MediWound Reports Third Quarter 2019 Financial Results

November 14, 2019

Total revenues of $5.1 million, driven primarily by revenues from development services

Initiated U.S. NexoBrid expanded access treatment (NEXT) protocol, with plans on track for NexoBrid® BLA filing in the second quarter of 2020

Expected to initiate patient treatment in EscharEx® U.S. Phase 2 adaptive design study for Venus Leg Ulcers in the fourth quarter of 2019

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

YAVNE, Israel, Nov. 14, 2019 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq: MDWD), a fully-integrated biopharmaceutical company bringing innovative therapies to address unmet needs in severe burn and wound management, today announced financial results for the quarter ended September 30, 2019.

Business and Financial Highlights for the Third Quarter 2019 and Recent Weeks include:

- Total revenues for the third quarter of 2019 were $5.1, driven primarily by revenues from development services;
- As of September 30, 2019, the Company had $32.9 million in cash and short-term investments, compared to $23.6 million as of December 31, 2018;
- Initiated the NexoBrid Expanded Access Treatment (NEXT) protocol 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);
- The safety data of cosmesis and function collected in the U.S Phase 3 (DETECT) twelve-months patients follow-up period, was comparable between the NexoBrid and the Standard of Care arm and no new safety signals were observed;
- Highlighted NexoBrid cost effectiveness data and use experience by leaders in the field of burn care in 39 scientific presentations at the 18th European Burns Association (EBA) Congress in Helsinki;
- Launched the next stage of the U.S. clinical development program for EscharEx, the Company's topical biological drug candidate for the debridement of chronic and hard-to-heal wounds, with plans to initiate patient treatment in an adaptive design Phase 2 study in Venus Leg Ulcer in the fourth quarter of 2019.

"We are very pleased with the progress we have made towards our significant upcoming milestones across both of our programs," said Sharon Malka, Chief Executive Officer of MediWound. "In our NexoBrid program, we had a positive pre-BLA meeting with the U.S. Food and Drug administration (FDA), and we are on track to file our BLA for NexoBrid in the second quarter of 2020. The twelve-months follow-up safety data of cosmesis, function and overall safety, have been analyzed and was comparable across all arms. Additionally, we recently initiated the NEXT program for NexoBrid, allowing for the continued clinical use of NexoBrid for U.S. patients prior to NexoBrid approval by the FDA. We believe this program will enhance national preparedness for burn mass casualty incidences and will further extend the number of NexoBrid-trained physicians and healthcare providers in the U.S. With the FDA's endorsement of our BLA submission plan, the ongoing NEXT program and our commercial collaboration with Vericel, we are highly confident in our ability to bring NexoBrid to the U.S. market where it has the potential to meaningfully impact patients' lives."

Mr. Malka continued, "We have submitted an adaptive design protocol for our second generation EscharEx to the FDA and Institutional Review Boards (IRBs) and are planning to initiate patient treatment in our U.S. Phase 2 adaptive design study for EscharEx this quarter. Our solid balance sheet continues to support our development plans and we look forward to several meaningful upcoming milestones."

Third Quarter Financial Results

Revenues for the third quarter of 2019 were $5.1 million, an increase of $4.2 million versus $0.9M in the third quarter of 2018, primarily driven by revenues from development services.

Gross profit for the third quarter of 2019 was $0.7 million, compared to a gross profit of $0.5 million for the third quarter of 2018.

Research and development net expenses for the third quarter of 2019, were $1.4 million, compared with the $1.2 million for the third quarter of 2018.

Selling, general and administrative expenses for the third quarter of 2019 were $2.0 million, compared with $1.5 million for the third quarter of 2018, primarily due to non-recurring costs.

Operating loss for the third quarter of 2019 was $2.7 million, compared with a loss of $2.2 million in the third quarter of 2018.

The Company posted a net loss of $0.2 million, or loss of $0.01 per share, for the third quarter of 2019 compared with a net loss of $2.9 million, or loss of $0.11 per share, for the third quarter of 2018. The decrease was primarily as a result of the settlement with certain PolyHeal shareholders resulting a

one-time profit from discontinued operation of $2.8 million.

Adjusted EBITDA, as defined below, for the third quarter of 2019 was a loss of $2.0 million, flat to the loss of $2.0 million for the third quarter of 2018.

Year-to-Date 2019 Financial Results
Looking at the first nine months results versus the prior year, revenues for the first nine months of 2019 were $26.3 million, compared with the $2.4 million in the nine months of 2018, driven by the $17.5 million upfront license payment from the Vericel's agreement and revenues from development services of $6.3 million.

Operating profit for the first nine months of 2019, which includes the $17.5 million upfront license payment and $1.7 million of deal related expenses, was $7.6 million. Excluding the upfront license payment net, operating loss for the first nine months of 2019 was $8.2 million, an improvement of 12% from the $9.2 million loss for the first nine months of 2018.

The Company's net profit for the first nine months of 2019, which includes the $17.5 million upfront license payment from Vericel net of related one-time expenses and $2.8 million of profit from discontinued operation, was $8.4 million, or a profit of $0.31 per share, compared with a net loss of $11.7 million, or a loss of $0.43 per share in the first nine months of 2018.

Balance Sheet Highlights
As of September 30, 2019, the Company had cash, cash equivalents and short-term bank deposits of $32.9 million, compared with $23.6 million at December 31, 2018. The Company remained on budget, utilizing $9.2 million in the first nine months of 2019 for its operational activities. Throughout the remainder of 2019, the Company will continue to invest primarily in research and development efforts for EscharEx, while NexoBrid research and development programs will be funded by BARDA.

We now expect cash use in 2019 to be in the range of $10.0 million to $12.0 million, including NexoBrid license related payments and repayment of contingent liabilities, lower than the Company's previous guidance for 2019 of $12.0 million to $14.0 million

Conference Call
MediWound management will host a conference call for investors today, Thursday, November 14, 2019 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 7077178. Investors may also access the live call via webcast link at: https://mediwound.gcs-web.com/events-and-presentations.

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
Funding and technical support for the development of NexoBrid is provided by the Biomedical Advanced Research and Development Authority (BARDA), under the Assistant Secretary for Preparedness and Response, within the U.S. Department of Health and Human Services, under ongoing USG Contract No. HHSO100201500035C. Programs funded under the BARDA contract include randomized, controlled pivotal clinical trial, randomized, controlled pivotal clinical trial for use in pediatric population, Continued Access program, 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 U.S.

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 initiation of 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. 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 with the U.S. Biomedical Advanced Research and Development Authority; 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, 2018 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

	September 30,		December 31,
	2019	2018	2018
	Un-audited		Audited
Cash, cash equivalents and short term deposits	32,856	25,738	23,633
Accounts and other receivable	5,156	4,704	7,400
Inventories	1,419	1,742	1,680
Total current assets	**39,431**	**32,184**	**32,713**
Long term deposits	14	57	48
Property, plant and equipment, net	2,169	2,004	2,020
Right of use assets	2,254	-	-
Intangible assets, net	446	512	495
Total long term assets	**4,883**	**2,573**	**2,563**
Total assets	**44,314**	**34,757**	**35,276**
Current maturities of long-term liabilities	810	533	146
Trade payables and accrued expenses	2,863	3,563	2,715
Liability in respect of discontinued operation	2,240	-	-
Other payables	4,898	1,792	2,036
Total current liabilities	**10,811**	**5,888**	**4,897**
Deferred revenues	1,134	1,169	1,158
Liabilities in respect of Israeli Innovation Authority grants net of current maturities	7,099	7,850	7,568
Contingent consideration for the purchase of shares net of current maturities	4,621	15,292	6,330
Liability in respect of discontinued operation	-	6,003	6,003

Lease liabilities net of current maturities	2,015	-	-
Severance pay liability, net	316	333	348
Total long term liabilities	**15,185**	**30,647**	**21,407**
Shareholders' equity (deficit)	**18,318**	**(1,778)**	**8,972**
Total liabilities & shareholder equity	**44,314**	**34,757**	**35,276**

MediWound, Ltd.

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

U.S. dollars in thousands

	Nine months ended September 30,		Three months ended September 30,	
	2019	**2018**	**2019**	**2018**
Revenues	26,347	2,409	5,140	858
Cost of revenues	8,202	1,396	4,414	386
Gross profit	**18,145**	**1,013**	**726**	**472**
Operating expenses:				
Research and development, gross	7,799	14,517	1,296	5,128
Participation by BARDA & IIA	(4,568)	(10,180)	56	(3,882)
Research and development, net	3,231	4,337	1,352	1,246
Selling, general & administrative	6,236	5,254	1,956	1,466
Other expenses, net	1,041	662	140	-
Operating Profit (loss)	7,637	(9,240)	(2,722)	(2,240)
Financial expenses, net	(2,045)	(2,420)	(242)	(704)
Profit (loss) from continuing operation	5,592	(11,660)	(2,964)	(2,944)
Profit from discontinued operation	2,806	-	2,756	-
Net Profit (loss) for the period	**8,398**	**(11,660)**	**(208)**	**(2,944)**
Foreign currency translation adjustments	17	9	15	1
Total comprehensive profit (loss)	**8,415**	**(11,651)**	**(193)**	**(2,943)**
Basic and diluted loss per share:				
Profit (loss) from continuing operations	0.21	(0.43)	(0.11)	(0.11)
Profit from discontinued operation	0.10	-	0.10	-
Net Profit (loss) per share	**0.31**	**(0.43)**	**(0.01)**	**(0.11)**
Weighted average number of ordinary shares used in the computation of basic and diluted profit /loss per share:	27,179	27,092	27,179	27,179

ADJUSTED EBITDA

U.S. dollars in thousands

	Nine months ended September 30,		Three months ended September 30,	
	2019	**2018**	**2019**	**2018**

Profit (Loss) for the period	8,398	(11,660)	(208)	(2,944)
Adjustments:				
Financial expenses, net	(2,045)	(2,420)	(242)	(704)
Profit from discontinued operation	2,806	-	2,756	-
Other expenses	(1,041)	(662)	(140)	-
Depreciation and amortization	(848)	(447)	(296)	(142)
Share-based compensation expenses	(931)	(502)	(332)	(135)
Total adjustments	(2,059)	(4,031)	1,746	(981)
Adjusted EBITDA	**10,457**	**(7,629)**	**(1,954)**	**(1,963)**

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

	Nine months ended September 30,		Three months ended September 30,	
	2019	**2018**	**2019**	**2018**
Cash Flows from Operating Activities:				
Net profit (loss)	**8,398**	**(11,660)**	**(208)**	**(2,944)**
Adjustments to reconcile net profit (loss) to net cash used in continuing operating activities:				
Adjustments to profit and loss items:				
Profit from discontinued operation	(2,806)	**-**	(2,756)	**-**
Depreciation and amortization	848	447	296	142
Share-based compensation	931	502	332	135
Revaluation of liabilities in respect of IIA grants	(99)	624	293	220
Revaluation of contingent consideration for the purchase of shares	1,519	1,694	197	582
Revaluation of lease liabilities	(291)	**-**	(485)	**-**
Increase (decrease) in severance liability, net	(32)	3	(22)	(3)
Financing income	(295)	(255)	(146)	(73)
Unrealized foreign currency (gain) loss	(52)	67	18	(59)
	(277)	**3,082**	**(2,273)**	**944**
Changes in asset and liability items:				
Decrease (increase) in trade receivables	(3,955)	(314)	(3,946)	107
Decrease in inventories	260	144	114	129
Decrease (increase) in other receivables	5,198	(1,321)	2,454	251
Increase (decrease) in trade payables	150	311	(1,207)	237
Increase (decrease) in other payables & deferred revenues	810	(389)	281	(53)
	2,463	**(1,569)**	**(2,304)**	**671**
Net cash provided by (used in) operating activities	**10,584**	**(10,147)**	**(4,785)**	**(1,329)**

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

	Nine months ended September 30,	Three months ended September 30,

	2019	2018	2019	2018
Cash Flows from Investment Activities:				
Purchase of property and equipment	(463)	(391)	(30)	(78)
Purchase of intangible assets	-	(13)	-	-
Interest received	104	44	60	42
Proceeds from (investment in) short term bank deposits, net of investments	(8,005)	(20,616)	(10,982)	549
Net cash provided by (used in) continuing investing activities	**(8,364)**	**(20,976)**	**(10,952)**	**513**
Net cash used in discontinued investing activities	**(957)**	**-**	**(1,007)**	**-**
Net cash provided by (used in) investing activities	**(9,321)**	**(20,976)**	**(11,959)**	**513**
Cash Flows from Financing Activities:				
Repayment of lease liabilities	**99**	**-**	411	**-**
Repayment of IIA grants, net of proceeds from IIA grants	**(376)**	46	(569)	16
Net cash (used in) provided by financing activities	**(277)**	**46**	**(158)**	**16**
Exchange rate differences on cash and cash equivalent balances	41	(125)	(22)	8
Increase (decrease) in cash and cash equivalents from continuing activities	1,984	(31,202)	(15,917)	(792)
Decrease in cash and cash equivalents from discontinued activities	(957)	**-**	(1,007)	**-**
Balance of cash and cash equivalents at the beginning of the period	6,716	36,069	24,667	5,659
Balance of cash and cash equivalents at the end of the period	**7,743**	**4,867**	**7,743**	**4,867**

Source: MediWound Ltd.