MediWound Reports Fourth Quarter and Full-Year 2020 Financial Results

February 25, 2021

Fourth Quarter Revenues of $6.7 Million - Up 23%
and Full-Year 2020 Revenues of $21.8 Million - Product Revenue Up 117%

Conference call begins today at 8:30 am ET

YAVNE, Israel, Feb. 25, 2021 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq: MDWD), a fully integrated biopharmaceutical company focused on next-generation bio-therapeutic solutions for tissue repair and regeneration, today announced financial results for the fourth quarter and full-year ended December 31, 2020.

Fourth Quarter and Full-Year 2020 Financial Highlights:

- Total revenues of $21.8 million for the full year of 2020.
- Total revenues of $6.7 million for the fourth quarter of 2020, an increase of 23% compared with $5.4 million for the fourth quarter of 2019, primarily driven by initiation of the Biomedical Advanced Research and Development Authority (BARDA) emergency stockpile procurement.
- The company had $21.6 million in cash and short-term investments as of December 31, 2020.

Fourth Quarter and Full-Year 2020 Business Highlights:

- U.S. Food and Drug Administration (FDA) accepted for review the Company's Biologics License Application (BLA) for NexoBrid® and assigned a Prescription Drug User Fee Act (PDUFA) target date of June 29, 2021.
- BARDA initiated the procurement of NexoBrid for emergency stockpile, valued at $16.5 million, with first deliveries accepted by BARDA in the third and fourth quarters of 2020, with additional deliveries planned through end of 2021.
- Completed enrollment in the company's NexoBrid pivotal Phase 3 (CIDS) study; top-line data, including twelve-month follow-up safety data, are anticipated in the second half of 2021.
- Completed U.S Phase 3 (DETECT) study, including patient long-term safety follow-up; the twenty-four-month safety data of cosmesis and function was comparable across all study arms with no new safety signals observed.
- Continued NexoBrid global expansion with additional distribution agreements in France, Switzerland and other EU countries; entered the Middle Eastern market with the signing of a distribution agreement in the United Arab Emirates.
- Adjusted the U.S. phase 2 adaptive design study of EscharEx® for the treatment of venous leg ulcers (VLUs) enrollment target to 120 patients down from the 174 originally planned; interim assessment is expected in mid-2021 and completion of enrollment by year-end 2021.
- Launched a new clinical development program to evaluate its product candidate MWPC005 in patients with non-melanoma skin cancers; a U.S. phase I/II clinical study for the treatment of basal cell carcinoma (BCC) is scheduled to begin in the second quarter of 2021.

"I am very proud of our team's perseverance and resilience in delivering positive results in our clinical programs and financial performance despite the enormous COVID-19 challenges that we all face globally. We look forward to 2021 as a pivotal year of important catalysts for MediWound," said Sharon Malka, Chief Executive Officer of MediWound. "We remain focused on our continued growth with the advancement of our EscharEx clinical program with a U.S phase 2 study interim assessment later this year. NexoBrid's global expansion continues as we look forward to NexoBrid's BLA approval in 2021. Finally, we are excited to initiate the clinical development program of MWPC005 as a treatment for BCC, leveraging our platform technology to enhance our diverse and innovative portfolio."

Fourth Quarter Financial Results

Revenues for the fourth quarter of 2020 were $6.7 million, compared with $5.4 million for the fourth quarter of 2019, an increase of 23%. Revenues from sale of product in the fourth quarter of 2020 were $2.8 million, reflecting an increase of 155% in comparison to the fourth quarter of 2019, primarily driven by BARDA emergency stockpile procurement.

Gross profit for the fourth quarter of 2020 was $2.3 million and 35%, compared with a gross profit of $1.1 million and 20% for the fourth quarter of 2019. Gross margin from sale of products in the fourth quarter of 2020 was 56% in comparison to 32% for the fourth quarter of 2019.

Research and development expenses for the fourth quarter of 2020, net of participations, were $2.2 million, compared with $1.7 million for the fourth quarter of 2019. The increase was primarily due to the ongoing EscharEx clinical development program.

Selling, general and administrative expenses for the fourth quarter of 2020 were $2.5 million, stable with the $2.4 million for the fourth quarter of 2019.

Operating loss for the fourth quarter of 2020 was $2.4 million, compared with an operating loss of $3.1 million in the fourth quarter of 2019, primarily as a result of revenue growth.

The Company posted a net loss of $1.7 million, or $0.06 per share, for the fourth quarter of 2020 compared with a net loss of $3.4 million, or $0.13 per share, for the fourth quarter of 2019.

Adjusted EBITDA, as defined below, for the fourth quarter of 2020 was a loss of $1.8 million, compared with a loss of $2.4 million for the fourth quarter of 2019.

Full Year 2020 Financial Results

Revenues for the year ended December 31, 2020 were $21.8 million compared with $31.8 million for the year ended December 31, 2019, which included a $17.5 million upfront payment from the Vericel license agreement for NexoBrid. Revenues from product for the full year of 2020 were $7.8 million, an increase of 117% compared with the full year of 2019, primarily driven by BARDA emergency stockpile procurement.

Gross profit for the year ended December 31, 2020 was $7.5 million, compared with a gross profit of $19.9 million in the prior year period. Excluding the $17.5 million upfront license payment net of $0.7 million of deal related expenses, gross profit for the year ended December 31, 2019, was $3.1 million. Gross margin from sale of products for the full year of 2020 was 60% in comparison to 35% for the full year of 2019.

Research and development expenses for the year ended December 31, 2020, net of participations, were $7.7 million, compared with $5.0 million in the prior year period. The increase was primarily as a result of the U.S. Phase 2 adaptive design study of EscharEx and a non-cash increase in participation from the Israeli innovation authority grant recorded in 2019.

Selling, general and administrative expenses for the year ended December 31, 2020 were $8.7 million compared with $9.3 million in the prior year period. The decrease was primarily due to the Company's headquarters' restructuring in Europe.

Operating loss for the year ended December 31, 2020 was $8.8 million compared to an operating profit of $4.5 million for the year ended December 31,2019, which included $17.5 million upfront license payment and $1.7 million of NexoBrid licensing deal related expenses. Excluding the upfront license payment, net of deal related costs, operating loss for full year of 2019 was $11.3 million.

The Company's net loss in 2020 was $9.2 million, or a loss of $0.34 per share, compared with a net profit of $5.0 million, or a profit of $0.18 per share for the same period in 2019, which included the $17.5 million upfront license payment and $1.7 million of NexoBrid licensing deal related expenses. Excluding the upfront license payment net of deal related costs, net loss for the year ended 2019 was $10.8 million, or $0.40 per share.

Adjusted EBITDA, for the year ended December 31, 2020, was a loss of $6.4 million, compared with a profit of $8.0 million for the year ended December 31, 2019, which included the upfront payment of $17.5 million from the Vericel licensing agreement, net of a royalty payment of $0.7 million.

Balance Sheet Highlights

The Company had $21.6 million in cash and short-term investments as of December 31, 2020, compared with $29.5 million as of December 31, 2019, with no debt. The Company utilized $7.9 million in cash to fund its ongoing operating activities and repayment of contingent liabilities during 2020, below its cash guidance for 2020 of $8.0 to $10.0 million. The Company expects cash use for 2021 to be in the range of $5.0 to $7.0 million.

Conference Call

MediWound management will host a conference call for investors today, Thursday, February 25, 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.) 1809 315 362 (Israel), or 678-894-3057 (outside the U.S. & Israel) and entering passcode 3049108. 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, bio-therapeutic solutions for tissue repair and regeneration. Our strategy is centered around our validated enzymatic platform technology, focused on next-generation bio-active therapies for burn and wound care and biological medicinal products for tissue repair.

NexoBrid, our first commercialized product for non-surgical and rapid eschar removal of deep, partial and full-thickness thermal burns without harming viable tissue, is currently marketed in the European Union and other International markets. On June 29, 2020, a BLA was submitted to the FDA and was assigned a PDUFA target date of June 29, 2021. NexoBrid is supported by 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.

MediWound's third innovative product candidate, MWPC005, is a topical drug under development for the treatment of non-melanoma skin cancer.

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

About BARDA

Funding and technical support for development of NexoBrid including the expanded access treatment protocol (NEXT), the pivotal Phase 3 pediatric clinical study (CIDS) and the marketing approval registration process for NexoBrid in the U.S. is provided by the Biomedical Advanced Research and Development Authority (BARDA), under the Assistant Secretary for Preparedness and Response (ASPR), within the U.S. Department of Health and Human Services (HHS), under ongoing USG Contract No. HHSO100201500035C. Additional projects for evaluation of NexoBrid funded under the BARDA contract include randomized, controlled pivotal clinical trial for use in adults population, establishment of a pre-emergency use data package and development of the health economic model to evaluate the cost savings impact to enable market adoption in the United States and readiness for emergencies. For more information, refer to www.phe.gov/about/BARDA.

Cautionary Note Regarding Forward-Looking Statements

MediWound caution 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, objectives, 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 preclinical studies and 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, 2019, filed with the Securities and Exchange Commission ("SEC") on February 25, 2020, 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
AUDITED
U.S. dollars in thousands

	December 31,	
	2020	**2019**
Cash, cash equivalents and short term deposits	21,584	29,458
Accounts and other receivable	3,229	4,557
Inventories	1,380	1,613
Total current assets	**26,193**	**35,628**
Property, plant and equipment, net	2,630	2,304
Right of-use assets, net	1,884	2,229
Intangible assets, net	363	429
Total long term assets	**4,877**	**4,962**
Total assets	**31,070**	**40,590**
Current maturities of long-term liabilities	1,750	569
Trade payables and accrued expenses	2,992	4,067
Other payables	3,524	5,737
Total current liabilities	**8,266**	**10,373**

Deferred revenues	1,234	1,135
Liabilities in respect of Israeli Innovation Authority grants net of current maturities	7,267	6,811
Liabilities in respect of the purchase of shares	4,998	4,853
Lease liabilities net of current maturities	1,741	2,006
Severance pay liability, net	292	243
Total long term liabilities	**15,532**	**15,048**
Shareholders' equity	7,272	15,169
Total liabilities & shareholder equity	**31,070**	**40,590**

MediWound, Ltd.
CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE PROFIT (LOSS)
U.S. dollars in thousands

	Year ended December 31,		Three months ended December 31,	
	2020	**2019**	**2020**	**2019**
	AUDITED		**UNAUDITED**	
Revenues	21,763	31,789	6,673	5,442
Cost of revenues	14,218	11,849	4,345	4,360
Gross profit	**7,545**	**19,940**	**2,328**	**1,082**
Operating expenses:				
Research and development, net of participations	7,698	4,969	2,225	1,676
Selling, general & administrative	8,687	9,306	2,489	2,419
Other expenses (income), net	-	1,172	-	131
Total operating expenses	**16,385**	**15,447**	**4,714**	**4,226**
Operating profit (loss)	**(8,840)**	**4,493**	**(2,386)**	**(3,144)**
Financial income (expenses), net	(436)	(2,427)	657	(382)
Profit (loss) from discontinued operation	80	2,889	(3)	83
Profit (loss) for the period	**(9,196)**	**4,955**	**(1,732)**	**(3,443)**
Foreign currency translation adjustments	(23)	8	(12)	(9)
Total comprehensive profit (loss)	**(9,219)**	**4,963**	**(1,744)**	**(3,452)**
Profit (loss) per share:				
Profit (loss) from continuing operations	(0.34)	0.08	(0.06)	(0.13)
Profit from discontinued operation	-	0.10	-	-
Net profit (loss) per share	**(0.34)**	**0.18**	**(0.06)**	**(0.13)**
Weighted average number of ordinary shares provided by (used in) the computation of basic and diluted profit (loss) per share (in thousands):	**27,210**	**27,203**	**27,213**	**27,179**

ADJUSTED EBITDA
U.S. dollars in thousand

	Year ended December 31,		Three months ended December 31,	
	2020	**2019**	**2020**	**2019**
Profit (loss) for the period	(9,196)	4,955	(1,732)	(3,443)
Adjustments:				
Financial (expenses) income, net	(436)	(2,427)	657	(382)
Profit (loss) from discontinued operation	80	2,889	(3)	83
Other (expenses) income, net	-	(1,172)	-	(131)
Depreciation and amortization	(1,090)	(1,149)	(224)	(301)
Share-based compensation expenses	(1,322)	(1,234)	(399)	(303)
Total adjustments	(2,768)	(3,093)	31	(1,034)
Adjusted EBITDA	**(6,428)**	**8,048**	**(1,763)**	**(2,409)**

MediWound, Ltd.
CONDENSED CONSOLIDATED STATEMENT OF CASH FLOW

U.S. dollars in thousands

	Year ended December 31,		Three months ended December 31,	
	2020	2019	2020	2019
	AUDITED		UNAUDITED	
Cash Flows from Operating Activities:				
Net profit (loss)	**(9,196)**	**4,955**	**(1,732)**	**(3,443)**
Adjustments to reconcile net profit (loss) to net cash provided by (used in) continuing operating activities:				
Adjustments to profit and loss items:				
Loss (profit)from discontinued operation	(80)	(2,889)	3	(83)
Depreciation and amortization	1,090	1,149	224	301
Share-based compensation	1,322	1,234	399	303
Revaluation of liabilities in respect of IIA grants	828	(392)	136	(293)
Revaluation of liabilities in respect of purchase of shares	(433)	1,690	(991)	171
Revaluation of lease liabilities	305	340	178	631
Increase (decrease) in severance liability, net	33	(105)	(2)	(73)
Financing income	(297)	(434)	(53)	(139)
Unrealized foreign currency gain	(211)	(152)	(203)	(100)
	2,557	**441**	**(309)**	**718**
Changes in asset and liability items:				
Decrease (increase) in trade receivables	1,386	(3,553)	(91)	402
Decrease (increase) in inventories	141	67	372	(193)
Decrease (increase) in other receivables	(13)	6,376	384	1,178
Increase (decrease) in trade payables & accrued expenses	(1,096)	1,355	(171)	1,205
Increase (decrease) in other payables & deferred revenues	(479)	247	(1,767)	(563)
	(61)	**4,492**	**(1,273)**	**2,029**
Net cash provided by (used in) continuing operating activities	**(6,700)**	**9,888**	**(3,314)**	**(696)**
Net cash used in discontinued operating activities	**(195)**	**(1,599)**	**(3)**	**(1,599)**
Net cash provided by (used in) operating activities	**(6,895)**	**8,289**	**(3,317)**	**(2,295)**
Cash Flows from Investment Activities:				
Purchase of property and equipment	(923)	(792)	(443)	(329)
Interest received	274	184	231	80
Proceeds from (investment in) short term bank deposits, net of investments	18,034	(5,050)	9,898	2,955
Net cash provided by (used in) continuing investing activities	**17,385**	**(5,658)**	**9,686**	**2,706**
Net cash used in discontinued investing activities	**-**	**(1,239)**	**-**	**(282)**
Net cash provided by (used in) investing activities	**17,385**	**(6,897)**	**9,686**	**2,424**
Cash Flows from Financing Activities:				
Repayment of lease liabilities	(508)	(630)	25	(729)
Repayment of IIA grants, net	(121)	(376)	-	-
Net cash provided by (used in) financing activities	**(629)**	**(1,006)**	**25**	**(729)**
Exchange rate differences on cash and cash equivalent balances	**273**	**140**	**241**	**99**
Increase (decrease) in cash and cash equivalents from continuing activities	**10,329**	**3,364**	**6,638**	**1,380**
Decrease in cash and cash equivalents from discontinued activities	(195)	(2,838)	(3)	(1,881)
Balance of cash and cash equivalents at the beginning of the period	7,242	6,716	10,741	7,743
Balance of cash and cash equivalents at the end of the period	**17,376**	**7,242**	**17,376**	**7,242**

Source: MediWound Ltd.