MediWound Reports Second Quarter 2023 Financial Results and Provides Company Update

August 15, 2023

EscharEx® Phase III study protocol: FDA/EMA-aligned; patient enrollment commencing early 2024; two key research collaborations with wound industry leaders

NexoBrid® U.S. commercial launch timing not anticipated to impact revenues in 2023-2024
Cash of $51.3 million; operating cash runway through profitability

Conference call on Wednesday, August 16 at 8:30 a.m. Eastern Time

YAVNE, Israel, Aug. 15, 2023 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq: MDWD), the global leader in next-generation enzymatic therapeutics for tissue repair, today announced financial results for the second quarter ended June 30, 2023, and provided a corporate update.

"We have achieved significant progress this quarter on many levels," stated Ofer Gonen, CEO of MediWound. "Our EscharEx Phase III study protocol is aligned with feedback from both FDA and EMA, and patient enrollment is planned for early 2024. Executing multiple collaborations on our EscharEx program with leading wound care companies, underscores the growing interest in this potential game-changing treatment and our commitment to maximize the likelihood of a successful study outcome." Mr. Gonen added, "We dispatched initial batches of NexoBrid to both Japan and the U.S., with commercial availability already underway in Japan. Furthermore, our new manufacturing facility, set to be active by mid-2024, will increase our production capabilities to meet the rising global demand."

Second Quarter 2023 Highlights and Recent Developments:

- Shipped NexoBrid finished product to Vericel for the U.S. commercial launch in June 2023. However, Vericel is unable to commercially release the product at this time due to a deviation associated with a third-party testing lab used during the manufacturing process. MediWound and Vericel are actively engaged with the U.S. Food and Drug Administration (FDA) to address this matter. Future production lots will not be impacted by this process deviation issue. Vericel expects to begin commercial sales of NexoBrid from a scheduled September 2023 production run, during the first quarter of 2024. MediWound believes that a possible delay in the U.S. launch, will not have an impact on NexoBrid revenues for the years 2023-2024.

- Received positive scientific advice from the Committee for Medicinal Products for Human Use (CHMP) within the European Medicine Agency (EMA) for the development of EscharEx. This advice aligns with feedback from the FDA, providing a clear path forward for the Company's global Phase III study in patients with venous leg ulcers (VLUs). The Company is in the process of qualifying study sites, selecting vendors (including CRO, data management, and central labs), and producing final batches of EscharEx for the clinical study. These activities are to be completed by the fourth quarter of 2023, with patient enrollment in the Phase III study expected to begin in early 2024.

- Secured research and development collaborations with leading wound care companies, MIMEDX and Mölnlycke, to advance the EscharEx Phase III clinical study. MediWound is actively engaged with additional prominent companies to explore further collaboration opportunities.

- Awarded an additional $10 million in funding from BARDA to support NexoBrid's $3 million replenishment, the pediatric indication sBLA submission, and the enrollment of an additional 50 patients in the expanded access treatment protocol (NEXT).

- Signed a turnkey scale-up agreement to bolster the Company's manufacturing infrastructure supporting its long-term growth trajectory. The Company will establish, commission, and validate a cutting-edge, sterile, and GMP-compliant manufacturing facility to significantly increase the Company's current production capacity. An estimated $12 million will be invested in this new state-of-the-art facility, which is projected to be completed by mid-2024, with full-scale manufacturing expected to commence in 2025.

- Announced commercial launch of NexoBrid in Japan for the treatment of deep partial thickness and full thickness burns in adults and pediatric patients with the Company's strategic partner, Kaken Pharmaceutical Co. Ltd., a top ranked Japanese pharmaceutical company.

- Reported positive data from its Phase I/II study of MW005 in low-risk basal cell carcinoma (BCC). Results showed MW005 to be safe and well-tolerated, with eleven of the fifteen patients enrolled achieving complete clearance of their BCCs, with a majority of the patients also having histologically confirmed complete clearance.

- Appointed Mr. Shmuel (Milky) Rubinstein as an independent director to the Company's Board of Directors. With a distinguished record of pharmaceutical and biotechnology leadership, Mr. Rubinstein previously held the position of CEO at Taro Pharmaceuticals (Nasdaq: TARO), which subsequently was acquired by Sun Pharmaceuticals. He currently holds the title of Chairperson of the Board at Trima Pharma and is a board member at Strata Skin Sciences (Nasdaq: SSKN), Medison Biotech, and Keystone Dental. Mr. Rubinstein will become a MediWound Board member, following the tenure of Mr. Assaf Segal, who stepped down from the MediWound Board of Directors.
- Cash and short-term deposits of $51.3 million as of June 30, 2023.

Second Quarter 2023 Financial Highlights

- **Revenues**: Revenues for the second quarter 2023 were $4.8 million, compared to $4.7 million in the second quarter of 2022.
- **Gross Profit**: Gross profit in the second quarter 2023 was $1.1 million, representing 24% of total revenue, unchanged from the second quarter 2022.
- **Expenditures**:
  - Research and development expenses in the second quarter 2023 were $2.0 million compared to $2.2 million in the second quarter of 2022.
  - Selling, general, and administrative expenses in the second quarter 2023 were $3.1 million, compared to $2.3 million in the second quarter of 2022. This increase is primarily attributed to the addition of several full-time employees to bolster future growth, along with greater share-based compensation expenses.
- **Operating Results**: Operating loss in the second quarter of 2023 was $4.0 million, compared to a $3.7 million loss in the second quarter of 2022.
- **Net Profit/Loss**: Net profit in the second quarter of 2023 was $0.9 million or $0.10 per share, compared to the net loss of $4.4 million, or $0.92 per share in the second quarter of 2022. This change is primarily attributed to a favorable adjustment from the revaluation of warrants.
- **Adjusted EBITDA**: Adjusted EBITDA in the second quarter of 2023 was a loss of $3.0 million, compared to a loss of $2.8 million in the second quarter of 2022.

Year-to-Date 2023 Financial Highlights

- **Revenues**: Total revenues in the first half of 2023 were $8.6 million, compared to $9.1 million in the first half of 2022. The decline in revenues is primarily a result of the sales to BARDA's emergency stockpile procurement in 2022.

- **Operating Results**: Operating loss in the first half of 2023 was $8.4 million, up from the $7.0 million loss in the first half of 2022. This increase is primarily attributed to the addition of several full-time employees to bolster future growth, along with greater share-based compensation expenses.

- **Net Loss**: Net loss in the first half of 2023 was $2.8 million, or $0.32 per share, compared to a net loss of $7.9 million or $1.79 per share in the first half of 2022. This decrease is primarily attributed to a favorable adjustment from the revaluation of warrants.

- **Adjusted EBITDA**: Adjusted EBITDA in the first half of 2023, as further detailed below, was a loss of $6.4 million, compared to a $5.4 million loss in the first half of 2022.

Balance Sheet Overview

As of June 30, 2023, the Company's cash and short-term deposits were $51.3 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. During the second quarter of 2023, the Company used $6.0 million to fund its operating activities. 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 on Wednesday, August 16, 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. 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, 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.

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MediWound, Ltd.

CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITIONS (UNAUDITED)

U.S. dollars in thousands

	June 30,		Dec 31,
	2023	2022	2022
	Unaudited		Audited
Cash and cash equivalents and short-term bank deposits	51,122	10,406	33,895
Trade and other receivable	3,818	4,412	9,982
Inventories	3,113	1,991	1,963
Total current assets	**58,053**	**16,809**	**45,840**
Other receivables	277	230	364
Property, plant and equipment, net	4,705	2,439	2,366
Right of use assets	1,133	1,364	1,215
Intangible assets, net	198	264	231
Total non-current assets	**6,313**	**4,297**	**4,176**
Total assets	**64,366**	**21,106**	**50,016**
Current maturities of long-term liabilities	1,961	2,479	2,242
Trade payables and accrued expenses	3,531	4,877	5,656
Other payables	2,817	3,060	4,159
Total current liabilities	**8,309**	**10,416**	**12,057**
Deferred revenues	-	61	-
Warrants	9,683	-	15,606
Liabilities in respect of IIA grants	7,806	8,131	7,445
Liability in respect of TEVA	2,529	3,361	2,788
Lease liabilities	677	1,053	846
Severance pay liability, net	433	319	360
Total non-current liabilities	**21,128**	**12,925**	**27,045**
Total equity (deficit)	**34,929**	**(2,235)**	**10,914**
Total liabilities and equity	**64,366**	**21,106**	**50,016**

MediWound, Ltd.

CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHET COMPREHENSIVE INCOME OR LOSS (UNAUDITED)

U.S. dollars in thousands

	Six months ended June 30,		Three months ended June 30,	
	2023	2022	2023	2022
Total revenues	8,572	9,075	4,773	4,668
Total cost of revenues	6,609	6,502	3,636	3,555
Gross profit	**1,963**	**2,573**	**1,137**	**1,113**

Research and development	4,126	4,599	2,024	2,191
Selling, general & administrative	6,208	4,623	3,120	2,287
Other expenses	-	309	-	309
Total operating expenses	**10,334**	**9,531**	**5,144**	**4,787**
Operating loss	**(8,371)**	**(6,958)**	**(4,007)**	**(3,674)**
Financial income (expenses), net	5,611	(977)	4,935	(676)
Profit (loss) before taxes on income	**(2,760)**	**(7,935)**	**928**	**(4,350)**
Taxes on income	(17)	(8)	(12)	(4)
Net profit (loss)	**(2,777)**	**(7,943)**	**916**	**(4,354)**
Foreign currency translation adjustments	(9)	22	-	17
Total comprehensive profit (loss)	**(2,786)**	**(7,921)**	**916**	**(4,337)**
Basic and diluted net profit (loss) per share:	**(0.32)**	(1.79)	**0.10**	(0.92)
Weighted average number of ordinary shares used in calculation basic and diluted net profit (loss) per share	**8,803**	**4,440**	**9,209**	**4,734**

MediWound, Ltd.

ADJUSTED EBITDA

U.S. dollars in thousands

	Six months ended June 30,		Three months ended June 30,	
	2023	**2022**	**2023**	**2022**
Net profit (loss) for the period	(2,777)	(7,943)	916	(4,354)
Adjustments:				
Financial income (expenses), net	5,611	(977)	4,935	(676)
Other expenses	-	(309)	-	(309)
Tax expenses	(17)	(8)	(12)	(4)
Depreciation and amortization	(618)	(650)	(315)	(329)
Share-based compensation expenses	(1,331)	(597)	(712)	(252)
Total adjustments	3,645	(2,541)	3,896	(1,570)
Adjusted EBITDA	**(6,422)**	**(5,402)**	**(2,980)**	**(2,784)**

MediWound, Ltd.

CONDENSED CONSOLIDATED STATEMENT OF CASH FLOW (UNAUDITED)

U.S. dollars in thousands

	Six months ended	Three months ended

	June 30,		June 30,	
	2023	**2022**	**2023**	**2022**
Cash Flows from Operating Activities:				
Net income (loss)	**(2,777)**	**(7,943)**	**916**	**(4,354)**
Adjustments to reconcile net profit (loss) to net cash used in operating activities:				
Adjustments to profit and loss items:				
Depreciation and amortization	618	650	315	329
Share-based compensation	1,331	597	712	252
Revaluation of warrants accounted at fair value	(5,923)	-	(4,990)	-
Revaluation of liabilities in respect of IIA grants	492	482	233	248
Revaluation of liabilities in respect of TEVA	241	272	119	135
Revaluation of lease liabilities	(22)	(152)	(9)	(138)
Increase (decrease) in severance liability, net	67	55	(10)	35
Net financing income	(1,005)	(11)	(759)	(11)
Un-realized foreign currency loss	466	528	120	283
	(3,735)	**2,421**	**(4,269)**	**1,133**
Changes in asset and liability items:				
Decrease (increase) in trade receivables	6,115	(2,024)	(707)	(1,445)
Increase in inventories	(1,162)	(747)	(579)	(37)
Decrease in other receivables	122	330	435	205
Increase (decrease) in trade payables and accrued expenses	(1,636)			
		11	312	(272)
Increase (decrease) in other payables and deferred revenues	(1,526)	(1,367)	(1,359)	(484)
	1,913	**(3,797)**	**(1,898)**	**(2,033)**
Net cash (used in) operating activities	**(4,599)**	**(9,319)**	**(5,251)**	**(5,254)**
Cash Flows from Investment Activities:				
Purchase of property and equipment	(2,570)	(298)	(1,065)	(138)
Interest received	879	-	577	-
Investment in short term bank deposits, net	(31,830)	(2,499)	(25,590)	(2,499)
Net cash used in investing activities	**(33,521)**	**(2,797)**	**(26,078)**	**(2,637)**
Cash Flows from Financing Activities:				
Repayment of lease liabilities	(334)	(350)	(157)	(172)
Proceeds from (repayment of) issuance of shares and warrants, net	24,909	9,861	(248)	(556)
Repayments to IIA, net	(310)	(162)	-	-
Repayment of liabilities in respect of TEVA	(417)	-	-	-
Net cash provided by (used in) financing activities	**23,848**	**9,349**	**(405)**	**(728)**
Exchange rate differences on cash and cash equivalent balances	**(457)**	(550)	**(120)**	(303)
Increase (decrease) in cash and cash equivalents from continuing activities	**(14,729)**	(3,317)	**(31,854)**	(8,922)
Balance of cash and cash equivalents at the beginning of the period	**33,895**	11,046	**51,020**	16,651
Balance of cash and cash equivalents at the end of the period	**19,166**	**7,729**	**19,166**	**7,729**