MediWound Reports Third Quarter 2024 Financial Results and Provides Company Update

November 26, 2024

EscharEx IND Submission by Year-End; Phase 3 Study to Begin Shortly Thereafter; KOL Event Set for January 8, 2025

FDA Approves NexoBrid for Pediatric Use

$25 Million Financing and €16.25 Million EIC Funding Strengthen Cash Runway to Profitability

NexoBrid Product Revenue Meets Expectations; Demand Exceeds Capacity as New Manufacturing Facility Commissioning Underway

Conference Call Today, November 26 at 8:30 a.m. Eastern Time

YAVNE, Israel, Nov. 26, 2024 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq: MDWD), a global leader in next-generation enzymatic therapeutics for tissue repair, today announced financial results for the third quarter ended September 30, 2024, and provided a corporate update.

"We made great headway toward our objectives this quarter, achieving a major milestone with NexoBrid approval for pediatric use in the U.S.," said Ofer Gonen, Chief Executive Officer of MediWound. "With the upcoming launch of the Phase 3 trial for EscharEx in venous leg ulcers, we're advancing closer to addressing critical unmet needs in a $2 billion market. Additionally, we will be conducting a head-to-head Phase 2 study vs. collagenase in 2025, to further demonstrate EscharEx's competitive advantage and maximize its commercial opportunity. We're also accelerating our diabetic foot ulcer program with Phase 2/3 preparations well underway. Our manufacturing expansion remains on track, positioning us to meet the growing demand for NexoBrid globally."

Third Quarter 2024 Highlights, Recent Developments and Upcoming Milestones:

NexoBrid

- Completed construction of the Company's new, state-of-the-art GMP-compliant manufacturing facility with commissioning underway. The facility is expected to reach full operational capacity by the end of 2025, increasing manufacturing output sixfold. Commercial availability will depend on securing the necessary regulatory approvals.
- Received U.S. Food and Drug Administration (FDA) approval of NexoBrid for pediatric patients aged newborn through 18 with deep partial-thickness and/or full-thickness thermal burns. NexoBrid is now authorized for use in the U.S. for all age groups, aligning with its indications in the European Union and Japan.
- U.S. launch by Vericel continues to gain traction, with over 70 burn center Pharmacy and Therapeutics (P&T) committee submissions, of which approximately 50 have received approval and have placed initial orders. NexoBrid received a Category III CPT code, which will be posted on the AMA website on January 1, 2025, and will go into effect on July 1, 2025.
- The World Health Organization (WHO) has recently recognized enzymatic debridement as a validated treatment for burn injuries. This recognition, featured in the WHO's *Standards and Recommendations for Burns Care in Mass Casualty Incidents (BMCI)* guidelines for emergency medical teams, highlights NexoBrid's critical role in emergency preparedness. It also bolsters efforts to implement strategic stockpiling plans within the European Union through the Health Emergency Preparedness and Response Authority (HERA), following the precedent set by the U.S. Biomedical Advanced Research and Development Authority (BARDA).
- The Company anticipates $20 million in total revenue for 2024, compared to prior guidance of $24 million. NexoBrid product revenues remain in line with expectations, driven by strong demand that exceeds current manufacturing capacity. Following FDA approval of NexoBrid's pediatric indication without additional post-approval requirements, BARDA funding for further development is no longer required, reducing expected revenue from development services. Additionally, based on a Type C meeting with the FDA regarding the NexoBrid temperature-stable formulation project for the U.S. Army, clinical activities have been scheduled for 2026, which affects anticipated revenue from the U.S. Department of Defense for 2024.

EscharEx

- The Phase 3 study of EscharEx for venous leg ulcers (VLUs) is set to commence, with FDA IND submission planned by

year-end. All setup activities for initiation are complete, and the Company has successfully passed the required EMA inspection in preparation for the trial.

- The Company plans to host a virtual KOL event on January 8, 2025. The event will provide an update on the EscharEx VLU Phase 3 trial and review the commercial opportunity.

- Announced a planned randomized, head-to-head Phase 2 study of EscharEx vs. collagenase in VLU patients. Set to begin in 2025, the trial will support the EscharEx Biologics License Application (BLA) submission and strengthen the Company's commercialization strategy. MediWound has secured additional R&D collaborations for this study with Solventum and Mölnlycke to optimize trial consistency and patient outcomes.

- Obtained €16.25 million in funding from the European Innovation Council (EIC) for the clinical development of EscharEx for treating diabetic foot ulcers (DFUs). This will expedite MediWound's DFU program, and its associated revenue projections by four years. DFUs are more prevalent than VLUs, with a higher percentage of patients requiring debridement. Preparations for the DFU Phase 2/3 study are progressing as planned.

Corporate Development

- Raised $25 million in a strategic private investment in public equity (PIPE) with several new and existing investors. Mölnlycke Health Care, a global leader in innovative wound care solutions, led the PIPE and entered into a collaboration agreement with MediWound.

Third Quarter 2024 Financial Highlights

- **Revenue**: Revenue for the third quarter of 2024 totaled $4.4 million, compared to $4.8 million in the same period of 2023. The decrease was primarily due to lower revenue from BARDA development services.

- **Gross Profit**: Gross profit for the third quarter of 2024 was $0.7 million, representing 16% of total revenue, compared to $0.9 million, representing 19% of total revenue in the third quarter of 2023. This decline in gross margin reflects a shift in the revenue mix.

- **Expenditures**:
  - **Research and Development**: R&D expenses for the quarter were $2.5 million, compared to $1.5 million in the third quarter of 2023. The increase was mainly due to costs associated with the EscharEx Phase 3 clinical trial.

  - **Selling, General, and Administrative**: SG&A expenses for the third quarter of 2024 were $3.2 million, compared to $2.6 million in the same period of 2023. The increase was primarily from share-based compensation costs.

- **Operating Results**: Operating loss for the third quarter of 2024 was $5.1 million, compared to a loss of $3.0 million in the third quarter of 2023.

- **Net Loss**: Net loss for the third quarter of 2024 was $10.3 million, or $0.98 per share, compared to a net loss of $2.2 million, or $0.24 per share, in the third quarter of 2023. This change was primarily due to financial expenses driven by the revaluation of warrants.

- **Non-GAAP Adjusted EBITDA**: Adjusted EBITDA was a loss of $3.7 million, compared to a loss of $2.6 million in the third quarter of 2023.

Year-to-Date 2024 Financial Highlights

- **Revenue:** Total revenues for the first nine months of 2024 reached $14.4 million, up from $13.3 million in the same period of 2023. The increase is mainly attributed to revenue contribution from Vericel.

- **Gross Profit**: Gross profit was $1.7 million, or 12% of total revenue, compared to $2.9 million, or 21% of total revenue, in the first nine months of 2023, reflecting changes in the revenue mix.

- **Expenditures**:
  - **Research and Development**: R&D expenses were $5.9 million, slightly higher than $5.7 million in the same period of 2023.

  - **Selling, General, and Administrative**: SG&A expenses totaled $9.1 million, compared to $8.8 million in the first nine months of 2023, driven primarily by increased share-based compensation costs.

- **Operating Results:** Operating loss for the first nine months of 2024 was $13.3 million, compared to $11.4 million in 2023.

- **Net Loss:** The net loss for the period was $26.3 million, or $2.72 per share, compared to a net loss of $5.0 million, or $0.56 per share, in the same period of 2023. This $21.3 million increase was mainly driven by net financial expenses, largely resulting from the revaluation of warrants due to a 78% rise in the Company's share price year to date.

- **Adjusted EBITDA:** Adjusted EBITDA for the first nine months was a loss of $9.9 million, compared to a loss of $9.0 million in 2023.

Balance Sheet Highlights

As of September 30, 2024, the Company had cash and cash equivalents and deposits totaling $46.0 million, compared to $42.1 million on December 31, 2023. During the first nine months of 2024, the Company raised $25 million through a PIPE offering, received $1.2 million from the exercise of Series A warrants, and fully settled its liability with Teva. The Company used $19.7 million to fund its operations in the first nine months of 2024, including $6.0 million allocated to CAPEX, primarily for facility scale-up.

Conference Call

MediWound management will host a conference call for investors on Tuesday, November 26, 2024, beginning at 8:30 a.m., Eastern Time to discuss these results. 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 a global leader in next-generation enzymatic therapeutics focused on non-surgical tissue repair. The Company specializes in the development, production and commercialization of innovative biologics that enhance existing standards of care and improve patient experiences while reducing healthcare costs and unnecessary surgeries.

MediWound's first drug, NexoBrid®, is an FDA- and EMA-approved orphan biologic for eschar removal in deep partial-thickness and/or full-thickness thermal burns, significantly reducing the need for surgical interventions. Leveraging its proprietary enzymatic technology, MediWound is advancing EscharEx®, a promising candidate currently in Phase 3 development for the debridement of chronic wounds. Phase 2 clinical trials have shown EscharEx has distinct advantages over the current $360+ million market leader, presenting a unique opportunity for significant market growth.

For more information visit www.mediwound.com and follow us 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; 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

	September 30,		December 31,
	2024	**2023**	**2023**
CURRENT ASSETS:			
Cash and cash equivalents and short-term deposits	45,562	45,523	41,708
Trade and other receivable	5,304	4,071	5,141
Inventories	3,022	3,656	2,846
Total current assets	**53,888**	**53,250**	**49,695**
NON-CURRENT ASSETS			
Trade and other receivables	50	50	233
Long-term restricted bank deposits	434	433	440
Property, plant and equipment, net	13,453	6,437	9,228
Right of use assets, net	6,793	6,665	6,698
Intangible assets, net	116	182	165
Total non-current assets	**20,846**	**13,767**	**16,764**
Total assets	**74,734**	**67,017**	**66,459**
CURRENT LIABILITIES:			
Current maturities of long-term liabilities	726	1,692	1,410
Warrants, net	19,056	8,901	7,296

Trade payables and accrued expenses	3,131	3,680	5,528
Other payables	2,664	3,069	3,891
Total current liabilities	**25,577**	**17,342**	**18,125**
NON- CURRENT LIABILITIES:			
Liabilities in respect of IIA grants	8,046	7,860	7,677
Liabilities in respect of TEVA	-	2,394	2,256
Lease liabilities	6,460	5,935	6,350
Severance pay liability, net	416	436	456
Total non-current liabilities	**14,922**	**16,625**	**16,739**
Shareholders' equity	34,235	33,050	31,595
Total liabilities & shareholder equity	**74,734**	**67,017**	**66,459**

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)

	Nine months ended September 30,		Three months ended September 30,		Year ended December 31,
	2024	**2023**	**2024**	**2023**	**2023**
Total Revenues	14,382	13,348	4,355	4,776	18,686
Cost of revenues	12,651	10,489	3,678	3,880	15,108
Gross profit	**1,731**	**2,859**	**677**	**896**	**3,578**
Research and development	5,892	5,659	2,524	1,533	7,467
Selling and Marketing	3,466	3,635	1,063	1,197	4,844
General and administrative	5,672	5,185	2,171	1,415	6,768
Other Income	-	(224)	-	(224)	(211)
Total operating expenses	**15,030**	**14,255**	**5,758**	**3,921**	**18,868**
Operating loss	**(13,299)**	**(11,396)**	**(5,081)**	**(3,025)**	**(15,290)**
Financial income (expenses), net	(12,974)	6,488	(5,180)	877	8,759
Taxes on income	(43)	(65)	(21)	(48)	(185)
Net loss	**(26,316)**	**(4,973)**	**(10,282)**	**(2,196)**	**(6,716)**
Foreign currency translation adjustments	3	(2)	(7)	7	(13)
Total comprehensive loss	**(26,313)**	**(4,975)**	**(10,289)**	**(2,189)**	**(6,729)**
Basic and diluted loss per share:					
Net loss per share	(2.72)	(0.56)	(0.98)	(0.24)	(0.75)
Weighted average number of ordinary shares	9,679,599	8,943,205	10,511,288	9,217,390	9,013,144

MediWound, Ltd.

Unaudited Condensed Consolidated Statements of Cash Flows
U.S. dollars in thousands

	Nine months ended	Three months ended	Year Ended

	Nine months ended September 30,		Three months ended September 30,		Year Ended December 31,
	2024	2023	2024	2023	2023
Cash Flows from Operating Activities:					
Net loss	**(26,316)**	**(4,973)**	**(10,282)**	**(2,196)**	**(6,716)**
Adjustments to reconcile net loss to net cash used in operating activities:					
Adjustments to profit and loss items:					
Depreciation and amortization	1,086	957	361	339	1,303
Share-based compensation	2,316	1,642	1,046	311	1,940
Revaluation of warrants accounted at fair value	12,668	(6,705)	4,661	(782)	(8,310)
Revaluation of liabilities in respect of IIA grants	711	709	241	217	427
Revaluation of liabilities in respect of TEVA	770	357	564	116	468
Financing income (expenses) and exchange differences of lease liability	238	(206)	221	(184)	257
Increase (decrease) in severance liability, net	(46)	80	(94)	13	83
Other income	-	(224)	-	(224)	(211)
Financial income, net	(1,486)	(1,395)	(568)	(390)	(2,231)
Un-realized foreign currency (gain) loss	74	534	(4)	68	189
	16,331	**(4,251)**	**6,428**	**(516)**	**(6,085)**
Changes in asset and liability items:					
Decrease (increase) in trade receivables	285	6,186	(468)	71	5,658
Decrease (increase) in inventories	(161)	(1,688)	184	(526)	(906)
Decrease (increase) in other receivables	(283)	(198)	291	(320)	(894)
Decrease in trade payables and accrued expenses	(1,948)	(1,687)	(48)	(51)	(594)
Increase (decrease) in other payables	105	(1,239)	139	287	(928)
	(2,002)	**1,374**	**98**	**(539)**	**2,336**
Net cash used in operating activities	**(11,987)**	**(7,850)**	**(3,756)**	**(3,251)**	**(10,465)**

Unaudited Condensed Consolidated Statements of Cash Flows
U.S. dollars in thousands

	Nine months ended September 30,		Three months ended September 30,		Year Ended December 31,
	2024	2023	2024	2023	2023
Cash Flows from Investment Activities:					
Purchase of property and equipment	(5,467)	(4,255)	(1,192)	(1,685)	(6,464)
Interest received	1,588	1,225	461	346	1,947
Investment in short term bank deposits, net	(9,346)	(36,319)	(13,555)	(4,489)	(29,804)
Net cash used in investing activities	**(13,225)**	**(39,349)**	**(14,286)**	**(5,828)**	**(34,321)**
Cash Flows from Financing Activities:					
Repayment of lease liabilities	(686)	(574)	(228)	(240)	(778)
Proceeds from exercise of warrants	1,210	-	600	-	-
Proceeds from issuance of shares and warrants, net	22,436	24,909	22,436	-	24,909
Repayments of IIA grants, net	(219)	(380)	(99)	(70)	(380)
Repayment of liabilities in respect of TEVA	(2,834)	(834)	(2,000)	(417)	(834)
Net cash provided by (used in) financing activities	**19,907**	**23,121**	**20,709**	**(727)**	**22,917**
Exchange rate differences on cash and cash equivalent balances	**(86)**	**(538)**	**18**	**(81)**	**(160)**
Increase (decrease) in cash and cash equivalents	**(5,391)**	**(24,616)**	**2,685**	**(9,887)**	**(22,029)**

Balance of cash and cash equivalents at the beginning of the period	11,866	33,895	3,790	19,166	33,895
Balance of cash and cash equivalents at the end of the period	**6,475**	**9,279**	**6,475**	**9,279**	**11,866**

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

	Nine months ended September 30,		Three months ended September 30,		Year Ended December 31,
	2024	**2023**	**2024**	**2023**	**2023**
Net loss	**(26,316)**	**(4,973)**	**(10,282)**	**(2,196)**	**(6,716)**
Adjustments:					
Financial income (expenses), net	(12,974)	6,488	(5,180)	877	8,759
Other Income, net	-	224	-	224	211
Taxes on income	(43)	(65)	(21)	(48)	(185)
Depreciation and amortization	(1,086)	(957)	(361)	(339)	(1,303)
Share-based compensation expenses	(2,316)	(1,642)	(1,046)	(311)	(1,940)
Total adjustments	(16,419)	4,048	(6,608)	403	5,542
Adjusted EBITDA	**(9,897)**	**(9,021)**	**(3,674)**	**(2,599)**	**(12,258)**