MediWound Reports Third Quarter 2021 Financial Results

November 16, 2021

Third Quarter Revenues of $6.4 Million; Year-to-Date 2021 Revenues Increased 21%

Clarity on Regulatory Pathway for Resubmission of NexoBrid BLA, Anticipated in Mid- 2022

EscharEx Phase 2 Program Top-Line Results Accelerated, Currently Expected in the First Quarter of 2022

Conference call begins today at 8:30 am ET

YAVNE, Israel, Nov. 16, 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 third quarter ended September 30, 2021.

Third Quarter and Recent Corporate and Financial Highlights:

- Total revenues for the third quarter of 2021 were $6.4 million, compared to $6.6 million in the third quarter of 2020
- Total revenues for the first nine months of 2021 were $18.3 million, an increase of 21% compared to $15.1 million in the same period 2020
- The Company had $13.9 million in cash and short-term investments as of September 30, 2021
- Following a productive Type A meeting with the U.S. Food and Drug Administration (FDA), the Company gained clarity on a path forward for resubmission of its NexoBrid® Biologics License Application (BLA), which is now anticipated in mid-2022
- Positive top line results from phase III pediatric study (CIDS) for eschar removal of severe thermal burns
- Completion of study enrollment in the EscharEx® U.S. phase II study for the treatment of venous leg ulcers (VLUs) expected by year-end with top-line data now expected in the first quarter of 2022
- 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
- Announced peer-reviewed publication of EscharEx in-vivo head-to-head comparator study in the Journal of Wound Care, which showed EscharEx to be more effective than the commercially available collagenase product
- 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 in the first half of 2022.

"We are pleased with the progress we have made this quarter across our portfolio. We gained regulatory clarity on the pathway for resubmission of NexoBrid BLA, and we continue to advance significantly the clinical development programs of EscharEx, where we remain on track to complete patient enrollment of the U.S. phase 2 study for the treatment of VLUs and generate data from the phase 2 pharmacology study by year-end," said Sharon Malka, Chief Executive Officer of MediWound. "As we approach the end of the year and look into 2022, we remain optimistic about our programs and believe 2022 will be a very meaningful year, as we are moving towards important milestones in the coming quarters. We look forward to continuing to build on the momentum as we execute on our strategic goals."

Third Quarter Financial Results

Revenues for the third quarter of 2021 were $6.4 million, a decrease of 4% compared to $6.6 million for the third quarter of 2020 primarily due to decrease in revenues from development services provided to BARDA, and up 5% sequentially.

Gross profit for the third quarter of 2021was $2.5 million with gross margins of 39%, compared to gross profit of $2.8 million and gross margins of 42% for the third quarter of 2020.

Research and development expenses for the third quarter of 2021 were $2.9 million, compared to $2.1 million for the third quarter of 2020. The increase in expenses was primarily due to clinical development for EscharEx.

Selling, general and administrative expenses for the third quarter of 2021 were $2.4 million, compared to $2.2 million in the third quarter of 2020.

Operating loss for the third quarter of 2021 was $2.9 million, compared to an operating loss of $1.5 million in the third quarter of 2020.

The Company posted a net loss of $3.3 million, or $0.12 per share, for the third quarter of 2021 compared to a net loss of $1.9 million, or $0.07 per share, for the third quarter of 2020.

Adjusted EBITDA, as defined below, for the third quarter of 2021 was a loss of $2.2 million, compared to a loss of $0.8 million for the third quarter of 2020.

Year-to-Date 2021 Financial Results

Revenues for the first nine months of 2021 were $18.3 million compared to $15.1 million in the first nine months of 2020, an increase of 21%. Product revenues in the first nine months of 2021 were $9.0 million, an increase of 81% compared to product revenues of $5.0 million for first nine months of 2020.

Operating loss for the first nine months of 2021 was $7.7 million, compared to an operating loss of $6.5 million in the first nine months of 2020, primarily due to increase in research and development expenses.

The Company's net loss for the first nine months of 2021 was $9.4 million or $0.34 per share compared to a net loss of $7.5 million or $0.27 per share for the first nine months of 2020.

Adjusted EBITDA, for the first nine months of 2021, was a loss of $5.5 million, compared to a loss of $4.7 million for the first nine months of 2020.

Balance Sheet Highlights

As of September 30, 2021, MediWound had $13.9 million in cash and short-term investments, compared to $21.6 million as of December 31, 2020. MediWound remained on budget, utilizing $7.7 million in the first nine months of 2021 for its operational activities. The Company reiterates its 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, Tuesday, November 16, 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.) or 678-894-3057 (outside the U.S. & Israel) and entering passcode 7771457. 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.

About MediWound Ltd.

MediWound is a biopharmaceutical company that develops, manufactures, and commercializes novel, cost effective, biotherapeutic 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 is 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; 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, 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.

Contacts:
Boaz Gur-Lavie
Chief Financial Officer
MediWound Ltd.
ir@mediwound.com

Monique Kosse
Managing Director
LifeSci Advisors
212-915-3820
monique@lifesciadvisors.com

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CONDENSED CONSOLIDATED BALANCE SHEETS
U.S. dollars in thousands

	September 30,		December 31,
	2021	**2020**	**2020**
	Unaudited		**Audited**
Cash, cash equivalents and short term deposits	13,866	25,023	21,584
Accounts and other receivable	3,553	3,495	3,229
Inventories	1,252	1,805	1,380
Total current assets	**18,671**	**323,30**	**26,193**
Property, plant and equipment, net	2,531	2,448	2,630
Right of use assets, net	1,650	2,170	1,884
Intangible assets, net	314	380	363
Total long-term assets	**4,495**	**4,998**	**4,877**
Total assets	**23,166**	**35,321**	**31,070**
Current maturities of long-term liabilities	1,867	1,081	1,750
Trade payables and accrued expenses	3,710	3,155	2,992
Other payables	4,384	7,394	3,524
Total current liabilities	**9,961**	**11,630**	**8,266**

Deferred revenues	352	1,283	1,234
Liability in respect of Israeli Innovation Authority grants net of current maturity	7,715	7,157	7,267
Contingent consideration for the purchase of shares net of current maturity	4,195	4,408	4,998
Lease liability, net of current maturity	1,483	1,942	1,741
Severance pay liability, net	281	284	292
Total long-term liabilities	**14,026**	**15,074**	**15,532**
Shareholders' equity (deficit)	(821)	8,617	7,272
Total liabilities & shareholder equity	**23,166**	**35,321**	**31,070**

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

U.S. dollars in thousands

	Nine months ended September 30,		**Three months ended September 30,**	
	2021	**2020**	**2021**	**2020**
Revenues	18,276	15,090	6,372	6,625
Cost of revenues	11,044	9,873	3,917	3,855
Gross profit	**7,232**	**5,217**	**2,455**	**2,770**
Operating expenses:				
Research and development, net	7,795	5,473	2,897	2,142
Selling, general & administrative	7,137	6,198	2,442	2,170
Operating loss	**(7,700)**	**(6,454)**	**(2,884)**	**(1,542)**
Financial expenses, net	(1,668)	(1,093)	(457)	(448)
Loss from continuing operations	**(9,368)**	**(7,547)**	**(3,341)**	**(1,990)**
Profit from discontinued operation	-	83	-	83
Loss before Taxes on Income	**(9,368)**	**(7,464)**	**(3,341)**	**(1,907)**

Taxes on Income	(23)	-	(4)	-
Net Loss	**(9,391)**	**(7,464)**	**(3,345)**	**(1,907)**
Foreign currency translation adjustments	15	(11)	7	(12)
Total comprehensive loss	**(9,376)**	**(7,475)**	**(3,338)**	**(1,919)**
Net loss per share	(0.34)	(0.27)	(0.12)	(0.07)
Weighted average number of ordinary shares used in the computation of basic and diluted loss per share:	27,243	27,206	27,179	27,179

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ADJUSTED EBITDA
U.S. dollars in thousands

	Nine months ended September 30,		**Three months ended September 30,**	
	2021	**2020**	**2021**	**2020**
Loss for the period	(9,391)	(7,464)	(3,345)	(1,907)
Adjustments:				
Financial expenses, net	(1,668)	(1,093)	(457)	(448)
Profit from discontinued operation	-	83	-	83
Tax Expenses	(23)	-	(4)	-
Depreciation and amortization	(962)	(866)	(335)	(327)
Share-based compensation expenses	(1,283)	(923)	(399)	(404)
Total adjustments	(3,936)	(2,799)	(1,195)	(1,096)
Adjusted EBITDA	**(5,455)**	**(4,665)**	**(2,150)**	**(811)**

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CONDENSED CONSOLIDATED STATEMENT OF CASH FLOW
(UNAUDITED)
U.S. dollars in thousands

	Nine months ended September 30,		**Three months ended September 30,**	
	2021	**2020**	**2021**	**2020**
Cash Flows from Operating Activities:				

Net loss	(9,391)	(7,464)	(3,345)	(1,907)
Adjustments to reconcile net loss to net cash used in operating activities:				
Adjustments to profit and loss items: Profit from discontinued operations	-	(83)	-	(83)
Depreciation and amortization	962	866	335	327
Share-based compensation	1,283	923	399	404
Revaluation of liabilities in respect of IIA grants	808	692	311	268
Revaluation of liabilities in respect of purchase of shares	446	558	147	210
Revaluation of lease liabilities	84	127	49	63
Increase (decrease) in severance liability, net	3	35	8	(5)
Financing income, net	(11)	(244)	-	(53)
Unrealized foreign currency (gain) loss	(238)	(8)	(12)	(36)
	3,337	**2,866**	**1,237**	**1,095**
Changes in asset and liability items:				
Decrease in trade receivables	697	1,477	17	136
Decrease (increase) in inventories	188	(231)	171	95
Increase in other receivables	(1,078)	(397)	(646)	(113)
Increase (decrease) in trade payables and prepaid expenses	733	(925)	(342)	724
Increase (decrease) in other payables & deferred revenues	(1,167)	1,288	90	1,202
	(627)	**1,212**	**(710)**	**2,044**
Net cash used in continuing operating activities	**(6,681)**	**(3,386)**	**(2,818)**	**1,232**
Net cash used in discontinued operating activities	-	(192)	-	(192)
Net cash used in operating activities	**(6,681)**	**(3,578)**	**(2,818)**	**1,040**

	Nine months ended September 30,		**Three months ended September 30,**	
	2021	**2020**	**2021**	**2020**
Cash Flows from Investment Activities:				
Purchase of property and equipment	(373)	(480)	(129)	(236)
Interest received	35	43	-	1
Proceeds from short term bank deposits, net of investments	4,002	8,136	-	(2,459)
Net cash provided by (used in) investing activities	**3,664**	**7,699**	**(129)**	**(2,694)**
Cash Flows from Financing Activities:				
Repayment of lease liabilities	(513)	(533)	(176)	(220)
Proceeds from IIA grants, net of repayments	(360)	(121)	(180)	(55)
Net cash used in financing activities	**(873)**	**(654)**	**(356)**	**(275)**
Exchange rate differences on cash and cash equivalent balances	197	32	(7)	58
Increase (decrease) in cash and cash equivalents from continuing activities	(3,693)	3,691	(3,310)	(1,679)
Decrease in cash and cash equivalents from discontinued activities	-	(192)	-	(192)
Balance of cash and cash equivalents at the beginning of the period	17,376	7,242	16,993	12,612
Balance of cash and cash equivalents at the end of the period	**13,683**	**10,741**	**13,683**	**10,741**

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