MediWound Reports Third Quarter 2023 Financial Results and Provides Company Update

November 21, 2023

NexoBrid® commercially launched in U.S. and Japan; Company prioritizes operational resources to meet increased global demand

EscharEx® Phase III study preparations progressing; Protocol submission to FDA expected in first quarter 2024

Cash of $46 million; Operating cash runway through profitability

Conference call on Tuesday, November 21 at 8:30 a.m. Eastern Time

YAVNE, Israel, Nov. 21, 2023 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq: MDWD), the global leader in next-generation enzymatic therapeutics for tissue repair, today announced financial results for the third quarter ended September 30, 2023, and provided a corporate update.

"This quarter marks a pivotal period for us, with significant achievements that set the stage for consistent future revenue growth. NexoBrid® was successfully launched in two key markets, the U.S. and Japan, enhancing our global footprint. In Europe, the potential expansion of the pediatric indication and our recent partnership with PolyMedics Innovations are key drivers for increased sales," said Ofer Gonen, CEO of MediWound.

"Global conflicts have also escalated the demand for NexoBrid: We have secured funding from the U.S. Department of Defense to develop field-care burn treatment for the U.S. Army; The entire non-U.S. NexoBrid inventory has been deployed to successfully treat those affected by the war in Israel. The successful outcomes in the field catalyzed additional interest from various governments. We have therefore prioritized our resources to meet the increased demand.

Looking ahead, preparations for the Phase III study of EscharEx® are progressing, with an updated protocol shaped by U.S. Food & Drug Administration (FDA) and European Medicines Agency (EMA) guidance. Anticipated enrollment is set to begin in the second half of 2024. A new collaboration with industry leader, 3M Healthcare, further validates EscharEx's anticipated impact on the wound care market," concluded Ofer Gonen.

Third Quarter 2023 Highlights and Recent Developments:

NexoBrid®

- Announced U.S. commercial availability of NexoBrid for the removal of eschar in adults with deep partial- and/or full-thickness thermal burns, with the Company's U.S. strategic partner, Vericel Corporation.
- Announced commercial availability 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., a top ranked Japanese pharmaceutical company.
- Deployed all available non-U.S. NexoBrid inventory to support the emergency demand from hospitals and military to treat mass burn casualties resulting from the war in Israel.
- Responded to surging U.S. and global demand for NexoBrid by strategically reallocating resources to prioritize production and the scale-up of manufacturing capabilities. The new GMP-compliant state-of-the-art manufacturing facility is projected to be completed by mid-2024, with full-scale manufacturing currently expected to commence in 2025.
- Announced positive Committee for Medicinal Products for Human Use (CHMP) opinion recommending a change to the terms of the marketing authorization for NexoBrid in Europe to include all age groups for the removal of eschar in patients with deep partial- and full-thickness thermal burns.
- 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.
- Secured $6.5 million R&D budget from the U.S. Department of Defense to advance the development of a new, temperature stable formulation of NexoBrid to be used by the U.S. Army as a first line, non-surgical solution for field-care burn treatment.
- Positive results from the NexoBrid U.S. Phase III (DETECT) study were published in the Journal of Burn Care & Research, demonstrating that treatment with NexoBrid resulted in early complete eschar removal in more than 90% of treated burn patients and reduced the need for surgical excision compared to gel vehicle and standard of care.

EscharEx®

- An updated Phase III protocol will be submitted in the first quarter of 2024 in accordance with recent discussions with the U.S. FDA and EMA. Simultaneously, plans are underway for other exploratory studies aimed at supporting the Biologics License Application (BLA) for EscharEx and enhancing future commercialization and market access strategies.

- The global Phase III clinical trial intends to enroll approximately 216 patients, randomly assigned in a 1:1 ratio to receive either EscharEx or the placebo gel vehicle. The study's co-primary endpoints are the incidence of complete debridement at the end of the daily visit period and the incidence of wound closure by the end of weekly follow-ups. An interim assessment is planned after 67% of the participants have completed the trial. Patient enrollment is currently expected to commence in the second half of 2024.

- Established research and development partnership with 3M Healthcare, adding to previously announced partnerships with MIMEDX, and Mölnlycke, to provide product and support for the EscharEx Phase III clinical study.

Corporate Development

- Appointed Shmulik Hess, Ph.D. as the Chief Operating Officer and Chief Commercial Officer effective as of December 1, 2023. Dr. Hess brings extensive global expertise in operations and commercial activities, along with a proven track record of success during pivotal phases in a company's development. His capabilities will significantly contribute to fortifying the Company as a world-class operation.

- Cash, restricted cash, and investments totaled $46 million as of September 30, 2023, ensuring an operating cash runway that extends through profitability.

Third Quarter 2023 Financial Highlights

- **Revenues**: Revenues for the third quarter of 2023 were $4.8 million, compared to $5.8 million in the same quarter of the previous year. The decrease is primarily attributed to the absence of nonrecurring income from BARDA.

- **Gross Profit**: Gross profit in the third quarter 2023 was $0.9 million, representing 19% of total revenues, compared to $2.4 million, representing 41.9% of total revenue in the third quarter of 2022. The decrease is primarily attributed to the absence of nonrecurring income from BARDA.

- **Expenditures**:
  - Research and development expenses in the third quarter of 2023 were $1.5 million compared to $2.9 million in the third 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 third quarter of 2023 were $2.6 million, compared to $3.1 million in the third quarter of 2022.

- **Operating Results**: Operating loss in the third quarter of 2023 was $3.0 million, compared to $3.5 million loss in the third quarter of 2022.

- **Net Loss**: Net loss in the third quarter of 2023 was $2.2 million or $0.24 per share, compared to the net loss of $4.2 million, or $0.88 per share in the third 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 third quarter of 2023 was a loss of $2.6 million, compared to a loss of $2.5 million in the third quarter of 2022.

Year-to-Date 2023 Financial Highlights

- **Revenues:** Total revenues for the first nine months of 2023 were $13.3 million, compared to $14.9 million in the first nine months of 2022. The decrease is primarily attributed to the absence of nonrecurring income from BARDA.
- **Operating results:** Operating loss for the first nine months of 2023 was $11.4 million, compared to the operating loss of $10.5 million recorded in the first nine months of 2022.
- **Net loss:** Net loss for the first nine months of 2023 was $5 million, or $0.56 per share compared to a net loss of $12.1 million or $2.67 per share for the first nine months of 2022.
- **Non-GAAP Adjusted EBITDA:** Adjusted EBITDA, for the first nine months of 2023, showed a loss of $9 million, compared to a loss of $7.9 million reported in the first nine months of 2022.

Balance Sheet Overview

As of September 30, 2023, the Company's cash, restricted cash, and investments were $46 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 third quarter of 2023, the Company used $5.4 million to fund its activities. Existing cash and cash equivalents are expected to provide sufficient funds for the Company’s current operating plan through profitability. The Company’s issued and outstanding shares of NIS 0.07 par value as of December 31, 2022,

June 30, 2023, and September 30, 2023, were 7,240,020, 9,216,520 and 9,219,261, respectively.

Conference Call

MediWound management will host a conference call for investors on Tuesday, November 21, 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 the 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.
Unaudited Condensed Interim Consolidated Statements of Financial Position
U.S. dollars in thousands

	September 30,		Dec 31,
	2023	**2022**	**2022**
Cash and cash equivalents	9,279	14,905	33,895
Short-term bank deposits	36,244	2,687	-
Trade and other receivable	4,071	4,976	9,982
Inventories	3,656	1,880	1,963
Total current assets	**53,250**	**24,448**	**45,840**
Other receivables	483	230	364
Property, plant and equipment, net	6,437	2,354	2,366
Right of use assets, net	6,665	1,305	1,215
Intangible assets, net	182	248	231
Total non-current assets	**13,767**	**4,137**	**4,176**
Total assets	**67,017**	**28,585**	**50,016**
Current maturities of non-current liabilities	1,692	2,461	2,242
Trade payables and accrued expenses	3,680	3,565	5,656
Other payables	3,069	2,986	4,159
Total current liabilities	**8,441**	**9,012**	**12,057**
Deferred revenues	-	31	-
Warrants	8,901	5,092	15,606
Liabilities in respect of IIA grants	7,860	8,451	7,445
Liability in respect of TEVA	2,394	3,076	2,788
Lease liabilities	5,935	952	846
Severance pay liability, net	436	315	360
Total non-current liabilities	**25,526**	**17,917**	**27,045**
Shareholders' equity			
Ordinary shares of NIS 0.07 par value: Issued and Outstanding: 9,219,261 as of September 30, 2023; 7,240,020 as of December 31, 2022, and 5,819,314 as of September 30, 2022	**33,050**	**1,656**	**27,045**
Total liabilities & equity	**67,017**	**28,585**	**50,016**

MediWound, Ltd.
Unaudited Condensed Interim Consolidated Statements of Profit or Loss and Other Comprehensive Income or Loss
U.S. dollars in thousands

	Nine months ended September 30,		Three months ended September 30,	
	2023	**2022**	**2023**	**2022**
Revenues	13,348	14,878	4,776	5,803

Cost of revenues	10,489	9,871	3,880	3,369
Gross profit	**2,859**	**5,007**	**896**	**2,434**
Operating (Income) expenses:				
Research and development	5,659	7,482	1,533	2,883
Selling, general and administrative	8,820	7,684	2,612	3,061
Other (income) expenses	(224)	309	(224)	-
Operating loss	**(11,396)**	**(10,468)**	**(3,025)**	**(3,510)**
Financial income (expenses), net	6,488	(1,661)	877	(684)
Loss before taxes on income	**(4,908)**	**(12,129)**	**(2,148)**	**(4,194)**
Taxes on income	(65)	(13)	(48)	(5)
Net loss	**(4,973)**	**(12,142)**	**(2,196)**	**(4,199)**
Foreign currency translation adjustments	(2)	34	7	12
Total comprehensive loss	**(4,975)**	**(12,108)**	**(2,189)**	**(4,187)**
Basic and diluted net loss per share - USD	**(0.56)**	(2.67)	**(0.24)**	(0.88)
Weighted average Number of shares used in calculating basic and diluted net loss per share	**8,943**	4,546	**9,217**	4,784

MediWound, Ltd.
Unaudited Condensed Interim Consolidated Statements of Cash Flows
U.S. dollars in thousands

	Nine months ended September 30,		Three months ended September 30,	
	2023	**2022**	**2023**	**2022**
Cash Flows from Operating Activities:				
Net loss	**(4,973)**	**(12,142)**	**(2,196)**	**(4,199)**
Adjustments to reconcile net loss to net cash used in operating activities:				
Adjustments to profit and loss items:				
Depreciation and amortization	957	988	339	338
Share-based compensation	1,642	1,304	311	707
Revaluation of warrants accounted at fair value	(6,705)	-	(782)	-
Revaluation of liabilities in respect of IIA grants	709	812	217	330
Revaluation of contingent in respect of TEVA	357	404	116	132
Revaluation of lease liabilities	(206)	(146)	(184)	6
Increase in severance liability, net	80	64	13	9
Other income	(224)	-	(224)	-
Net financing income	(1,395)	334	(390)	345
Un-realized foreign currency (gain) loss	534	465	68	(63)
	(4,251)	**4,225**	**(516)**	**1,804**
Changes in asset and liability items:				
Decrease (increase) in trade receivables	6,186	(2,445)	71	(421)
Decrease (increase) in inventories	(1,688)	(608)	(526)	139
Decrease (increase) in other receivables	(198)	143	(320)	(187)
Decrease in trade payables and accrued expenses	(1,687)	(1,232)	(51)	(1,243)
Increase (decrease) in other payables and deferred revenues	(1,239)	(1,826)	287	(459)
	1,374	**(5,968)**	(539)	**(2,171)**
Net cash used in operating activities	**(7,850)**	**(13,885)**	(3,251)	(4,566)

MediWound, Ltd.
Unaudited Condensed Interim Consolidated Statements of Cash Flows
U.S. dollars in thousands

Cash Flows from Investing Activities:				
Purchase of property and equipment	(4,255)	(381)	(1,685)	(83)
Interest received	1,225	3	346	3
Investment in short term bank deposits, net	(36,319)	(2,499)	(4,489)	-
Net cash used in investing activities	**(39,349)**	**(2,877)**	**(5,828)**	**(80)**
Cash Flows from Financing Activities:				
Repayment of lease liabilities	(574)	(531)	(240)	(181)
Proceeds from issuance of shares and warrants, net	24,909	21,915	-	12,054
Repayments of IIA grants, net	(380)	(258)	(70)	(96)
Repayment of liabilities in respect of TEVA	(834)	-	(417)	-
Net cash provided by (used in) financing activities	**23,121**	**21,126**	**(727)**	**11,777**
Exchange rate differences on cash and cash equivalent balances	**(538)**	**(505)**	**(81)**	**45**
Increase (decrease) in cash and cash equivalents	**(24,616)**	**3,859**	**(9,887)**	**7,176**
Balance of cash and cash equivalents at the beginning of the period	33,895	11,046	19,166	7,729
Balance of cash and cash equivalents at the end of the period	9,279	14,905	9,279	14,905

MediWound, Ltd.
Adjusted EBITDA
U.S. dollars in thousands

	Nine months ended September 30,		Three months ended September 30,	
	2023	**2022**	**2023**	**2022**
Net loss	(4,973)	(12,142)	(2,196)	(4,199)
Adjustments:				
Financial income (expenses), net	6,488	(1,661)	877	(684)
Other income (expenses)	224	(309)	224	-
Taxes on income	(65)	(13)	(48)	(5)
Depreciation and amortization	(957)	(988)	(339)	(338)
Share-based compensation	(1,642)	(1,304)	(311)	(707)
Total adjustments	4,048	(4,275)	403	(1,734)
Adjusted EBITDA	**(9,021)**	**(7,867)**	**(2,599)**	**(2,465)**