(3,734)	(4,364)	(15,290)
Financial income (expenses), net	(5,971)	676	8,759
Taxes on income	(24)	(5)	(185)
Net loss	(9,729)	(3,693)	(6,716)
Foreign currency translation adjustments	8	(9)	(13)
Total comprehensive loss	(9,721)	(3,702)	(6,729)
Basic and diluted loss per share:			
Net loss per share	(1.05)	(0.44)	(0.75)
Weighted average number of ordinary shares	9,234,104	8,388,109	9,013,144

# MediWound, Ltd. Unaudited Condensed Consolidated Statements of Cash Flows

U.S. dollars in thousands

Three months ended March 31,		ar Ended ember 31,
2024	2023	2023

## **Cash Flows from Operating Activities:**

Net loss	(9,729)	(3,693)	(6,716)
Adjustments to reconcile net loss to net cash used in operating activities:			
Adjustments to profit and loss items:			
Depreciation and amortization	368	303	1,303
Share-based compensation	512	619	1,940
Revaluation of warrants accounted at fair value	6,080	(932)	(8,310)
Revaluation of liabilities in respect of IIA grants	233	259	427
Revaluation of liabilities in respect of TEVA	107	122	468
Financing income and exchange differences of lease liability	28	(13)	257
Increase in severance liability, net	35	77	83
Other income	-	-	(211)
Financial income, net	(513)	(246)	(2,231)
Un-realized foreign currency loss	67	345	189
	6,917	534	(6,085)
Changes in asset and liability items:			
Decrease (Increase) in trade receivables	(123)	6,822	5,658
Increase in inventories	(448)	(583)	(906)
Increase in other receivables	(115)	(313)	(894)
Decrease in trade payables and accrued expenses	(1,370)	(1,948)	(594)
Increase (decrease) in other payables	260	(167)	(928)
	(1,796)	3,811	2,336
Net cash provided by (used in) operating activities	(4,608)	652	(10,465)
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	Three months ended March 31,		Year Ended December 31,
	2024	2023	2023
Cash Flows from Investment Activities:			
Purchase of property and equipment	(1,259)	(1,505)	(6,464)
Interest received	605	302	1,947
Investment in short term bank deposits, net	(1,130)	(6,240)	(29,804)
Net cash used in investing activities	(1,784)	(7,443)	(34,321)
Cash Flows from Financing Activities:			
Repayment of lease liabilities	(244)	(177)	(778)
Proceeds from issuance of shares and warrants, and exercise of warrants, net	499	25,157	24,909
Repayments of IIA grants, net	(120)	(310)	(380)
Repayment of liabilities in respect of TEVA	(834)	(417)	(834)
Net cash provided by (used in) financing activities	(699)	24,253	22,917
Exchange rate differences on cash and cash equivalent balances	(89)	(337)	(160)
Increase (decrease) in cash and cash equivalents	(7,180)	17,125	(22,029)
Balance of cash and cash equivalents at the beginning of the period	11,866	33,895	33,895
Balance of cash and cash equivalents at the end of the period	4,686	51,020	11,866

# MediWound Ltd. ADJUSTED EBITDA

U.S. dollars in thousands

Three months ended March 31,

Year ended December 31,

	2024	2023	2023
Net loss	(9,729)	(3,693)	(6,716)
Adjustments:			
Financial income (expenses), net	(5,971)	676	8,759
Other Income, net	-	-	211
Taxes on income	(24)	(5)	(185)
Depreciation and amortization	(368)	(303)	(1,303)
Share-based compensation expenses	(512)	(619)	(1,940)
Total adjustments	(6,875)	(251)	5,542
Adjusted EBITDA	(2,854)	(3,442)	(12,258)