MediWound Reports Fourth Quarter and Full-Year 2019 Financial Results

February 25, 2020

Generated total full-year 2019 revenues of $31.8 million, driven primarily by Vericel license payment and development services to BARDA

Initiated U.S. Phase 2 adaptive design study of EscharEx for the treatment of venous leg ulcers

BARDA initiated the procurement of NexoBrid valued at $16.5 million for emergency response

Conference call begins today at 8:30 a.m. Eastern Time

YAVNE, Israel, Feb. 25, 2020 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq: MDWD), a fully-integrated biopharmaceutical company bringing innovative therapies to address unmet medical needs in severe burn and wound management, today announced financial results for the fourth quarter and full-year ended December 31, 2019.

Fourth Quarter and Full-Year 2019 Financial Highlights:

- Total revenues of $31.8 million for the full-year 2019.
- Total revenues of $5.4 million for the fourth quarter of 2019, an increase of $4.4 million from the $1.0 million of fourth quarter of 2018, driven primarily by revenues from development services.
- The Company had $29.5 million in cash and short-term investments as of December 31, 2019.

Fourth Quarter and Full-Year 2019 Business Highlights:

- Announced positive top-line results from the pivotal U.S. Phase 3 DETECT study in NexoBrid for eschar removal of severe thermal burns. The safety data of cosmesis and function collected in the twelve-month patient follow-up period, was comparable across all study arms, and no new safety signals were observed.
- Entered into exclusive license and supply agreements with Vericel Corporation in May to commercialize NexoBrid in North America for an upfront payment of $17.5 million, sales royalties, and up to $132.5 million in potential milestones.
- Initiated the NexoBrid Expanded Access Treatment protocol (NEXT) to treat burn patients with deep partial and full-thickness burns in the U.S. during the ongoing preparation and review of the NexoBrid Biologics License Application (BLA).
- Initiated a U.S. Phase 2 adaptive design clinical study of EscharEx, the Company's topical biologic drug candidate designed to enzymatically debride chronic wounds, for the treatment of venous leg ulcers (VLUs).
- The U.S. Biomedical Advanced Research and Development Authority (BARDA) initiated the procurement of NexoBrid for emergency response, valued at $16.5 million.
- Continued global expansion of NexoBrid through new distribution agreement in Australia, Ukraine and additional EU countries.

"2019 was a transformational year for MediWound, and we have continued building on this momentum in what we believe will be a meaningful 2020," said Sharon Malka, Chief Executive Officer of MediWound. "We are very pleased to have our U.S. Phase 2 adaptive design study for EscharEx up and running. This study is designed to assess the efficacy and safety of our advanced once-a-day topical treatment in the debridement of venous leg ulcers. The study enables the comparison of EscharEx to placebo control, as well as a head-to-head comparison with the current non-surgical standard of care in the U.S. We believe EscharEx can be a game-changer, addressing a significant unmet medical need, and we anticipate having an interim assessment for this study by the end of the year."

Mr. Malka continued, "With regard to NexoBrid, we announced in early 2019 the results of the U.S. phase 3 DETECT study, which were robust across all endpoints, and subsequently reported the long-term follow-up safety data, which was comparable across all study arms. We are currently targeting the NexoBrid BLA submission for midyear 2020 and are actively preparing for commercial launch in the U.S. with our partner, Vericel. In addition, the NEXT program is up and running, allowing for the continued clinical use of NexoBrid for U.S. patients during the preparation and review of the NexoBrid BLA. Finally, the initiation of the NexoBrid procurement by BARDA prior to BLA submission is a significant milestone in our partnership with BARDA, which we believe will

significantly increase U.S. readiness for burn mass casualty incidents."

"Our solid balance sheet and near-term cash inflows will continue to support our development plans and we look forward to several meaningful upcoming milestones in each of our programs," concluded Mr. Malka.

Fourth Quarter Financial Results

Revenues for the fourth quarter of 2019 were $5.4 million, an increase of $4.4 million versus the $1.0 million in the fourth quarter of 2018, primarily driven by revenues from development services. Starting in May 2019, following entrance into the Vericel license and supply agreements, funding by BARDA was classified as revenues from development services. As a result, we now generate also revenues from development services provided to BARDA.

Gross profit for the fourth quarter of 2019 was $1.1 million, compared to a gross profit of $0.3 million for the fourth quarter of 2018, due to the increase in revenues.

Research and development expenses, net of participations for the fourth quarter of 2019, were $1.7 million, compared with the $0.3 million for the fourth quarter of 2018. The increase is attributed primarily to the initiation of our U.S. Phase 2 adaptive design study of EscharEx for the treatment of venous leg ulcers.

Selling, general and administrative expenses for the fourth quarter of 2019 were $2.4 million, compared with $2.2 million for the fourth quarter of 2018.

Operating loss for the fourth quarter of 2019 was $3.1 million, compared with a loss from ongoing operational activities of $2.2 million in the fourth quarter of 2018. In the fourth quarter of 2018, we recognized one-time other income from settlement with Teva of $7.4, resulting an operating profit of $5.3 million.

The Company posted a net loss of $3.4 million, or loss of ($0.13) per share, for the fourth quarter of 2019 compared with a net profit of $10.6 million, or $0.39 per share, for the fourth quarter of 2018. The Company's net profit in 2018 included one-time other income of $12.1 million as a result of the settlement with Teva, which was partially recorded as discontinued operation.

Adjusted EBITDA, as defined below, for the fourth quarter of 2019 was a loss of $2.4 million, compared with a loss of $1.9 million in the fourth quarter of 2018.

Full-Year 2019 Financial Results

Total revenues for the year ended December 31, 2019 were $31.8 million, compared with $3.4 million for the year ended December 31, 2018. The increase was primarily due to the up-front payment of $17.5 million from Vericel and $10.7 million funding by BARDA which was classified as revenues from development services as a result of the exclusive license and supply agreements with Vericel.

Gross profit for the year ended December 31, 2019 was $19.9 million, compared with a gross profit of $1.3 million in the prior year period.

Research and development expenses for the year ended December 31, 2019, net of participations, were $5.0 million, compared with $4.1 million in the prior year period, primarily as a result of the initiation of the U.S. Phase 2 adaptive design study of EscharEx.

Selling, general and administrative expenses for the year ended December 31, 2019 were $9.3 million compared with $8.0 million in the prior year period. The increase was primarily due to non-recurring costs associated with management changes and increase in professional fees.

Operating profit for the year ended December 31, 2019, which includes a $17.5 million upfront license payment and $1.7 million of deal related expenses, was $4.5. million. Operating loss for the full-year 2018, which included other one-time net income of $6.8 million primarily as a result settlement with Teva was $4.0 million.

The Company's net profit in 2019, which includes the $17.5 million upfront license payment from Vericel net of $1.7 million related one-time expenses and $2.8 million of profit from discontinued operation, was $5.0 million, or a profit of $0.18 per share, compared with a net loss of $1.1 million, or a loss of ($0.04) per share for the same period in 2018.

Adjusted EBITDA, as defined below, for the year ended December 31, 2019 was a profit of $8.0 million, compared with a loss of $9.5 million for the prior year period.

Balance Sheet Highlights

As of December 31, 2019, the Company had cash, cash equivalents and short-term bank deposits of $29.5 million, compared with $23.6 million at December 31, 2018. The Company utilized $11.6 million in cash to fund its ongoing operating activities during 2019, NexoBrid license related payments and repayment of contingent liabilities, in line with the Company's guidance for 2019 of $10.0 million to $12.0 million.

The Company will continue to invest primarily in research and development efforts for EscharEx, while NexoBrid is expected to be

cash flow positive primarily due to anticipated inflows from BARDA and from the Vericel collaboration. As a result, the Company expects cash use for 2020 to be in the range of $11 million to $13 million, including repayment of contingent liabilities.

Conference Call
MediWound management will host a conference call for investors today, Tuesday, February 25, 2020 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 877-602-7940 (in the U.S.) , 1809 457 877 (Israel) or 678-894-3057 (outside the U.S. & Israel) and entering passcode 1809315362. Investors may also access the live call via webcast link at: https://edge.media-server.com/mmc/p/ugn4f67k

An archived version of the webcast 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 fully-integrated biopharmaceutical company focused on developing, manufacturing and commercializing novel therapeutics based on its patented proteolytic enzyme technology to address unmet needs in the fields of severe burns, chronic and other hard-to-heal wounds. MediWound's first innovative biopharmaceutical product, NexoBrid® has demonstrated in clinical trials, with statistical significance the ability to non-surgically and rapidly remove the eschar earlier and without harming viable tissue. The product has received marketing authorization from the European Medicines Agency as well as the Israeli, Argentinian, South Korean, Russian and Peruvian Ministries of Health. MediWound's second innovative product, EscharEx® is a topical biological drug candidate for the debridement of chronic and other hard-to-heal wounds using the same proteolytic enzyme technology as NexoBrid. In two Phase 2 studies, EscharEx has demonstrated safety and efficacy in the debridement of various chronic and other hard-to-heal wounds, within a few daily applications. For more information, please visit www.mediwound.com.

About BARDA
The Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response within the U.S. Department of Health and Human Services, provides an integrated, systematic approach to the development and purchase of the necessary vaccines, drugs, therapies and diagnostic tools for public health medical emergencies. For more information, refer to www.phe.gov/about/BARDA. Funding and technical support for development of NexoBrid including the expanded access treatment protocol (NEXT), the pivotal U.S. Phase 3 clinical study (DETECT) 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 pediatric 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.

Cautionary Note Regarding Forward-Looking Statements
This release includes forward-looking statements within the meaning of Section 27A of the U.S. Securities Act of 1933, as amended, Section 21E of the US Securities Exchange Act of 1934, as amended, and the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements are statements that are not historical facts, such as statements regarding assumptions and results related to the content of the BLA filing package, the timeline for the BLA filing; FDA acceptance of the BLA; the ability to fund the development of NexoBrid until BLA submission; the ability to successfully complete the development and commercialize NexoBrid, expected funding from BARDA; our ability to meet the timeline for the NEXT treatment protocol, results of the NEXT treatment protocol and Vericel's ability to commercialize NexoBrid, the design of the Phase 2 study, the timeline for the Phase 2 study and the interim assessment; the ability of the Phase 2 study to serve as one of the two adequately controlled studied required for BLA submission our development plan for EscharEx; expected revenues from Vericel and the ability to fund the development of EscharEx until BLA submission; the ability to fit EscharEx into treatment workflow and reimbursement programs; our expectations regarding the wound care market; and the ability to successfully develop and commercialize EscharEx. In some cases, you can identify forward-looking statements by terminology such as "believe," "may," "estimate," "continue," "anticipate," "intend," "should," "plan," "expect," "predict," "potential," or the negative of these terms or other

similar expressions. Forward-looking statements are based on MediWound's current knowledge and its present beliefs and expectations regarding possible future events and are subject to risks, uncertainties and assumptions. Actual results and the timing of events could differ materially from those anticipated in these forward-looking statements as a result of several important factors. In particular, you should consider that the FDA may not accept part or all of our BLA; FDA may require additional information, which we may or may not able to provide; FDA may not provide marketing approval for NexoBrid in the United States; we may not submit the BLA to FDA in the timeframe expected; risks related to our collaboration with Vericel; our ability to obtain marketing approval of NexoBrid or EscharEx in the U.S.; the clinical utility, potential advantages and timing or likelihood of regulatory filings and approvals of NexoBrid and EscharEx; our commercialization, marketing and manufacturing capabilities and strategy; risks related to our contract BARDA; the impact of government laws and regulations; and the additional risks discussed under the heading "Risk Factors" in our annual report on Form 20-F for the year ended December 31, 2019 as well as information contained in other documents filed with or furnished to the Securities and Exchange Commission. You should not rely upon forward-looking statements as predictions of future events. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee that future results, levels of activity, performance and events and circumstances reflected in the forward-looking statements will be achieved or will occur. The forward-looking statements made herein speak only as of the date of this announcement and MediWound undertakes no obligation to update publicly such forward-looking statements to reflect subsequent events or circumstances, except as otherwise required by law.

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MediWound, Ltd.
CONDENSED CONSOLIDATED BALANCE SHEETS
U.S. dollars in thousands

	December 31,	
	2019	**2018**
Cash, cash equivalents and short term deposits	29,458	23,633
Accounts and other receivable	4,551	7,400
Inventories	1,613	1,680
Total current assets	**35,622**	**32,713**
Long term deposits	6	48
Property, plant and equipment, net	2,304	2,020
Right of-use assets, net	2,229	-
Intangible assets, net	429	495
Total long term assets	**4,968**	**2,563**
Total assets	**40,590**	**35,276**
Current maturities of long-term liabilities	569	146
Trade payables and accrued expenses	4,067	2,715
Other payables	5,737	2,036
Total current liabilities	**10,373**	**4,897**
Deferred revenues	1,135	1,158
Liabilities in respect of Israeli Innovation Authority grants net of current maturities	6,811	7,568
Contingent consideration for the purchase of shares	4,853	6,330
Liability in respect of discontinued operation	-	6,003
Lease liabilities net of current maturities	2,006	-
Severance pay liability, net	243	348
Total long term liabilities	**15,048**	**21,407**
Shareholders' equity	15,169	8,972
Total liabilities & shareholder equity	**40,590**	**35,276**

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

	Year ended December 31,		Three months ended December 31,	
	2019	**2018**	**2019**	**2018**
	AUDITED		**UNAUDITED**	
Revenues	31,789	3,401	5,442	992
Cost of revenues	11,849	2,088	4,360	692
Gross profit	**19,940**	**1,313**	**1,082**	**300**
Operating expenses:				
Research and development, gross	10,070	17,915	2,209	3,941
Participation by BARDA & IIA	(5,101)	(13,843)	(533)	(3,663)
Research and development, net	4,969	4,072	1,676	278
Selling, general & administrative	9,306	7,987	2,419	2,190
Other expenses (income), net	1,172	(6,786)	131	(7,448)
Total operating expenses (income)	**15,447**	**5,273**	**4,226**	**(4,980)**
Operating profit (loss)	**4,493**	**(3,960)**	**(3,144)**	**5,280**
Financial income (expenses), net	(2,427)	(1,705)	(382)	715
Profit from discontinued operation	2,889	4,608	83	4,608
Profit (loss) for the period	**4,955**	**(1,057)**	**(3,443)**	**10,603**
Foreign currency translation adjustments	8	13	(9)	4
Total comprehensive profit (loss)	**4,963**	**(1,044)**	**(3,452)**	**10,607**
Profit (loss) per share:				
Profit (loss) from continuing operations	0.08	(0.21)	(0.13)	0.22
Profit from discontinued operation	0.11	0.17	-	0.17
Net profit (loss) per share	**0.18**	**(0.04)**	**(0.13)**	**0.39**
Weighted average number of ordinary shares provided by (used in) the computation of basic and diluted profit (loss) per share (in thousands):	**27,179**	**27,114**	**27,179**	**27,179**

ADJUSTED EBITDA
U.S. dollars in thousands

	Year ended December 31,		Three months ended December 31,	
	2019	**2018**	**2019**	**2018**
Profit (loss) for the period	4,955	(1,057)	(3,443)	10,603
Adjustments:				
Financial (expenses) income, net	(2,427)	(1,705)	(382)	715
Profit from discontinued operation	2,889	4,608	83	4,608
Other (expenses) income, net	(1,172)	6,786	(131)	7,448
Depreciation and amortization	(1,149)	(577)	(301)	(131)
Share-based compensation expenses	(1,234)	(645)	(303)	(143)
Total adjustments	(3,093)	8,467	(1,034)	12,497
Adjusted EBITDA	**8,048**	**(9,524)**	**(2,409)**	**(1,894)**

MediWound, Ltd.
CONDENSED CONSOLIDATED STATEMENT OF CASH FLOW
U.S. dollars in thousands

	Year ended December 31,		Three months ended December 31,	
	2019	**2018**	**2019**	**2018**
	AUDITED		**UNAUDITED**	
Cash Flows from Operating Activities:				
Net profit (loss)	**4,955**	**(1,057)**	**(3,443)**	**10,603**
Adjustments to reconcile net profit (loss) to net cash provided by (used in) continuing operating activities:				
Adjustments to profit and loss items:				
Profit from discontinued operation	(2,889)	(4,608)	(83)	(4,608)
Depreciation and amortization	1,149	577	301	130
Share-based compensation	1,234	645	303	143
Revaluation of liabilities in respect of IIA grants	(392)	287	(293)	(337)
Revaluation of contingent consideration for purchase of shares	1,690	758	171	(936)
Other income from settlement agreement	-	(7,537)	-	(7,537)
Revaluation of lease liabilities	340	-	60	-
Increase in severance liability, net	(105)	19	(73)	16
Financing income	(434)	(412)	(139)	(157)
Unrealized foreign currency (gain) loss	(152)	182	(100)	115
	441	**(10,089)**	**147**	**(13,171)**
Changes in asset and liability items:				
Decrease (increase) in trade receivables	(3,553)	(211)	402	103
Decrease (increase) in inventories	67	206	(193)	62
Decrease (increase) in other receivables	6,376	(306)	1,178	1,015
Increase (decrease) in trade payables & accrued expenses	1,355	(536)	1,205	(847)
Increase (decrease) in other payables & deferred revenues	247	(161)	(563)	228
	4,492	**(1,008)**	**2,029**	**561**
Net cash provided by (used in) continuing operating activities	**9,888**	**(12,154)**	**(1,267)**	**(2,007)**
Net cash used in discontinued operating activities	**(1,599)**	-	**(1,599)**	-
Net cash provided by (used in) operating activities	**8,289**	**(12,154)**	**(2,866)**	**(2,007)**
Cash Flows from Investment Activities:				
Purchase of property and equipment	(792)	(522)	(329)	(131)
Purchase of intangible assets	**-**	(12)	**-**	-
Interest received	184	106	80	62
Proceeds from (investment in) short term bank deposits, net of investments	(5,050)	(16,612)	2,955	4,005
Net cash provided by (used in) continuing investing activities	**(5,658)**	**(17,040)**	**2,706**	**3,936**
Net cash used in discontinued investing activities	**(1,239)**	-	**(282)**	-
Net cash provided by (used in) investing activities	**(6,897)**	**(17,040)**	**2,424**	**3,936**
Cash Flows from Financing Activities:				
Repayment of lease liabilities	(630)	-	(158)	-
Proceeds from (repayment of) IIA grants, net	(376)	46	-	-
Net cash provided by (used in) financing activities	**(1,006)**	**46**	(158)	**-**
Exchange rate differences on cash and cash equivalent balances	**140**	**(205)**	**99**	**(80)**
Increase (decrease) in cash and cash equivalents from continuing activities	3,364	(29,353)	1,380	1,849
Decrease in cash and cash equivalents from discontinued activities	(2,838)	-	(1,881)	-

Balance of cash and cash equivalents at the beginning of the period	6,716	36,069	7,743	4,867
Balance of cash and cash equivalents at the end of the period	**7,242**	**6,716**	**7,242**	**6,716**

Source: MediWound Ltd.