



MediWound Reports First Quarter 2023 Financial Results and Provides a Company Update

May 30, 2023

*On track to initiate EscharEx® Phase III study in fourth quarter 2023
NexoBrid® U.S. launch expected in early third quarter 2023
Cash of over \$57 million; Operating cash runway through profitability*

Conference call begins today at 8:30 a.m. Eastern Time

YAVNE, Israel, May 30, 2023 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq: MDWD), the global leader in next-generation enzymatic therapeutics for tissue repair, today announced financial results for the first quarter ended March 31, 2023 and provided a corporate update.

"This quarter has been extremely productive as our dedicated team has worked diligently to advance the key components of our strategic plan. The outcomes of our focused efforts are evident, as we are on track to initiate the Phase III study for our flagship product, EscharEx, in the fourth quarter of this year. This represents a significant commercial opportunity and addresses a major unmet need. Furthermore, we are excited to partner with Vericel for the upcoming U.S. launch of NexoBrid. Simultaneously we are making rapid progress in our manufacturing scale-up plan to meet the surging global demand. Importantly, MediWound is now in a strong financial position, with over \$57 million in cash. This provides the company with ample resources to effectively execute its corporate initiatives and drive continuous innovation," stated Ofer Gonen, Chief Executive Officer of MediWound.

First Quarter 2023 Highlights and Recent Developments:

- The Company's global Phase III clinical study for EscharEx is expected to begin in the fourth quarter of 2023. The pivotal trial protocol is aligned with feedback from the U.S. Food and Drug Administration (FDA); protocol feedback from the European Medicines Agency (EMA) anticipated in mid-year 2023. This multicenter, prospective, randomized, placebo-controlled trial aims to evaluate the safety and efficacy of EscharEx in patients with venous leg ulcers (VLUs). Approximately 244 patients will be randomized to either EscharEx or gel vehicle (placebo control) in a 1:1 ratio. The treatment protocol will include a daily visit period of up to 14 days, during which EscharEx or gel vehicle will be applied once a day for a maximum of 8 applications. Patients will be followed for up to 22 weeks after treatment, during which all patients will be treated with standard of care. The co-primary endpoints are the incidence of complete debridement at the end of the daily visit period, and time to achieve wound closure.
- Initiated the expansion of the Company's manufacturing facility to address the increasing global demand for NexoBrid. This expansion project is scheduled for completion by the end of 2024 and will increase production capacity by five-fold. The Company is dedicated to ensuring the availability of NexoBrid, particularly in the United States, the largest market for this product.
- Received a \$7.5 million milestone payment from Vericel, triggered by the FDA's approval of NexoBrid for eschar removal in adults with deep partial-thickness and/or full-thickness thermal burns. NexoBrid commercial launch in the U.S. is planned for early third quarter 2023.
- Announced the award of an additional \$10 million in funding from the Biomedical Advanced Research and Development Authority (BARDA) to support the \$3 million replenishment of expired product previously procured for emergency preparedness, the pediatric indication sBLA submission to the U.S. FDA, and enrollment of an additional 50 patients in the ongoing expanded access treatment protocol (NEXT).
- Strengthened its management team with the addition of highly experienced executives. The Company welcomed Hani Luxenburg as its new Chief Financial Officer, Barry Wolfenson as Executive Vice President of Strategy and Corporate Development, and Alicia Torrenova as Vice President of European Operations.
- Raised gross proceeds of \$27.5 million in a registered direct offering of ordinary shares, with participation from new and current institutional shareholders, including top-tier investors such as Point 72, Israel Biotech Fund, Deep Insight and aMoon.
- Cash and short-term investments of \$57.4 million as of March 31, 2023.

First Quarter 2023 Financial Highlights

- Total revenues were \$3.8 million, compared to \$4.4 million for the first quarter of 2022. Revenues from development

services were \$2.6 million, compared to \$3.1 million in the first quarter of 2022. This decrease was primarily attributed to the NexoBrid approval in December 2022. Revenues from products were \$1.2 million, compared to \$1.1 million in the first quarter of 2022.

- Gross profit was \$0.8 million, or 22% of the total revenue, compared to a gross profit of \$1.5 million, or 33% of the total revenue, for the first quarter of 2022. The decrease in gross profit was primarily due to changes in the revenue mix and nonrecurring production costs.
- Research and development expenses were \$2.1 million, compared to \$2.4 million in the first quarter of 2022.
- Selling, general and administrative expenses were \$3.1 million, compared to \$2.3 million in the first quarter of 2022. The increase was primarily due to the addition of personnel to support future growth, along with share-based compensation expenses.
- Operating loss was \$4.4 million, compared to a loss of \$3.3 million in the first quarter of 2022.
- The Company posted a net loss of \$3.7 million, or \$0.44 per share, compared to a net loss of \$3.6 million, or \$0.87 per share, for the first quarter of 2022.
- Adjusted EBITDA, as defined below, was a loss of \$3.4 million, compared to a loss of \$2.6 million for the first quarter of 2022.
- As of March 31, 2023, the Company had \$57.4 million in cash and short-term investments, compared with \$34.1 million as of December 31, 2022. The Company utilized \$1.8 million to fund its operating activities in the first quarter of 2023. Existing cash and cash equivalents are expected to provide sufficient funds for the Company's current operating plan through profitability.

Conference Call

MediWound management will host a conference call for investors today, Tuesday, May 30, 2023, 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. Specializing in the development, production and commercialization of solutions that seek to replace 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 biologic for debridement of chronic wounds with significant advantages over the \$300 million monopoly legacy drug and an opportunity to expand the market. The Phase III study is expected to start in Q4 2023. Additionally, MediWound has a Phase I/II biologic for basal cell carcinoma, MW005, with results expected in Q3 2023.

For more information, please 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[®] 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, 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.

Contacts:

Hani Luxenburg
Chief Financial Officer
MediWound Ltd.
ir@mediwound.com

Monique Kosse
Managing Director, LifeSci Advisors
212-915-3820
monique@lifesciadvisors.com

MediWound Ltd.

CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITIONS

U.S. dollars in thousands

	March 31,		December 31,
	2023	2022	2022
	Un-audited		Audited
Cash, cash equivalents	51,020	16,651	33,895
Restricted deposits	-	185	-
Short-term bank deposits	6,184	-	-
Trade receivables	2,520	2,348	9,332
Inventories	2,536	1,920	1,963
Other receivables	1,011	852	650
Total current assets	63,271	21,956	45,840
Trade and other receivables	305	230	364
Property, plant and equipment, net	3,724	2,471	2,366
Right of use assets, net	1,151	1,429	1,215
Intangible assets, net	215	281	231
Total non-current assets	5,395	4,411	4,176
Total assets	68,666	26,367	50,016

Current maturities of long-term liabilities	2,139	2,572	2,242
Trade payables and accrued expenses	3,403	5,623	5,656
Other payables	3,722	3,055	4,159
Total current liabilities	9,264	11,250	12,057
Deferred revenues	-	91	-
Warrants, net	14,674	-	15,606
Liabilities in respect of IIA grants	7,580	7,897	7,445
Liabilities in respect of TEVA	2,660	3,642	2,788
Lease liabilities	743	1,239	846
Severance pay liability, net	445	303	360
Total non-current liabilities	26,102	13,172	27,045
Shareholders' equity	33,300	1,945	10,914
Total liabilities & shareholder equity	68,666	26,367	50,016

MediWound Ltd.
CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE LOSS (UNAUDITED)

U.S. dollars in thousands

	Three months ended March 31,		Year ended December 31,
	2023	2022	2022
Revenues	3,799	4,407	26,496
Cost of revenues	2,973	2,947	13,331
Gross profit	826	1,460	13,165
Operating expenses:			
Research and development	2,102	2,408	10,181
Selling, general and administrative	3,088	2,336	10,645
Other expenses, net	-	-	684
Operating loss	(4,364)	(3,284)	(8,345)
Financial income (expenses), net	676	(301)	(11,176)
Loss before taxes on income	(3,688)	(3,585)	(19,521)
Taxes on income	(5)	(4)	(78)
Net loss	(3,693)	(3,589)	(19,599)
Foreign currency translation adjustments	(9)	5	14
Total comprehensive loss	(3,702)	(3,584)	(19,585)
Basic and diluted loss per share:			
Net loss per share	(0.44)	(0.87)	(3.93)
Weighted average number of ordinary shares used in the computation of basic and diluted loss per share:	8,388	4,105	4,987

MediWound Ltd.
ADJUSTED EBITDA

U.S. dollars in thousands

	Three months ended March 31,		Year ended December 31,
	2023	2022	2022
Loss for the period	(3,693)	(3,589)	(19,599)
Adjustments:			

Financial income (expenses), net	676	(301)	(11,176)
Other expenses, net	-	-	(684)
Tax expenses	(5)	(4)	(78)
Depreciation and amortization	(303)	(321)	(1,272)
Share-based compensation expenses	(619)	(345)	(1,946)
Total adjustments	(251)	(971)	(15,156)
Adjusted EBITDA	(3,442)	(2,618)	(4,443)

MediWound Ltd.
CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS (UNAUDITED)

U.S. dollars in thousands

	<u>Three months ended</u> <u>March 31,</u>		<u>Year Ended</u> <u>December 31,</u>
	<u>2023</u>	<u>2022</u>	<u>2022</u>
<u>Cash Flows from Operating Activities:</u>			
Net loss	(3,693)	(3,589)	(19,599)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:			
Adjustments to profit and loss items:			
Depreciation and amortization	303	321	1,272
Share-based compensation	619	345	1,946
Revaluation of warrants accounted at fair value	(932)	-	8,977
Issuance expenses of warrants through profit and loss	-	-	1,911
Revaluation of contingent liabilities in respect of IIA grants	259	234	(132)
Revaluation of liabilities in respect of TEVA	122	137	533
Revaluation of lease liabilities	(13)	(14)	(109)
Increase in severance liability, net	77	20	109
Net financing income	(246)	-	(74)
Un-realized foreign currency loss	345	245	525
	534	1,288	14,958
Changes in asset and liability items:			
Decrease (Increase) in trade receivables	6,822	(579)	(7,582)
Increase in inventories	(583)	(710)	(721)
Decrease (Increase) in other receivables	(313)	125	364
Increase (Decrease) in trade payables & accrued expenses	(1,948)	283	414
Increase (Decrease) in other payables & deferred revenues	(167)	(883)	281
	3,811	(1,764)	(7,244)
Net cash provided by (used in) operating activities	652	(4,065)	(11,885)
<u>Cash Flows from Investment Activities:</u>			
Purchase of property and equipment	(1,505)	(160)	(555)
Interest received	302	-	74
Investment in short term bank deposits, net	(6,240)	-	-
Net cash used in investing activities	(7,443)	(160)	(481)
<u>Cash Flows from Financing Activities:</u>			
Repayment of lease liabilities	(177)	(178)	(701)
Repayment of liabilities in respect of TEVA	(417)	-	(1,667)
Repayment of contingent liabilities in respect of IIA grants	(310)	(162)	(258)
Proceeds from issuance of shares and warrants, net	25,157	10,417	38,390
Net cash provided by financing activities	24,253	10,077	35,764
Exchange rate differences on cash and cash equivalent balances	(337)	(247)	(549)
Increase in cash and cash equivalents	17,125	5,605	22,849

Balance of cash and cash equivalents at the beginning of the period

33,895

11,046

11,046

Balance of cash and cash equivalents at the end of the period

51,020

16,651

33,895