MediWound Reports Fourth Quarter and Fiscal Year 2018 Financial Results

March 25, 2019

Met Primary and All Secondary Endpoints in its Pivotal Phase 3 Study (DETECT) in NexoBrid® for Eschar Removal of Severe Thermal Burns

Awarded Additional BARDA Contract Valued up to $43 Million for the Development of NexoBrid for Sulfur Mustard Injuries

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

YAVNE, Israel, March 25, 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 and year ended December 31, 2018.

Fourth Quarter and Full-Year 2018 Financial Highlights:

- Total revenues for the fourth quarter of 2018 were $1.0 million, an 87% increase from the fourth quarter of 2017.
- Total revenues for the full-year 2018 were $3.4 million, a 36% increase from 2017.
- One-time income of $12.1 million as a result of a Settlement Agreement with Teva.

Fourth Quarter and Full-Year 2018 Business Highlights:

- Announced positive top-line results in January 2019 from the pivotal Phase 3 DETECT study in NexoBrid for eschar removal of severe thermal burns.
- Plan to file Biologics License Application (BLA) for NexoBrid in the second half of 2019.
- Awarded a new contract by the Biomedical Advanced Research and Development Authority (BARDA) valued at up to $43 million to develop NexoBrid for the treatment of sulfur mustard injuries.
- Expanded the pediatric NexoBrid Phase 3 Children Innovation Debridement Study (CIDS) to the U.S.
- NexoBrid received marketing approval from South Korea's Ministry of Health in June and from Russia's Ministry of Health in September.
- Announced Executive Leadership changes.

"2018 was a pivotal year for MediWound as we made significant progress on several fronts. On the development side, after completing enrollment in our Phase 3 DETECT study of NexoBrid last summer, we announced in January 2019 that we met the primary and all secondary endpoints with statistically significant results compared with the control group," said Gal Cohen, MediWound's President and Chief Executive Officer. "These excellent top-line results corroborated our previous positive European Phase 3 clinical study results and further demonstrate how meaningfully NexoBrid can impact patients' lives. We plan to file the BLA in the second half of 2019, subject to Food and Drug Administration (FDA) concurrence in a pre BLA meeting planned for the second quarter of 2019. In addition, we expanded our NexoBrid Phase 3 CIDS study in children, to U.S. burn centers after receiving FDA concurrence on the protocol and BARDA funding for the study. For EscharEx, as requested by the FDA, we submitted information on the additional suggested secondary efficacy endpoints, and subject to FDA agreement, plan to advance the EscharEx® clinical development program in the first half of 2019.

"We were also pleased to receive marketing authorization from the Ministries of Health in both South Korea and Russia in 2018. These approvals further validate our strategy of using the EMA approved registration file for seeking approval in additional markets," continued Mr. Cohen. "Additionally, BARDA's award of another contract for the development of NexoBrid for sulfur mustard injuries was a further endorsement of our technology. This supplementary award of up to $43 million will fund the research and development activities, under the FDA Animal Rule, allowing the Agency to grant marketing approval based on adequate and well-controlled animal efficacy studies.

"As reported, we reached a settlement agreement with Teva Pharmaceuticals Ltd., resulting in a one-time income recognition of $12.1 million. In addition, we entered into a settlement agreement with certain shareholders of PolyHeal Ltd., which, contingent upon the Israeli Supreme Court's approval of the settlement agreement, will result in the acceptance of our appeal by the Supreme Court and the cancellation of the 2017 ruling that was issued by the District Court against MediWound," added Mr. Cohen.

"Finally, we announced earlier this month that I will step down as President and Chief Executive Officer by the end of May and that Sharon Malka, our Chief Operating Officer and Chief Financial Officer, will assume the role of CEO at that time. I would like to thank our Board, management team, employees, and shareholders for more than 12 exciting and productive years, and I wish Sharon, Steve and the entire team continued success and prosperity in the future," concluded Mr. Cohen.

"I am excited for the opportunity to become MediWound's CEO and to lead our talented team at this important time for our Company," said Mr. Malka. "I would also like to thank Gal for his long tenure of leadership and dedication to MediWound and to our employees and shareholders. I have enjoyed working with him and wish him the best in his future endeavors."

Stephen T. Wills, MediWound's Active Chairman, added, "We continue to move ahead with the strategic process related to a potential transaction or collaboration, which is in advanced stages, in order to generate the highest possible value for our shareholders. The Board continues to be advised by Moelis & Company regarding evaluation and assessment of all strategic options and avenues. As stated, there can be no assurances that a

definitive agreement between the parties or any other agreement will be reached. I would like to conclude by thanking Gal on behalf of the Company's Board of Directors for more than a decade of uncompromising leadership, professionalism and dedication and wishing Sharon great success in his new role as CEO, leading MediWound's talented team to continued growth and further success."

Fourth Quarter Financial Results
Revenues for the fourth quarter of 2018 were $1.0 million, an increase of 87% compared to $0.5 million for the fourth quarter of 2017.

Gross profit for the fourth quarter of 2018 was $0.3 million, compared to a gross profit of $0.1 million for the prior year period.

Research and development expenses for the fourth quarter of 2018, net of participations, were $0.3 million, decrease of 77% compared with $1.2 million for the fourth quarter of 2017. The decrease was as a result of a decrease of $0.5 million in the gross research and development expenses, and an increase of $0.4 million in participations by BARDA and the Israeli Innovation Authority.

Selling, general and administrative expenses for the fourth quarter of 2018 were $2.2 million, compared with $2.5 million for the fourth quarter of 2017.

Operating loss from operational activities for the fourth quarter of 2018 was $2.2 million, an improvement of 38% from $3.5 million in the fourth quarter of 2017, primarily due to the decrease in research and development expenses, net and increase in revenues. In the fourth quarter of 2018, we recognized one-time other income from settlement with Teva of $7.5 million which was offset by other one-time expenses of $0.1 million associated with review and analysis of potential strategic transactions, resulting an operating profit of $5.3 million in the fourth quarter of 2018.

The Company posted a net profit of $10.6 million, or $0.39 per share, for the fourth quarter of 2018 compared with a net loss of $2.4 million, or ($0.09) per share, for the fourth quarter of 2017.

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 2018 was a loss of $1.9 million, compared with a loss of $3.0 million for the fourth quarter of 2017.

Full-Year 2018 Financial Results
Total revenues for the year ended December 31, 2018 were $3.4 million compared with $2.5 million for the year ended December 31, 2017, an increase of 36%.

Gross profit for the year ended December 31, 2018 was $1.3 million, compared with a gross profit of $0.9 million in the prior year period, reflecting a gross margin of about 40%.

Research and development expenses for the year ended December 31, 2018, net of participations, were $4.1 million, compared with $5.5 million recorded in the year ended December 31, 2017. The decrease in research and development, net, was as a result of an increase of $3.3 million primarily in NexoBrid clinical trials expenses offset by an increase of $4.7 million in participation by BARDA in the Company's R&D expenses.

Selling, general and administrative expenses for the year ended December 31, 2018 were $8.0 million compared with $9.1 million in the prior year period. The decrease was primarily due to decrease in sales and marketing expenses associated with launch activities and a decrease in non-cash share-based compensation.

Operating loss for the year ended December 31, 2018 was $4.0 million, down from $13.7 million in the year ended December 31, 2017. Operating expenses in the year ended December 31, 2018 included other one-time other income of $7.5 million as a result settlement with Teva which was offset by other one-time expenses of $0.7 million associated with review and analysis of potential strategic transactions. The decrease in operating loss was primarily due to the one-time other income, increased revenues and the decrease in operating expenses in 2018 compared to the prior year period.

For the year ended December 31, 2018, the Company posted a net loss of $1.1 million, or ($0.04) per share, compared with a net loss of $22.1 million, or ($0.95) per share, for the same period in 2017. The Company's net loss 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 year ended December 31, 2018 was a loss of $9.5 million, compared with a loss of $11.8 million for the prior year period.

Balance Sheet Highlights
As of December 31, 2018, the Company had cash, cash equivalents and short-term bank deposits of $23.6 million, compared with $36.1 million at December 31, 2017. The Company utilized $12.5 million in cash to fund ongoing operating activities during 2018.

Throughout 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. As a result, the Company expects cash use for operating activities in 2019 to be in the range of $12.0 million to $14.0 million.

Conference Call
MediWound management will host a conference call for investors today, Monday, March 25, 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 2997019. The call also will be broadcast live on the Internet on the Company's website at http://ir.mediwound.com/events-and-presentations.

A replay of the call will be accessible two hours after its completion through April 8, 2019 by dialing 855-859-2056 (in the U.S.) or 404-537-3406 (outside the U.S.) and entering passcode 2997019. The call will also be archived 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 ®, received marketing authorization from the European Medicines Agency as well as the Israeli, Argentinian and South Korean Ministries of Health, for removal of dead or damaged tissue, known as eschar, in adults with deep partial and full-thickness thermal burns. NexoBrid® represents a new paradigm in burn care management, and clinical trials have demonstrated, with statistical significance, its ability to non-surgically and rapidly remove the eschar earlier and without harming viable tissues.

MediWound's second innovative product, EscharEx®, is a topical biological drug being developed for debridement of chronic and other hard-to-heal wounds and is complementary to the large number of existing wound healing products, which require a clean wound bed in order to heal the wound. EscharEx® contains the same proteolytic enzyme technology as NexoBrid®, and benefits from the wealth of existing development data on NexoBrid®. In two Phase 2 studies, EscharEx® has demonstrated safety and efficacy in the debridement of chronic and other hard-to-heal wounds, within a few daily applications.

For more information, please visit www.mediwound.com.

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 regulatory authorizations and launch dates. 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 factors. In particular, you should consider the risks discussed under the heading “Risk Factors” in our annual report on Form 20-F for the year ended December 31, 2018 and 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,	
	2018	**2017**
Cash, cash equivalents and short-term deposits	23,633	36,069
Accounts and other receivable	7,400	3,565
Inventories	1,680	1,886
Total current assets	**32,713**	**41,520**
Long-term deposits	48	56
Property, plant and equipment, net	2,020	1,924
Intangible assets, net	495	635
Total long-term assets	**2,563**	**2,615**
Total assets	**35,276**	**44,135**

Trade payables and accrued expenses	2,715	3,251
Other payables	2,182	2,182
Total current liabilities	**4,897**	**5,433**
Deferred revenues	1,158	988
Liabilities in respect of Israeli Innovation Authority grants net of current maturities	7,568	7,380
Contingent consideration for the purchase of shares net of current maturities	6,330	14,381
Liability in respect of discontinued operation	6,003	6,003
Severance pay liability, net	348	330
Total long-term liabilities	**21,407**	**29,082**
Shareholders' equity	8,972	9,620
Total liabilities & shareholder equity	**35,276**	**44,135**

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

	Year ended December 31,		Three months ended December 31,	
	2018	**2017**	**2018**	**2017**
	AUDITED		**UNAUDITED**	
Revenues	3,401	2,496	992	530
Cost of revenues	2,088	1,578	692	416
Gross profit	**1,313**	**918**	**300**	**114**
Operating expenses:				
Research and development, gross	17,915	14,625	4,010	4,558
Participation by BARDA & IIA	(13,843)	(9,163)	(3,732)	(3,375)
Research and development, net	4,072	5,462	278	1,183
Selling, general & administrative	7,987	9,143	2,190	2,455
Other income, net	6,786	-	7,448	-
Total operating expenses (income)	**5,273**	**14,605**	**(4,980)**	**3,638**
Operating profit (loss)	**(3,960)**	**(13,687)**	**5,280**	**(3,524)**
Financial income (expenses), net	(1,705)	(846)	715	1,271
Profit (loss) from discontinued operation	4,608	(7,616)	4,608	(116)
Loss for the period	**(1,057)**	**(22,149)**	**10,603**	**(2,369)**
Foreign currency translation adjustments	13	(29)	4	(10)
Total comprehensive profit (loss)	**(1,044)**	**(22,178)**	**10,607**	**(2,379)**
Profit (loss) per share:				
Profit (loss) from continuing operations	(0.21)	(0.62)	0.22	(0.09)
Profit (loss) from discontinued operation	0.17	(0.33)	0.17	(0.00)
Net profit (loss) per share	**(0.04)**	**(0.95)**	**0.39**	**(0.09)**
Weighted average number of ordinary shares used in the computation of basic and diluted loss per share (in thousands):	**27,114**	**23,341**	**27,179**	**27,048**

ADJUSTED EBITDA
U.S. dollars in thousands

	Year ended December 31,		Three months ended December 31,	
	2018	**2017**	**2018**	**2017**
Profit (loss) for the period	(1,057)	(22,149)	10,603	(2,369)
Adjustments:				
Financial (expenses) income, net	(1,705)	(846)	715	1,271
Profit (loss) from discontinued operation	4,608	(7,616)	4,608	(116)
Other income, net	6,786	-	7,448	-
Depreciation and amortization	(577)	(567)	(130)	(137)
Share-based compensation expenses	(645)	(1,363)	(143)	(351)
Total adjustments	8,467	(10,392)	12,498	667
Adjusted EBITDA	**(9,524)**	**(11,757)**	**(1,895)**	**(3,036)**

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

	Year ended December 31,		Three months ended December 31,	
	2018	**2017**	**2018**	**2017**
	AUDITED		**UNAUDITED**	
Cash Flows from Operating Activities:				
Net profit (loss)	**(1,057)**	**(22,149)**	**10,603**	**(2,369)**
Adjustments to reconcile net profit (loss) to net cash used in continuing operating activities:				
Adjustments to profit and loss items:				
Loss (profit) from discontinued operation	(4,608)	7,616	(4,608)	116
Depreciation and amortization	577	567	130	137
Share-based compensation	645	1,363	143	350
Revaluation of liabilities in respect of IIA grants	287	229	(337)	(122)
Revaluation of contingent consideration for purchase of shares	758	351	(936)	(1,321)
Other income from settlement agreement	(7,537)	-	(7,537)	-
Increase in severance liability, net	19	111	16	88
Financing income	(412)	(349)	(155)	(158)
Unrealized foreign currency (gain) loss	182	(185)	115	(57)
	(10,089)	**9,703**	**(13,169)**	**(967)**
Changes in asset and liability items:				
Decrease (increase) in trade receivables	(211)	28	103	253
Decrease (increase) in inventories	206	(1,042)	62	(249)
Decrease (increase) in other receivables	(306)	(1,227)	1,015	321
Decrease in trade payables & accrued expenses	(536)	(135)	(847)	(89)
Increase (decrease) in other payables & deferred revenues	(161)	(70)	228	258
	(1,008)	**(2,446)**	**561**	**494**
Net cash used in operating activities	**(12,154)**	**(14,892)**	**(2,005)**	**(2,842)**
Net cash used in discontinued operating activities	-	(1,563)	-	(1,563)
Net cash used in operating activities	**(12,154)**	**(16,455)**	**(2,005)**	**(4,405)**

Cash Flows from Investment Activities:				
Purchase of property and equipment	(522)	(1,045)	(131)	(181)
Purchase of intangible assets	(12)	(30)	-	(30)
Interest received	106	349	62	297
Proceeds from (investment in) short-term bank deposits, net of investments	(16,612)	1,163	4,004	15,000
Net cash provided by (used in) investing activities	**(17,040)**	**437**	**3,935**	**15,086**
Cash Flows from Financing Activities:				
Proceeds from exercise of options	-	7	-	-
Proceeds from issuance of shares and warrants, net	-	22,658	-	(136)
Proceeds from IIA grants, net of repayments	46	330	-	2
Net cash provided by (used in) financing activities	**46**	**22,995**	**-**	**(134)**
Exchange rate differences on cash and cash equivalent balances	**(205)**	**226**	**(81)**	**120**
Increase (decrease) in cash and cash equivalents from continuing activities	(29,353)	8,766	1,849	12,230
Decrease in cash and cash equivalents from discontinued activities	-	(1,563)	-	(1,563)
Balance of cash and cash equivalents at the beginning of the period	36,069	28,866	4,867	25,402
Balance of cash and cash equivalents at the end of the period	**6,716**	**36,069**	**6,716**	**36,069**

Source: MediWound Ltd.