MediWound Reports Second Quarter 2024 Financial Results and Provides Company Update

August 14, 2024

Completed Construction of New NexoBrid® Manufacturing Facility

€16.25 Million EIC Funding Expedites EscharEx® Development for Diabetic Foot Ulcers, Significantly Expanding the Addressable Market; Phase III Study for Venous Leg Ulcers to Begin in H2 2024

$25 Million Strategic Investment Led by Mölnlycke Health Care

Conference Call Today, August 14 at 8:30am Eastern Time

YAVNE, Israel, Aug. 14, 2024 (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, 2024, and provided a corporate update.

“This has been another strong quarter for MediWound as we continue to successfully execute our strategic plan,” said Ofer Gonen, Chief Executive Officer of MediWound. “We have completed construction of our new GMP-compliant, state-of-the-art manufacturing facility for NexoBrid® addressing the growing global demand for this product. We are well on track to achieving our two remaining key goals: accelerating NexoBrid's revenue growth and initiating the Phase III clinical trial for EscharEx.

In addition to these strategic milestones, we secured €16.25 million in funding from the European Innovation Council (EIC) to expand EscharEx’s indications to include diabetic foot ulcers, significantly increasing the product’s total addressable market. Furthermore, we raised $25 million in financing led by Mölnlycke Health Care, an industry leader, demonstrating confidence in our technology and further strengthening our financial position.”

Second Quarter 2024 Highlights, Recent Developments and Upcoming Milestones:

NexoBrid

- Construction of our new, state-of-the-art GMP-compliant manufacturing facility is complete. Commissioning will begin soon, aiming for full operational capacity in 2025. This expansion will increase manufacturing capacity sixfold.
- U.S. launch by Vericel continues to build momentum. Approximately 70 burn centers have completed submissions to Pharmacy and Therapeutics (P&T) committees, with 40+ centers already obtaining approval, and nearly all of those placing initial product orders. Vericel reported a notable increase in hospital orders and the number of patients treated, driving a revenue growth of 76% over prior quarter.
- Results from the U.S. NexoBrid Expanded Access Protocol (NEXT) were positive and aligned with the findings from Phase III studies. Conducted at 29 burn centers across the U.S. with 239 patients enrolled, and designed to ensure continuous availability until commercialization, NEXT reaffirmed NexoBrid's proven safety and efficacy in eschar removal, significantly reducing the need for surgical procedures in burn patients.
- U.S. Food and Drug Administration (FDA) approval of the pediatric indication is expected in the third quarter of 2024.

EscharEx

- Phase III study of EscharEx for treating venous leg ulcers (VLUs) is scheduled to start in the second half of 2024, as planned.
- €16.25 million in funding from the EIC will accelerate 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 them requiring debridement. Preparations for the DFU Phase II/III study are currently underway.
- Results of EscharEx Phase II ChronEx study were published in THE LANCET’s eClinicalMedicine journal. EscharEx outperformed non-surgical SOC in debridement and promotion of healthy granulation tissue.

Corporate Developments

- Secured $25 million in a strategic private investment in public equity with several new and existing investors. Mölnlycke Health Care, a global leader in innovative wound care solutions, led the PIPE and has entered into a collaboration agreement with MediWound.
- Company included in the Russell 3000® Index, as part of the 2024 Russell indexes annual reconstitution.

Second Quarter 2024 Financial Highlights

- **Revenue**: Revenue for the second quarter of 2024 was $5.1 million, up from $4.8 million in the same period of 2023. The increase is primarily attributed to revenue from Vericel.
- **Gross Profit**: Gross profit for the second quarter of 2024 was $0.4 million, representing 9% of total revenue, compared to $1.1 million, representing 24% of total revenue in the second quarter of 2023. The decrease in gross margin is mainly due to changes in the revenue mix and nonrecurring production costs.
- **Expenditures**:
  - **Research and Development**: R&D expenses for the second quarter of 2024 were $1.9 million, compared to $2.0 million in the same period of 2023.
  - **Selling, General, and Administrative**: SG&A expenses for the second quarter of 2024 were $3.0 million, compared to $3.1 million in the second quarter of 2023.
- **Operating Results**: Operating loss for the second quarter of 2024 was $4.5 million, compared to an operating loss of $4.0 million in the second quarter of 2023.
- **Net Profit (Loss)**: Net loss for the second quarter of 2024 was $6.3 million, or $0.68 per share, compared to a net profit of $0.9 million, or $0.10 per share, in the second quarter of 2023. This change is primarily due to financial expenses driven by the revaluation of warrants.
- **Non-GAAP Adjusted EBITDA**: Adjusted EBITDA for the second quarter of 2024 was a loss of $3.4 million, compared to a loss of $3.0 million in the same period of 2023.

Year-to-Date 2024 Financial Highlights

- **Revenue:** Total revenues for the first half of 2024 were $10.0 million, up from $8.6 million in the first half of 2023. The increase is mainly attributed to revenue from Vericel and new contracts with the U.S. Department of Defense (DoD).
- **Gross Profit**: Gross profit for the first half of 2024 was $1.1 million, or 11% of total revenue, compared to $2.0 million, or 23% of total revenue, in the first half of 2023.
- **Expenditures**:
  - **Research and Development**: R&D expenses for the first half of 2024 were $3.4 million, compared to $4.1 million in the first half of 2023. This decrease is primarily due to the completion of the EscharEx Phase II study.
  - **Selling, General, and Administrative**: SG&A expenses for the first half of 2024 were $5.9 million, down from $6.2 million in the first half of 2023.
- **Operating Results:** Operating loss for the first half of 2024 was $8.2 million, compared to an operating loss of $8.4 million in the same period of 2023.
- **Net Loss:** Net loss for the first half of 2024 was $16.0 million, or $1.73 per share, compared to a net loss of $2.8 million, or $0.32 per share, in the first half of 2023. The increase in net loss is primarily attributable to financial expenses from the revaluation of warrants, which amounted to $8 million, driven by a 53% increase in the Company's share price.
- **Adjusted EBITDA:** Adjusted EBITDA for the first half of 2024 was a loss of $6.2 million, compared to a loss of $6.4 million in the first half of 2023.

Balance Sheet Highlights

As of June 30, 2024, the Company had cash and cash equivalents, restricted cash, and deposits totaling $29.7 million, compared to $42.1 million as of December 31, 2023. In the first half of 2024, the Company received $0.6 million from the exercise of Series A warrants. The Company utilized $12.9 million to fund its activities in the first half of 2024, including $4.3 million allocated to CAPEX primarily for facility scale-up.
On July 15, the Company successfully raised $25 million through a PIPE offering. Following the PIPE, the issued and outstanding shares of NIS 0.07 par value were 10,786,423.

Conference Call

MediWound management will host a conference call for investors on Wednesday, August 14, 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 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. 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 ®, 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-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® 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, 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

	June 30,		December 31,
	2024	**2023**	**2023**
CURRENT ASSTS:			
Cash and cash equivalents and short-term deposits	29,215	51,122	41,708
Trade and other receivable	4,888	3,818	5,141
Inventories	3,210	3,113	2,846
Total current assets	**37,313**	**58,053**	**49,695**
Non-current assets			
Trade and other receivables	238	277	233
Long-term restricted bank deposits	453	-	440
Property, plant and equipment, net	12,308	4,705	9,228
Right of use assets, net	6,852	1,133	6,698
Intangible assets, net	132	198	165
Total non-current assets	**19,983**	**6,313**	**16,764**
Total assets	**57,296**	**64,366**	**66,459**
CURRENT LIABILITIES:			
Current maturities of long-term liabilities	1,496	1,961	1,410
Warrants, net	14,902	9,683	7,296
Trade payables and accrued expenses	2,745	3,531	5,528
Other payables	3,468	2,817	3,891
Total current liabilities	**22,611**	**17,992**	**18,125**
NON- CURRENT LIABILITIES:			
Liabilities in respect of IIA grants	8,009	7,806	7,677
Liabilities in respect of TEVA	1,962	2,529	2,256
Lease liability	6,355	677	6,350
Severance pay liability, net	490	433	456
Total non-current liabilities	**16,816**	**11,445**	**16,739**
Shareholders' equity	17,869	34,929	31,595
Total liabilities & shareholder equity	**57,296**	**64,366**	**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)

	Six months ended June 30,		Three months ended June 30,		Year ended December 31,
	2024	**2023**	**2024**	**2023**	**2023**
Total Revenues	10,027	8,572	5,063	4,773	18,686
Cost of revenues	8,973	6,609	4,616	3,636	15,108
Gross profit	**1,054**	**1,963**	**447**	**1,137**	**3,578**
Research and development	3,368	4,126	1,898	2,024	7,467
Selling and Marketing	2,403	2,438	1,224	1,332	4,844
General and administrative	3,501	3,770	1,809	1,788	6,768
Other Income	-	-	-	-	(211)
Total operating expenses	**9,272**	**10,334**	**4,931**	**5,144**	**18,868**

Operating loss	**(8,218)**	**(8,371)**	**(4,484)**	**(4,007)**	**(15,290)**
Financial income (expenses), net	(7,794)	5,611	(1,823)	4,935	8,759
Taxes on income	(22)	(17)	2	(12)	(185)
Net profit (loss)	**(16,034)**	**(2,777)**	**(6,305)**	**916**	**(6,716)**
Foreign currency translation adjustments	10	(9)	2	-	(13)
Total comprehensive profit (loss)	**(16,024)**	**(2,786)**	**(6,303)**	**916**	**(6,729)**
Basic and diluted loss per share:					
Net profit (loss) per share	(1.73)	(0.32)	(0.68)	0.1	(0.75)
Weighted average number of ordinary shares	9,256,862	8,803,065	9,279,370	9,208,902	9,013,144

MediWound, Ltd.

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

	Six months ended June 30,		Three months ended June 30,		Year Ended December 31,
	2024	**2023**	**2024**	**2023**	**2023**
Cash Flows from Operating Activities:					
Net profit (loss)	**(16,034)**	**(2,777)**	**(6,305)**	**916**	**(6,716)**
Adjustments to reconcile net profit (loss) to net cash used in operating activities:					
Adjustments to profit and loss items:					
Depreciation and amortization	725	618	357	315	1,303
Share-based compensation	1,270	1,331	758	712	1,940
Revaluation of warrants accounted at fair value	8,007	(5,923)	1,927	(4,990)	(8,310)
Revaluation of liabilities in respect of IIA grants	470	492	237	233	427
Revaluation of liabilities in respect of TEVA	206	241	99	119	468
Financing income and exchange differences of lease liability	17	(22)	(11)	(9)	257
Increase in severance liability, net	48	67	13	(10)	83
Other income	-	-	-	-	(211)
Financial income, net	(918)	(1,005)	(405)	(759)	(2,231)
Un-realized foreign currency loss	78	466	11	120	189
	9,903	**(3,735)**	**2,986**	**(4,269)**	**(6,085)**
Changes in asset and liability items:					
Decrease (increase) in trade receivables	753	6,115	876	(707)	5,658
Decrease (increase) in inventories	(345)	(1,162)	103	(579)	(906)
Decrease (increase) in other receivables	(574)	122	(459)	435	(894)
Increase (decrease) in trade payables and accrued expenses	(1,900)	(1,636)	(530)	312	(594)
Decrease in other payables	(34)	(1,526)	(294)	(1,359)	(928)
	(2,100)	**1,913**	**(304)**	**(1,898)**	**2,336**
Net cash used in operating activities	**(8,231)**	**(4,599)**	**(3,623)**	**(5,251)**	**(10,465)**

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

	Six months ended June 30,		Three months ended June 30,		Year Ended December 31,
	2024	**2023**	**2024**	**2023**	**2023**
Cash Flows from Investment Activities:					

Purchase of property and equipment	(4,275)	(2,570)	(3,016)	(1,065)	(6,464)
Interest received	1,127	879	522	577	1,947
Proceeds from (investment in) short term bank deposits, net	4,209	(31,830)	5,339	(25,590)	(29,804)
Net cash provided by (used in) investing activities	**1,061**	**(33,521)**	**2,845**	**(26,078)**	**(34,321)**
Cash Flows from Financing Activities:					
Repayment of lease liabilities	(458)	(334)	(214)	(157)	(778)
Proceeds from exercise of warrants	610	(*)	111	(*)	-
Proceeds from issuance of shares and warrants, net	-	24,909	-	(248)	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	**(802)**	**23,848**	**(103)**	**(405)**	**22,917**
Exchange rate differences on cash and cash equivalent balances	(104)	(457)	(15)	(120)	(160)
Decrease in cash and cash equivalents	(8,076)	(14,729)	(896)	(31,854)	(22,029)
Balance of cash and cash equivalents at the beginning of the period	11,866	33,895	4,686	51,020	33,895
Balance of cash and cash equivalents at the end of the period	**3,790**	**19,166**	**3,790**	**19,166**	**11,866**

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

	Six months ended June 30,		Three months ended June 30,		Year Ended December 31,
	2024	**2023**	**2024**	**2023**	**2023**
Net profit (loss)	**(16,034)**	**(2,777)**	**(6,305)**	**916**	**(6,716)**
Adjustments:					
Financial income (expenses), net	(7,794)	5,611	(1,823)	4,935	8,759
Other Income, net	-	-	-	-	211
Taxes on income	(22)	(17)	2	(12)	(185)
Depreciation and amortization	(725)	(618)	(357)	(315)	(1,303)
Share-based compensation expenses	(1,270)	(1,331)	(758)	(712)	(1,940)
Total adjustments	(9,811)	3,645	(2,936)	3,896	5,542
Adjusted EBITDA	**(6,223)**	**(6,422)**	**(3,369)**	**(2,980)**	**(12,258)**