



MediWound Reports Second Quarter Financial Results

August 10, 2021

Second Quarter Revenues of \$6.1 Million - Increase of 50% Year-over-Year

*Positive Interim Assessment Outcome for EscharEx U.S. Phase II Clinical Study
No Changes to Study Sample Size – No Safety Concerns Identified*

Conference call begins today at 8:30 am ET

YAVNE, Israel, Aug. 10, 2021 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq: MDWD) (the "Company"), a fully-integrated biopharmaceutical company focused on next-generation biotherapeutic solutions for tissue repair and regeneration, today announced financial results for the second quarter ended June 30, 2021.

Second Quarter and Recent Weeks Corporate and Financial Highlights:

- Total revenues for the second quarter of 2021 were \$6.1 million, an increase of 50% compared with the second quarter of 2020
- The Company had \$17.2 million in cash and short-term investments as of June 30, 2021
- Positive outcome of interim assessment for EscharEx U.S. phase II adaptive design study with no changes to study sample size of 120 patients and no safety concerns identified; full study enrollment expected by year-end 2021 and data readout expected in the first half of 2022
- Received a Complete Response Letter (CRL) from U.S. FDA for NexoBrid biologics license application (BLA); working together with our partners, Vericel and BARDA, towards BLA resubmission
- Positive top line results from phase III pediatric study (CIDS) for eschar removal of severe thermal burns; met all primary endpoints with a high degree of statistical significance, as well as certain secondary endpoints; the study showed NexoBrid to be safe and well tolerated
- Initiated a U.S. phase I/II study of MW005 for the treatment of low-risk basal cell carcinoma (BCC); phase II investigator-initiated trial in non-melanoma skin cancers running in parallel with data from both expected by year-end of 2021

"The second quarter of 2021 and the subsequent weeks, have been eventful with positive interim assessment for EscharEx phase II clinical study, FDA feedback on our NexoBrid BLA and positive top line results from NexoBrid phase III pediatric study," said Sharon Malka, Chief Executive Officer of MediWound. "Moving forward with the best possible outcome of the interim assessment for our U.S. phase II adaptive design study of EscharEx, we have made significant progress in advancing our EscharEx development program, and we look forward to additional significant clinical milestones in the months ahead as we complete enrollment in our phase II study and generate data from our phase II pharmacology study later this year. Chronic wounds impact millions of people worldwide and these important catalysts could advance us one step closer to bringing EscharEx to market as an improvement upon the current standard of care in chronic wound management. We are also excited to commence the clinical development program for MW005 in basal cell carcinoma with two phase II trials underway and look forward to providing further updates on their progress later this year."

Mr. Malka commented further "Though we were disappointed with the receipt of the NexoBrid CRL, we believe the FDA's comments can be addressed, and remain optimistic about the prospects of NexoBrid in the U.S. We are working closely with our partners Vericel and BARDA, to meet with the FDA as soon as possible and provide the FDA with a detailed response to the CRL. Regarding our CIDS pediatric phase III study, we were pleased with the robust clinical data generated, which met all of its primary endpoints with highly statistically significant results, reinforcing the strong clinical safety and efficacy profile of NexoBrid. We believe that this data will further support our global expansion of NexoBrid as we continue to gain commercial traction in multiple geographies around the world."

Second Quarter Financial Results

Revenues for the second quarter of 2021 were \$6.1 million, compared with \$4.0 million for the second quarter of 2020, an increase of 50%. Product revenues in the second quarter of 2021 were \$3.0 million, an increase of 175% compared to \$1.1 million for the second quarter of 2020, primarily driven by the procurement of NexoBrid by BARDA for emergency response preparedness and sales increase outside the U.S.

Gross profit for the second quarter of 2021 was \$2.4 million or 39% of net revenues compared to a gross profit of \$1.2 million or 30% of net revenues for the second quarter of 2020.

Research and development expenses for the second quarter of 2021 were \$2.7 million, compared with \$1.6 million for the second quarter of 2020. The increase was primarily due to EscharEx clinical development program.

Selling, general and administrative expenses for the second quarter of 2021 were \$2.6 million, compared with \$2.3 million in the second quarter of 2020. As a percentage of revenues, selling, general and administrative expenses for the second quarter decreased from 57% in the second quarter of 2020 to 43% in the second quarter of 2021

Operating loss for the second quarter of 2021 was \$2.9 million, compared with an operating loss of \$2.7 million in the second quarter of 2020.

The Company posted a net loss of \$3.2 million, or \$0.12 per share, for the second quarter of 2021 compared with a net loss of \$3.1 million, or \$0.11 per share, for the second quarter of 2020.

Adjusted EBITDA, as defined below, for the second quarter of 2021 was a loss of \$2.0 million, compared with a loss of \$2.1 million for the second quarter of 2020.

Year-to-Date 2021 Financial Results

Revenues for the first half of 2021 were \$11.9 million compared with \$8.5 million in the first half of 2020, an increase of 41%. Product revenues in the first half of 2021 were \$5.9 million, an increase of 224% compared to \$1.8 million for the first half 2020. .

Operating loss for the first half of 2021 was \$4.8 million, compared with an operating loss of \$4.9 million in the first half of 2020.

The Company's net loss for the first half of 2021 was \$6.0 million or \$0.22 per share compared with net loss of \$5.6 million or \$0.20 per share for the first half of 2020.

Adjusted EBITDA, for the first half of 2021, was a loss of \$3.3 million, compared with a loss of \$3.9 million for the first half of 2020.

Balance Sheet Highlights

As of June 30, 2021, MediWound had \$17.2 million in cash and short-term investments, compared with \$21.6 million as of December 31, 2020, and no debt. MediWound remained on budget, utilizing \$4.4 million in the first half of 2021 for its operational activities. Throughout the remainder of 2021, the company will continue to invest primarily in research and development efforts for EscharEx, while the planned NexoBrid BLA resubmission and its related ongoing development programs will be funded by BARDA. We now expect cash use for 2021 to be in the range of \$9.0 to \$11.0 million.

Conference Call

MediWound management will host a conference call for investors today, Thursday, August 10, 2021, 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 877-602-7189 (in the U.S.) 1 809 315 362 (Israel), or 678-894-3057 (outside the U.S. & Israel) and entering passcode 3782335. The call also will be webcast live on the Company's website at <http://ir.mediwound.com/events-and-presentations>.

A replay of the call will be available on the Company 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 Ltd.

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 in the U.S. NexoBrid is supported by the U.S. Biomedical Advanced Research and Development Authority (BARDA).

EscharEx, our next-generation bioactive topical therapeutic under development in the U.S. for debridement of chronic and hard to heal wounds. In two Phase 2 studies, EscharEx was 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.

MW005, our topical biological drug for the treatment of non-melanoma skin cancers, is a clinical-stage product candidate under development.

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, 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; our ability to obtain marketing approval of our products and product candidates in the U.S. or other markets; timing or likelihood of approval by the U.S. Food & Drug Administration (FDA) of a Biologics License Application (BLA) for NexoBrid for treatment of severe burns in the United States following the receipt of a complete response for NexoBrid on June 28, 2021, 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, including availability of funding from 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 on our business or the economy generally.

For example, we are unable to predict how the COVID-19 pandemic will affect the overall healthcare infrastructure, including the ability to recruit patients, the ability to conduct the studies in medical sites and may impact the response times of governmental agencies, including the FDA, to future regulatory submissions and/or conduct necessary reviews or inspections of our manufacturing facilities, any or all of which may result in timelines being materially delayed, which could affect the development and ultimate commercialization of our products, including NexoBrid. Other disruptions or potential disruptions of the COVID-19 pandemic include restrictions on the ability of Company personnel to travel and access customers for training, promotion and case support, delays in product development efforts, and additional government-imposed quarantines and requirements to “shelter at home” or other incremental mitigation efforts or initiatives that 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.

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, 2020, filed with the Securities and Exchange Commission (“SEC”) on February 25, 2021, 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 BALANCE SHEETS

U.S. dollars in thousands

	June 30,		December 31,
	2021	2020	2020
	Un-audited		Audited
Cash, cash equivalents and short term deposits	17,175	24,382	21,584
Accounts and other receivable	2,948	3,492	3,229
Inventories	1,397	1,934	1,380
Total current assets	21,520	29,808	26,193
Property, plant and equipment, net	2,565	2,326	2,630
Right of use assets, net	1,789	2,086	1,884
Intangible assets, net	330	396	363
Total long-term assets	4,684	4,808	4,877
Total assets	26,204	34,616	31,070
Current maturities of long-term liabilities	1,681	1,321	1,750
Trade payables and accrued expenses	4,060	2,423	2,992
Other payables	3,920	6,040	3,524
Total current liabilities	9,661	9,784	8,266
Deferred revenues	405	1,174	1,234
Liability in respect of Israeli Innovation Authority grants net of current maturity	7,671	7,130	7,267
Liabilities in respect of purchase of shares net of current maturity	4,465	4,249	4,998
Lease liability, net of current maturity	1,604	1,866	1,741
Severance pay liability, net	280	281	292
Total long-term liabilities	14,425	14,700	15,532
Shareholders' equity	2,118	10,132	7,272
Total liabilities & shareholder equity	26,204	34,616	31,070

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CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE PROFIT (LOSS) (ANAUDITED)

U.S. dollars in thousands

	Six months ended		Three months ended	
	June 30,		June 30,	
	2021	2020	2021	2020
Revenues	11,904	8,465	6,057	4,027
Cost of revenues	7,127	6,018	3,696	2,810
Gross profit	4,777	2,447	2,361	1,217
Operating expenses:				
Research and development	4,898	3,331	2,656	1,612
Selling, general & administrative	4,695	4,028	2,600	2,311
Operating loss	(4,816)	(4,912)	(2,895)	(2,706)
Financial expenses, net	(1,211)	(645)	(281)	(390)
Loss before tax on income	(6,027)	(5,557)	(3,176)	(3,096)
Tax on income	(19)	-	(19)	-
Loss for the period	(6,046)	(5,557)	(3,195)	(3,096)
Foreign currency translation adjustments	8	1	(3)	(7)
Total comprehensive loss	(6,038)	(5,556)	(3,198)	(3,103)

Net loss per share	(0.22)	(0.20)	(0.12)	(0.11)
Weighted average number of ordinary shares used in the computation of basic and diluted loss per share:	27,241	27,207	27,211	27,052

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ADJUSTED EBITDA

U.S. dollars in thousands

	Six months ended June 30,		Three months ended June 30,	
	2021	2020	2021	2020
Loss for the period	(6,046)	(5,557)	(3,195)	(3,096)
Adjustments:				
Financial expenses, net	(1,211)	(645)	(281)	(390)
Tax on income	(19)	-	(19)	-
Depreciation and amortization	(627)	(539)	(354)	(271)
Share-based compensation expenses	(884)	(519)	(500)	(346)
Total adjustments	(2,741)	(1,703)	(1,154)	(1,007)
Adjusted EBITDA	(3,305)	(3,854)	(2,041)	(2,089)

MediWound, Ltd.

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

U.S. dollars in thousands

	Six months ended June 30,		Three months ended June 30,	
	2021	2020	2021	2020
Cash Flows from Operating Activities:				
Net loss	(6,046)	(5,557)	(3,195)	(3,096)
Adjustments to reconcile net loss to net cash used in operating activities:				
Adjustments to profit and loss items:				
Depreciation and amortization	627	539	319	271
Share-based compensation	884	519	500	346
Revaluation of liabilities in respect of IIA grants	497	424	222	226
Revaluation of liabilities in respect of purchase of shares	299	348	147	196
Revaluation of lease liabilities	35	64	79	100
Increase (decrease) in severance liability, net	(5)	40	5	19
Financing income, net	(11)	(191)	-	(81)
Unrealized foreign currency (gain) loss	(226)	28	(482)	(51)
	2,100	1,771	790	1,026
Changes in asset and liability items:				
Increase in trade receivables	680	1,341	3,087	444
Decrease (increase) in inventories	17	(326)	62	65
Increase in other receivables	(432)	(284)	(469)	(383)
Increase (decrease) in trade payables and prepaid expenses	1,075	(1,649)	803	(1,004)
Increase in other payables & deferred revenues	(1,257)	86	(2,063)	133
	83	(832)	1,420	(745)
Net cash used in operating activities	(3,863)	(4,618)	(985)	(2,815)
Cash Flows from Investment Activities:				
Purchase of property and equipment	(244)	(244)	(26)	(100)

Interest received	35	42	-	39
Proceeds from short term bank deposits, net of investments	4,002	10,595	(4)	7,603
Net cash provided by (used in) investing activities	3,793	10,393	(30)	7,542
Cash Flows from Financing Activities:				
Repayment of lease liabilities	(337)	(313)	(171)	(153)
Proceeds from IIA grants, net of repayments	(180)	(66)	-	-
Net cash used in financing activities	(517)	(379)	(171)	(153)
Exchange rate differences on cash and cash equivalent balances	204	(26)	495	57
Increase (decrease) in cash and cash equivalents from activities	(383)	5,370	(691)	4,631
Balance of cash and cash equivalents at the beginning of the period	17,376	7,242	17,684	7,981
Balance of cash and cash equivalents at the end of the period	16,993	12,612	16,993	12,612



Source: MediWound Ltd.