



MediWound Reports Second Quarter 2022 Financial Results and Provides Company Updates

August 9, 2022

Positive Results in Two Phase 2 Trials of EscharEx

FDA Assigned PDUFA Target Date of January 1, 2023 for NexoBrid BLA

Enhanced the Board and Leadership Team

Conference Call Begins Today at 8:30 AM Eastern Time

YAVNE, Israel, Aug. 09, 2022 (GLOBE NEWSWIRE) -- MediWound Ltd. (NASDAQ: MDWD), a fully integrated biopharmaceutical company focused on next-generation biotherapeutic solutions for tissue repair and regeneration, today announced financial results for the second quarter ending June 30, 2022.

Second Quarter Highlights and Recent Developments:

- Enhanced the Company's Board and executive leadership team with the appointments of Nachum (Homi) Shamir as Chairman of the Board of Directors, Ofer Gonen as Chief Executive Officer, Tzvi Palash as Chief Operating Officer and Dr. Robert J. Snyder as Chief Medical Officer.
- Announced positive results from its U.S. Phase 2 clinical study of EscharEx[®] for the debridement of venous leg ulcers (VLUs). The study met its primary and key secondary endpoints with statistically significant results compared to control arms, showing significant improvement over the current non-surgical standard-of-care, with no deleterious effect on wound closure and no observed safety issues.
- Announced positive results from the Company's Phase 2 pharmacology study of EscharEx for the debridement of lower leg ulcers. The data showed EscharEx to be a safe, rapid, and effective treatment for the debridement of venous leg ulcers (VLUs) and diabetic foot ulcers (DFUs). The study also demonstrated EscharEx reduces wound size, biofilm, and bacterial burden.
- Hosted a KOL Event on EscharEx for analysts and investors covering recent Phase 2 results, current wound debridement practices, the unmet medical need, and the potential market and commercial opportunity for EscharEx.
- Announced acceptance by the U.S. Food and Drug Administration (FDA) of the re-submitted Biologics License Application (BLA) filing for NexoBrid[®] for the debridement of deep partial-thickness and/or full thickness thermal burns. The FDA assigned a Prescription Drug User Fee Act (PDUFA) target date of January 1, 2023.
- Announced positive initial data from the Company's U.S. Phase I/II study of MW005 for the treatment of low-risk basal cell carcinoma (BCC). The initial data showed MW005 to be safe and well-tolerated, and target lesions clearance data provided clinical efficacy proof-of-concept.
- Total revenues for the second quarter of 2022 were \$4.7 million compared to \$6.1 million in the second quarter of 2021.
- Cash and short-term investments of \$10.4 million as of June 30, 2022.

"I am very proud of our accomplishments this quarter. We have made significant strides and achievements across our deep pipeline of game-changing therapies," said Ofer Gonen, Chief Executive Officer of MediWound. "While we view NexoBrid's potential FDA approval as a meaningful step forward for burn care in the U.S., EscharEx remains our primary focus. We believe it has the potential to be a transformative treatment option for millions of patients suffering from chronic wounds. We foresee it becoming a best-in-class debridement preference throughout the medical community, capturing a significant portion of the billion-dollar chronic wound debridement market in the U.S. We look forward to the second half of this year where we expect to gain clarity from the FDA on the development path for EscharEx."

Second Quarter Financial Highlights

Total revenues for the second quarter of 2022 were \$4.7 million, compared to \$6.1 million for the second quarter of 2021. This was primarily due to a decrease in revenues from products and licenses of \$1.9 million, compared to \$3.0 million in the second quarter of 2021. This resulted from \$0.7 million decrease in emergency stockpile procurement by BARDA and \$0.6 million shift in revenues, due to the temporary shortage in the supply chain of gel jars.

Gross profit for the second quarter of 2022 was \$1.1 million, or 24% of net revenues, compared to a gross profit of \$2.4 million, or 39% of net

revenues, for the second quarter of 2021.

Research and development expenses for the second quarter of 2022 were \$2.2 million compared to \$2.7 million in the second quarter of 2021. The decrease was primarily a result of the completion of the Company's U.S. Phase 2 EscharEx trial.

Selling, general and administrative expenses for the second quarter of 2022 were \$2.3 million, compared to \$2.6 million in the second quarter of 2021. The decrease was primarily a result of the vesting completion of share base compensation.

Other expenses for the second quarter of 2022 were \$0.3 million, and are non-recurring in nature, resulting from management changes.

Operating loss for the second quarter of 2022 was \$3.7 million compared to \$2.9 million in the second quarter of 2021.

The Company posted a net loss for the second quarter of 2022 of \$4.4 million, or \$0.13 per share, compared to a net loss of \$3.2 million, or \$0.12 per share, for the second quarter of 2021.

Adjusted EBITDA, as defined below, for the second quarter of 2022 was a loss of \$2.8 million, compared to a loss of \$2.0 million for the second quarter of 2021.

Year-to-Date 2022 Financial Results

Total revenues for the first half of 2022 were \$9.1 million compared to \$11.9 million in the first half of 2021. Revenue from products and licenses in the first half of 2022 were \$3.2 million compared to \$5.9 million for the first half of 2021. This was primarily a result of a \$1.9 million decrease in emergency stockpile procurement by BARDA and \$0.6 million shift in revenues, due to a temporary shortage in the supply chain of gel jars.

Operating loss for the first half of 2022 was \$7.0 million, compared to an operating loss of \$4.8 million in the first half of 2021.

Net loss for the first half of 2022 was \$7.9 million or \$0.26 per share compared to a net loss of \$6.0 million or \$0.22 per share for the first half of 2021.

Adjusted EBITDA, as defined below, for the first half of 2022, was a loss of \$5.4 million, compared to a loss of \$3.3 million for the first half of 2021.

Balance Sheet Highlights

As of June 30, 2022, MediWound had \$10.4 million in cash and short-term investments, compared with \$11.0 million as of December 31, 2021, and no debt. MediWound utilized \$6.4 million in the second quarter of 2022 for its operational activities, which was affected by \$1.8 million delay in collection from customers subsequently received in July, and a \$0.6 million shift in revenue to the third quarter of 2022 due to a temporary shortage in the supply chain. In addition, cash use for the quarter included \$0.6 million in commissions related to the equity raise during the first quarter. The Company is updating its cash use for 2022 to be between \$13 million to \$15 million, from \$11 million to \$13 million due to the impact of management changes and projected revenues shifting to 2023.

Conference Call

MediWound management will host a conference call for investors today, Tuesday, August 9, 2022, 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 800-715-9871 (in the U.S.), 972-3-376-1144 (Israel), or 646-307-1963 (outside the U.S. & Israel) and entering passcode 2969306. The call will be webcast live on the Events & Presentations page of Company's website at: <https://ir.mediwound.com/events-and-presentations>

A replay of the call will be available on the Company's website for 90 days 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 is a biopharmaceutical company that develops, manufactures, and commercializes novel, cost effective, bio-therapeutic solutions for tissue repair and regeneration. Our strategy leverages our enzymatic technology platform, focused on next-generation bioactive therapies for burn care, wound care, and tissue repair.

NexoBrid, our commercial orphan biological product for non-surgical eschar removal of deep-partial and full-thickness thermal burns, is a bromelain-based biological product containing a sterile mixture of proteolytic enzymes that selectively removes burn eschar within four hours without harming surrounding viable tissue. NexoBrid is currently marketed in the European Union and other international markets and is at registration-stage with the Food and Drug Administration (FDA). NexoBrid is supported by the U.S. Biomedical Advanced Research and Development Authority (BARDA).

EscharEx, our next-generation bioactive topical therapeutic, is under development in the U.S. for debridement of chronic and hard to heal wounds. EscharEx is well-tolerated and has demonstrated safety and efficacy in the debridement of various chronic and other hard-to-heal wounds, within a

few daily applications in several Phase 2 trials. A meeting with the FDA to discuss the pivotal study design is targeted for the second half of 2022.

MW005, our topical biological drug for the treatment of non-melanoma skin cancers, is a clinical-stage product candidate under development. The initial data from a Phase I/II study shows MW005 to be safe and well-tolerated, with a majority of the patients who completed the study with MW005 achieving complete histological clearance of their target lesions. The Company anticipates announcing the final data in the second half of 2022.

Committed to innovation, we are dedicated to improving quality of care and patient lives. For more information, please visit www.mediwound.com.

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. 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 European Medicines Agency, FDA 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. For Example, we cannot predict whether current geopolitical tensions between the U.S. and China will affect or delay the FDA’s ability to conduct inspection of the NexoBrid manufacturing facility located in Taiwan; 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 COVID-19 pandemic. For example, we are unable to predict how the pandemic will affect the overall healthcare infrastructure, including the ability to recruit patients, the ability to conduct the studies in medical sites and the pace with which governmental agencies, such as the FDA, will review and approve regulatory submissions. Additional government-imposed quarantines and requirements to “shelter at home” or other incremental mitigation efforts also may impact 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, 2021, filed with the Securities and Exchange Commission (“SEC”) on March 17, 2022, 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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CONDENSED CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands

	June 30,		December 31,
	2022	2021	2021
	Unaudited		Audited
Cash, cash equivalents and short-term deposits	10,406	17,175	11,046
Accounts and other receivables	4,412	2,948	2,706
Inventories	1,991	1,397	1,200

Total current assets	16,809	21,520	14,952
Other receivables	230	-	469
Property, plant and equipment, net	2,439	2,565	2,478
Right of use assets, net	1,364	1,789	1,548
Intangible assets, net	264	330	297
Total long-term assets	4,297	4,684	4,792
Total assets	21,106	26,204	19,744
Current maturities of non-current liabilities	2,479	1,681	2,408
Trade payables and accrued expenses	4,877	4,060	4,693
Other payables	3,060	3,920	3,620
Total current liabilities	10,416	9,661	10,721
Deferred revenues	61	405	119
Liabilities in respect of IIA grants	8,131	7,671	7,885
Liabilities in respect of purchase of shares	3,361	4,465	3,922
Lease liabilities	1,053	1,604	1,391
Severance pay liability, net	319	280	288
Total non-current liabilities	12,925	14,425	13,605
Shareholders' equity (deficit)	(2,235)	2,118	(4,582)
Total liabilities & shareholder equity	21,106	26,204	19,744

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CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE PROFIT (LOSS) (UNAUDITED)
U.S. dollars in thousands

Six months ended

Three months ended

	June 30,		June 30,	
	2022	2021	2022	2021
Revenues	9,075	11,904	4,668	6,057
Cost of revenues	6,502	7,127	3,555	3,696
Gross profit	2,573	4,777	1,113	2,361
Operating expenses:				
Research and development	4,599	4,898	2,191	2,656
Selling, general & administrative	4,623	4,695	2,287	2,600
Other expenses	309	-	309	-
Operating loss	(6,958)	(4,816)	(3,674)	(2,895)
Financial expenses, net	(977)	(1,211)	(676)	(281)
Loss before tax on income	(7,935)	(6,027)	(4,350)	(3,176)
Tax on income	(8)	(19)	(4)	(19)
Net Loss	(7,943)	(6,046)	(4,354)	(3,195)
Foreign currency translation adjustments	22	8	17	(3)
Total comprehensive loss	(7,921)	(6,038)	(4,337)	(3,198)
Net loss per share	(0.26)	(0.22)	(0.13)	(0.12)
Weighted average number of ordinary shares used in the computation of basic and diluted loss per share:	31,079	27,241	33,140	27,241

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ADJUSTED EBITDA
U.S. dollars in thousands

Six months ended	Three months ended
June 30,	June 30,

	2022	2021	2022	2021
	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Loss for the period	(7,943)	(6,046)	(4,354)	(3,195)
Adjustments:				
Financial expenses, net	(977)	(1,211)	(676)	(281)
Other expenses	(309)	-	(309)	-
Tax on income	(8)	(19)	(4)	(19)
Depreciation and amortization	(650)	(627)	(329)	(319)
Share-based compensation expenses	(597)	(884)	(252)	(500)
	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Total adjustments	(2,541)	(2,741)	(1,570)	(1,119)
	<u> </u>	<u> </u>	<u> </u>	<u> </u>
Adjusted EBITDA	(5,402)	(3,305)	(2,784)	(2,076)

MediWound, Ltd.

**CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS
(UNAUDITED)**

U.S. dollars in thousands

	Six months ended		Three months ended	
	June 30,		June 30,	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Cash Flows from Operating Activities:				
Net loss	(7,943)	(6,046)	(4,354)	(3,195)
Adjustments to reconcile net loss to net cash used in operating activities:				
Adjustments to profit and loss items:				
Depreciation and amortization	650	627	329	319
Share-based compensation	597	884	252	500
Revaluation of liabilities in respect of IIA grants	482	497	248	222
Revaluation of liabilities in respect of purchase of shares	272	299	135	147

Revaluation of lease liabilities	(152)	35	(138)	79
Increase (decrease) in severance pay liability, net	55	(5)	35	5
Net financing income	(11)	(11)	(11)	-
Un-realized foreign currency (gain) loss	528	(226)	283	(482)
	<u>2,421</u>	<u>2,100</u>	<u>1,133</u>	<u>790</u>
Changes in asset and liability items:				
(Increase) decrease in trade receivables	(2,024)	680	(1,445)	3,087
(Increase) decrease in inventories	(747)	17	(37)	62
Decrease (increase) in other receivables	330	(432)	205	(469)
Increase (decrease) in trade payables and accrued expenses	11	1,075	(272)	803
Decrease in other payables and deferred revenues	(1,367)	(1,257)	(484)	(2,063)
	<u>(3,797)</u>	<u>83</u>	<u>(2,033)</u>	<u>1,420</u>
Net cash used in operating activities	(9,319)	(3,863)	(5,254)	(985)

Cash Flows from Investment Activities:

Purchase of property and equipment	(298)	(244)	(138)	(26)
Interest received	-	35	-	-
(Increase) decrease in short term bank deposits, net	(2,499)	4,002	(2,499)	(4)
	<u>(2,797)</u>	<u>3,793</u>	<u>(2,637)</u>	<u>(30)</u>
Net cash provided by (used in) investing activities	(2,797)	3,793	(2,637)	(30)

Cash Flows from Financing Activities:

Repayment of leases liabilities	(350)	(337)	(172)	(171)
Proceeds from issuance of shares, net	9,861	-	(556)	-
Proceeds from IIA grants, net	(162)	(180)	-	-

Net cash provided by (used in) financing activities	9,349	(517)	(728)	(171)
Exchange rate differences on cash and cash equivalent balances	(550)	204	(303)	495
Decrease in cash and cash equivalents	(3,317)	(383)	(8,922)	(691)
Balance of cash and cash equivalents at the beginning of the period	11,046	17,376	16,651	17,684
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Balance of cash and cash equivalents at the end of the period	7,729	16,993	7,729	16,993



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