MediWound Reports Third Quarter 2018 Financial Results

November 13, 2018

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, Nov. 13, 2018 (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 three and nine months ended September 30, 2018.

Third Quarter Highlights:

- Revenues for the third quarter of 2018 were $0.9 million, a 16% increase from $0.7 million in the third quarter of 2017
- MediWound Awarded Additional Biomedical Advanced Research and Development Authority (BARDA) Contract Valued Up to $43 Million for Development of NexoBrid® for Sulfur Mustard Injuries
- NexoBrid® received marketing authorization from Russian's Ministry of Health. Genfa Medica S.A., MediWound's exclusive distribution partner in Russia, intends to launch NexoBrid in the first half of 2019

"This has been an active quarter, and we continue to make progress on numerous fronts. We were very pleased to have been awarded an additional BARDA contract for the development of NexoBrid® for Sulfur Mustard injuries," commented Gal Cohen, MediWound's President and Chief Executive Officer. "The contract provides approximately $12 million of funding to support research and development activities up to pivotal studies in animals, under the U.S. Food and Drug Administration (FDA) Animal Rule, allowing for marketing approval based on animal studies. It also includes options for additional funding of up to $31 million for additional and subsequent development activities, including animal pivotal studies and FDA Biologics License Application (BLA) submission."

"Now that the last enrolled patient in our NexoBrid® Phase 3 DETECT study has completed the acute treatment and entered the follow-up period, we look forward to announcing top line results in January 2019," added Mr. Cohen. "Additionally, we continue to recruit patients in the U.S. and Europe for our expanded NexoBrid® Phase 3 CIDS study in children after receiving both FDA concurrence on the protocol and BARDA funding. As planned, we have submitted our pivotal protocol for clinical development of EscharEx® to the FDA, and we recently met with the Agency. We had a constructive discussion, received concurrence on many aspects, and suggested additional secondary efficacy endpoints on which we were requested to provide additional information. We plan to submit, the information, and subject to FDA concurrence, to initiate EscharEx® clinical development program in the first half of 2019."

"Finally, we were also happy to receive marketing authorization from the Russian Ministry of Health to sell NexoBrid® to patients with deep partial and full-thickness thermal burns. This authorization augments additional clearances we have secured from the European Medicines Agency (EMA) and from the Israeli, Argentinian and South Korea's Ministries of Health for the same indication. It also further validates our strategy of using the EMA approved registration file for seeking approval in international markets through collaboration with local companies that possess the expertise in the local regulatory, market access and marketing efforts, and assume the financial commitment and diligence," concluded Mr. Cohen.

Stephen T. Wills, MediWound's Chairman, added, "As we have discussed in our prior earnings calls, MediWound was approached earlier this year by a third party to consider a potential strategic transaction. Subsequently, we engaged an investment bank to help us review the proposal and advise in our discussions. We commenced discussions, and thereafter, received approaches and engaged in discussions and diligence with other strategic parties on different strategic transaction scenarios. At this stage, we continue to be in discussions and diligence with a subset of those parties. The Board continues to be advised by Moelis & Company regarding evaluation and assessment of all strategic options and avenues. As we have said, there can be no assurances that a definitive agreement between the parties or any other agreement will be reached."

Third Quarter Financial Results

Revenues for the third quarter of 2018 were $0.9 million, an increase of 16% compared to $0.7 million of revenues for the third quarter of 2017.

Gross profit for the third quarter of 2018 was $0.5 million, compared to a gross profit of $0.4 million for the third quarter of 2017.

Research and development expenses for the third quarter of 2018, net of participations, were $1.1 million, increase of 26% compared with $0.8 million for the third quarter of 2017. The increase was as a result of an increase of $1.5 million in the gross research and development expenses, which was offset by an increase of $1.2 million in participation, primarily by BARDA.

Selling, general and administrative expenses for the third quarter of 2018 were $1.6 million, compared with $2.4 million for the third quarter of 2017.

Operating loss for the third quarter of 2018 was $2.2 million, an improvement of 20% from $2.8 million in the third quarter of 2017, as a result of the decrease in operating expenses.

The Company posted a net loss of $2.9 million, or ($0.11) per share, for the third quarter of 2018 compared with a net loss of $11.0 million, or ($0.49) per share, for the third quarter of 2017.
The Company's net loss in 2017 included one-time loss from discontinued operation in the amount of $7.5 million as a result of the district court ruling and a full provision for the PolyHeal's shares purchase price plus the accrued interest.

Adjusted EBITDA, as defined below, for the third quarter of 2018 was a loss of $2.0 million, compared with a loss of $2.3 million for the third quarter of 2017.

Year-to-Date 2018 Financial Results
Revenues for the first nine months of 2018 were $2.4 million compared with $2.0 million for the first nine months of 2017, an increase of 23%.

Gross profit for the first nine months of 2018 was $1.0 million, compared with a gross profit of $0.8 million in the prior year period, reflecting a gross margin of 40%.

Research and development expenses, net of participations, were $3.8 million for the first nine months of 2018, compared with $4.3 million for the first nine months of 2017. The decrease in research and development, net, was as a result of an increase of $3.8 million primarily in NexoBrid® clinical trials expenses, which was offset by an increase of $4.3 million in participations in the Company's R&D expenses, primarily by BARDA.

Selling, general and administrative expenses in the first nine months of 2018 were $5.8 million compared with $6.7 million in the prior year period.

Operating loss for the first nine months of 2018 was $9.2 million, down 9% from $10.2 in the first nine months of 2017. Operating expenses in the first nine months of 2018 included 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 increased revenues and the decrease in operating expenses in the first nine months of 2018 compared to the prior year period, which was offset by one-time other expenses as mentioned above.

For the nine months ended September 30, 2018, the Company posted a net loss of $11.7 million, or ($0.43) per share, compared with a net loss of $19.8 million, or ($0.89) per share, for the same period in 2017. The Company's net loss in 2017 included one-time loss from discontinued operation in the amount of $7.5 million as a result of the district court ruling and a full provision for the PolyHeal's shares purchase price.

Adjusted EBITDA, as defined below, for the nine months of 2018 was a loss of $7.6 million, compared with a loss of $8.7 million for the first nine months of 2017.

Balance Sheet Highlights
As of September 30, 2018, the Company had cash, cash equivalents and short-term bank deposits of $25.7 million, compared with $36.1 million at December 31, 2017.

For the remainder of 2018, the Company intends to allocate its cash resources to advance the development of EscharEx® while the NexoBrid® development plans are fully funded by BARDA.

We now expect cash use to support ongoing operating activities in 2018 will be in the range of $13 to $14 million, lower than the Company's previous guidance for 2018 of $14.0 million to $16.0 million.

Conference Call
MediWound management will host a conference call for investors today, Tuesday, November 13, 2018 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 800-289-0438 (in the U.S.) 1809 212 883 (Israel), or 323-794-2423 (outside the U.S. & Israel) and entering passcode 8091639. 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 November 27, 2018 by dialing 844-512-2921 (in the U.S.) or 412-317-6671 (outside the U.S.) and entering passcode 8091639. 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, South Korean and Russian 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, 2017 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

	September 30,		December 31,
	2018	2017	2017
	Unaudited		Audited
Cash, cash equivalents and short term deposits	25,738	40,593	36,069
Accounts and other receivable	4,704	4,238	3,565
Inventories	1,742	1,637	1,886
Total current assets	**32,184**	**46,468**	**41,520**
Long term deposits	57	60	56
Property, plant and equipment, net	2,004	1,834	1,924
Intangible assets, net	512	649	635
Total long term assets	**2,573**	**2,543**	**2,615**
Total assets	**34,757**	**49,011**	**44,135**
Trade payables and accrued expenses	3,563	3,289	3,251
Liability in respect of discontinued operation	-	7,500	-
Other payables	2,325	2,190	2,182
Total current liabilities	**5,888**	**12,979**	**5,433**
Deferred revenues	1,169	937	988
Liabilities in respect of Israeli Innovation Authority grants net of current maturities	7,850	7,395	7,380
Contingent consideration for the purchase of shares net of current maturities	15,292	15,673	14,381
Liability in respect of discontinued operation	6,003	-	6,003
Severance pay liability, net	333	242	330
Total long term liabilities	**30,647**	**24,247**	**29,082**
Shareholders' equity (deficiency)	(1,778)	11,785	9,620
Total liabilities & shareholder equity	**34,757**	**49,253**	**44,135**

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

	Nine months ended September 30,		Three months ended September 30,	
	2018	2017	2018	2017
Revenues	2,409	1,966	858	739
Cost of revenues	1,396	1,162	386	338
Gross profit	**1,013**	**804**	**472**	**401**
Operating expenses:				
Research and development, gross	13,904	10,068	4,877	3,446
Participation by BARDA & IIA	(10,110)	(5,789)	(3,812)	(2,602)
Research and development, net	3,794	4,279	1,065	844
Selling, general & administrative	5,797	6,688	1,647	2,354
Other expenses	662	0	0	0
Total operating expenses	**10,253**	**10,967**	**2,712**	**3,198**
Operating loss	**(9,240)**	**(10,163)**	**(2,240)**	**(2,797)**
Financial income (expenses), net	(2,420)	(2,117)	(704)	(707)
Loss from discontinued operation	-	(7,500)	-	(7,500)
Loss for the period	**(11,660)**	**(19,780)**	**(2,944)**	**(11,004)**
Foreign currency translation adjustments	9	(19)	1	(2)

Total comprehensive loss	**(11,651)**	**(19,799)**	**(2,943)**	**(11,006)**
Loss from continuing operations	(0.43)	(0.56)	(0.11)	(0.16)
Loss from discontinued operation	-	(0.33)	-	(0.33)
Net loss per share	**(0.43)**	**(0.89)**	**(0.11)**	**(0.49)**
Weighted average number of ordinary shares used in the computation of basic and diluted loss per share (in thousands):	**27,092**	**22,105**	**27,179**	**22,438**

MediWound Ltd.
ADJUSTED EBITDA
U.S. dollars in thousands

	Nine months ended September 30,		Three months ended September 30,	
	2018	**2017**	**2018**	**2017**
Loss for the period	(11,660)	(19,780)	(2,944)	(11,004)
Adjustments:				
Financial (expenses) income, net	(2,420)	(2,117)	(704)	(707)
Loss from discontinued operation	0	(7,500)	0	(7,500)
Other expenses	(662)	-	0	-
Depreciation and amortization	(447)	(430)	(142)	(128)
Share-based compensation expenses	(502)	(1,012)	(135)	(347)
Total adjustments	(4,031)	(11,059)	(981)	(8,682)
Adjusted EBITDA	**(7,629)**	**(8,721)**	**(1,963)**	**(2,322)**

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

	Nine months ended September 30,		Three months ended September 30,	
	2018	**2017**	**2018**	**2017**
Cash Flows from Operating Activities:				
Net loss	**(11,660)**	**(19,780)**	**(2,944)**	**(11,004)**
Adjustments to reconcile net loss to net cash used in continuing operating activities:				
Adjustments to profit and loss items:				
Loss from discontinued operation	-	7,500	-	7,500
Depreciation and amortization	447	430	142	128
Share-based compensation	502	1,013	135	347.8
Revaluation of liabilities in respect of IIA grants	624	351	220	(51)
Revaluation of contingent consideration for the purchase of shares	1,694	1,672	582	552
Increase (decrease) in severance liability, net	3	23	(3)	3
Financing income	(255)	(191)	(73)	(145)
Unrealized foreign currency (gain) loss	67	(128)	(59)	91
	3,082	**10,670**	**944**	**8,426**

Changes in asset and liability items:				
Increase (decrease) in trade receivables	(314)	(225)	107	16
Decrease (increase) in inventories	144	(793)	129	(514)
Decrease (increase) in other receivables	(1,321)	(1,548)	251	(1,271)
Increase (decrease) in trade payables & accrued expenses	311	(46)	237	1,164
Increase (decrease) in other payables & deferred revenues	(389)	(328)	(53)	131
	(1,569)	**(2,940)**	**671**	**(474)**
Net cash used in operating activities	**(10,147)**	**(12,050)**	**(1,329)**	**(3,052)**
Cash Flows from Investment Activities:				
Purchase of property and equipment	(391)	(864)	(78)	(499)
Purchase of intangible assets	(13)	0	0	0
Interest received	44	52	42	25
Proceeds from (investment in) short term bank deposits, net of investments	(20,616)	(13,837)	549	3,000
Net cash provided by (used in) investing activities	**(20,976)**	**(14,649)**	**513**	**2,526**
Cash Flows from Financing Activities:				
Proceeds from exercise of options	-	7	-	7
Proceeds from issuance of shares and warrants, net	-	22,794	-	22,792
Proceeds from IIA grants, net of repayments	46	328	16	365
Net cash provided by financing activities	**46**	**23,129**	**16**	**23,164**
Exchange rate differences on cash and cash equivalent balances	**(125)**	**106**	**8**	**(11)**
Decrease in cash and cash equivalents from continuing activities	(31,202)	(3,464)	(792)	22,627
Balance of cash and cash equivalents at the beginning of the period	36,069	28,866	5,659	2,775
Balance of cash and cash equivalents at the end of the period	**4,867**	**25,402**	**4,867**	**25,402**

Source: MediWound Ltd.