MediWound Reports Second Quarter 2018 Financial Results

August 7, 2018

Completion of enrollment of Phase 3 DETECT Study of NexoBrid®
Strategic discussions advancing with multiple parties

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

YAVNE, Israel, Aug. 07, 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 six months ended June 30, 2018.

Second Quarter Highlights

- Revenues for the second quarter of 2018 were $1.0 million, a 50% increase from $0.7 million in the second quarter of 2017, underscoring the continued growth of NexoBrid® sales
- Completed enrollment of Phase 3 DETECT Study of NexoBrid®. Top-line data anticipated around year-end 2018
- Expanded NexoBrid Phase 3 Children Innovation Debridement Study (CIDS) to the United States following approval of the study protocol by the U.S. Food and Drug Administration (FDA) and BARDA funding of the study
- NexoBrid® received marketing authorization from South Korea's Ministry of Health. BL&H Co., Ltd., the Company's exclusive distribution partner in South Korea, intends to launch NexoBrid in the second half of 2018
- FDA cleared the development pathway for NexoBrid® in Sulfur Mustard injuries in accordance with FDA Animal Efficacy Rule (also known as the Animal Rule).

"We are pleased with the progress we have made this quarter in our development programs. Importantly, we have completed enrollment in our Phase 3 DETECT study of NexoBrid and now look forward to sharing the top line results around year-end 2018," said Gal Cohen, MediWound's President and Chief Executive Officer. "Additionally, we expanded our NexoBrid Phase 3 CIDS study in children to the U.S. after obtaining both FDA concurrence on the protocol and BARDA funding for the study. We continue to be committed and enthusiastic about the significant medical need and commercial opportunity for EscharEx and are on track to submit the protocol to the FDA in the second half of 2018 for the EscharEx clinical development program. Furthermore, we agreed with FDA on the development pathway of NexoBrid in Sulfur Mustard injuries in accordance with FDA Animal Rule as it is neither ethical nor feasible to conduct human trials with chemical warfare agents.

"The marketing authorization in South Korea is built upon NexoBrid's marketing authorization from the European Medicines Agency (EMA) for the same indication and validates MediWound's 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.

"Last but not least, we were pleased to be able to assist the medical delegation that treated victims suffering burns in the massive volcano eruption in Guatemala. We have seen again that NexoBrid has a key role in the routine treatment of burn victims, and even more so in mass casualty events, where surgical capacity is limited and the need for injury diagnosis and rapid medical intervention are critical. We will continue to seek cooperation with other countries and international agencies as part of their preparations for future mass casualty events," added Mr. Cohen.

Stephen T. Wills, MediWound's Chairman, said, "As a reminder, MediWound was approached earlier this year by a third-party to consider a potential strategic transaction. At this point, we are engaged in advancing discussions and diligence with several parties. We are in the process of analyzing specific business transaction scenarios and proposals related to these parties. The Board continues to be advised by Moelis & Company regarding evaluation and assessment of these potential strategic transactions. Importantly, there can be no assurances that a definitive agreement between the parties or any other agreement will be reached."

Second Quarter Financial Results
Revenues for the second quarter of 2018 were $1.0 million, an increase of 50% compared to $0.7 million of revenues for the second quarter of 2017.

Gross profit for the second quarter of 2018 was $0.4 million, compared to a gross profit of $0.2 million for the second quarter of 2017.

Research and development expenses for the second quarter of 2018, net of participations, were $1.5 million, down 8% compared with $1.7 million for the second quarter of 2017. The decrease was as a result of an increase of $1.9 million in BARDA's participation and an increase of $1.7 million in the gross research and development expenses.

Selling, general and administrative expenses for the second quarter of 2018 were $2.1 million, compared with $2.2 million for the second quarter of 2017.

Operating loss for the second quarter of 2018 was $3.3 million, an improvement of 11% from $3.7 million in the second quarter of 2017, as a result of the improvement in gross profit and the decrease in operating expenses.

The Company posted a net loss of $4.2 million, or ($0.15) per share, for the second quarter of 2018 compared with a net loss of $4.5 million, or ($0.20) per share, for the second quarter of 2017.

Adjusted EBITDA, as defined below, for the second quarter of 2018 was a loss of $2.9 million, compared with a loss of $3.2 million for the second quarter of 2017.

First Half 2018 Financial Results
Revenues for the first half of 2018 were $1.6 million compared with $1.2 million for the first half of 2017, an increase of 26%.

Gross profit for the first half of 2018 was $0.5 million, compared with a gross profit of $0.4 million in the prior year period, reflecting a gross margin of 35%.

Research and development expenses, net of participations, were $2.7 million for the first half of 2018, compared with $3.4 million for the first half of 2017. The decrease in research and development, net, was as a result of an increase of $2.4 million primarily in NexoBrid clinical trials expenses which was offset by an increase of $3.1 million in participation by BARDA in the Company's R&D expenses.

Selling, general and administrative expenses in the first half of 2018 were $4.2 million compared with $4.3 million in the prior year period.

Operating loss for the first half of 2018 was $7.0 million, down 5% from $7.4 million in the first half of 2017. Operating expenses in the first half 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 improvement in gross profits and the decrease in operating expenses in the first half of 2018 compared to the prior year period, which was offset by one-time other expenses as mentioned above.

For the six months ended June 30, 2018, the Company posted a net loss of $8.7 million, or ($0.32) per share, compared with a net loss of $8.8 million, or ($0.40) per share, for the same period in 2017.

Adjusted EBITDA, as defined below, for the first half of 2018 was a loss of $5.7 million, compared with a loss of $6.4 million for the first half of 2017.

Balance Sheet Highlights
As of June 30, 2018, the Company had cash, cash equivalents and short-term bank deposits of $27.0 million, compared with $36.1 million at December 31, 2017.

Throughout 2018, 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, cash use for operating activities in 2018 is expected to be in the range of $14.0 million to $16.0 million.

Conference Call
MediWound management will host a conference call for investors today, Tuesday, August 7, 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 370010. 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 August 24, 2018 by dialing 844-512-2921 (in the U.S.) or 412-317-6671 (outside the U.S.) and entering passcode 370010. 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, 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

	June 30,		December 31,
	2018	2017	2017
	Unaudited		Audited
Cash, cash equivalents and short term deposits	27,004	20,922	36,069
Accounts and other receivable	5,224	3,089	3,565
Inventories	1,871	1,124	1,886
Total current assets	**34,099**	**25,135**	**41,520**
Long term deposits	65	75	56
Property, plant and equipment, net	2,051	1,425	1,924
Intangible assets, net	528	685	635
Total long term assets	**2,644**	**2,185**	**2,615**
Total assets	**36,743**	**27,320**	**44,135**
Trade payables and accrued expenses	3,327	2,121	3,251
Other payables	2,339	2,115	2,182
Total current liabilities	**5,666**	**4,236**	**5,433**
Deferred revenues	1,178	966	988
Liabilities in respect of Israeli Innovation Authority grants net of current maturities	7,793	7,153	7,380
Contingent consideration for the purchase of shares net of current maturities	14,737	15,082	14,381
Liability in respect of discontinued operation	6,003	-	6,003
Severance pay liability, net	336	239	330
Total long term liabilities	**30,047**	**23,440**	**29,082**
Shareholders' equity (deficiency)	1,030	(356)	9,620
Total liabilities & shareholder equity	**36,743**	**27,320**	**44,135**

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

	Six months ended	Three months ended

	June 30,		June 30,	
	2018	2017	2018	2017
Revenues	1,551	1,227	1,031	687
Cost of revenues	1,010	824	629	484
Gross profit	**541**	**403**	**402**	**203**
Operating expenses:				
Research and development, gross	9,027	6,622	4,987	3,181
Participation by BARDA & IIA	(6,298)	(3,187)	(3,451)	(1,517)
Research and development, net	2,729	3,435	1,536	1,664
Selling, general & administrative	4,150	4,334	2,090	2,242
Other expenses	662	-	62	-
Total operating expenses	**7,541**	**7,769**	**3,688**	**3,906**
Operating loss	**(7,000)**	**(7,366)**	**(3,286)**	**(3,703)**
Financial income (expenses), net	(1,716)	(1,410)	(879)	(759)
Loss for the period	**(8,716)**	**(8,776)**	**(4,165)**	**(4,462)**
Foreign currency translation adjustments	8	(17)	18	(14)
Total comprehensive loss	**(8,708)**	**(8,793)**	**(4,147)**	**(4,476)**
Net loss per share	**(0.32)**	**(0.40)**	**(0.15)**	**(0.20)**
Weighted average number of ordinary shares used in the computation of basic and diluted loss per share (in thousands):	**27,050**	**21,938**	**27,052**	**21,946**

ADJUSTED EBITDA
U.S. dollars in thousands

	Six months ended June 30,		Three months ended June 30,	
	2018	2017	2018	2017
Loss for the period	(8,716)	(8,776)	(4,165)	(4,462)
Adjustments:				
Financial (expenses) income, net	(1,716)	(1,410)	(879)	(759)
Other expenses	(662)	-	(62)	-
Depreciation and amortization	(305)	(302)	(170)	(146)
Share-based compensation expenses	(367)	(665)	(149)	(337)
Total adjustments	(3,050)	(2,377)	(1,260)	(1,242)
Adjusted EBITDA	**(5,666)**	**(6,399)**	**(2,905)**	**(3,220)**

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

	Six months ended June 30,		Three months ended June 30,	
	2018	2017	2018	2017
Cash Flows from Operating Activities:				
Net loss	**(8,716)**	**(8,776)**	**(4,165)**	**(4,462)**

Adjustments to reconcile net loss to net cash used in continuing operating activities:				
Adjustments to profit and loss items:				
Depreciation and amortization	305	302	170	146
Share-based compensation	367	665	149	337
Revaluation of liabilities in respect of IIA grants	404	402	218	221
Revaluation of contingent consideration for the purchase of shares	1,112	1,120	569	570
Increase (decrease) in severance liability, net	6	20	(5)	12
Financing income	(182)	(174)	(115)	(88)
Unrealized foreign currency (gain) loss	126	(91)	85	(39)
	2,138	**2,244**	**1,071**	**1,159**
Changes in asset and liability items:				
Increase in trade receivables	(421)	(241)	(494)	(201)
Decrease (increase) in inventories	15	(279)	149	(132)
Decrease (increase) in other receivables	(1,572)	(277)	(1,690)	278
Increase (decrease) in trade payables & accrued expenses	74	(1,210)	(51)	(2,487)
Increase (decrease) in other payables & deferred revenues	(336)	(459)	(507)	1,606
	(2,240)	**(2,466)**	**(2,593)**	**(936)**
Net cash used in operating activities	**(8,818)**	**(8,998)**	**(5,687)**	**(4,239)**
Cash Flows from Investment Activities:				
Purchase of property and equipment	(313)	(365)	(197)	(169)
Purchase of intangible assets	(13)	0	(13)	0
Interest received	2	27	2	12
Proceeds from (investment in) short term bank deposits, net of investments	(21,165)	(16,837)	1,680	3,007
Net cash provided by (used in) investing activities	**(21,489)**	**(17,175)**	**1,472**	**2,850**
Cash Flows from Financing Activities:				
Proceeds from issuance of shares and warrants, net	-	2	-	2
Proceeds from IIA grants, net of repayments	30	(37)	-	(65)
Net cash provided by (used in) financing activities	**30**	**(35)**	**0**	**(63)**
Exchange rate differences on cash and cash equivalent balances	**(133)**	**117**	**(117)**	**76**
Decrease in cash and cash equivalents from continuing activities	(30,410)	(26,091)	(4,332)	(1,376)
Balance of cash and cash equivalents at the beginning of the period	36,069	28,866	9,991	4,151
Balance of cash and cash equivalents at the end of the period	**5,659**	**2,775**	**5,659**	**2,775**

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Source: MediWound Ltd.