

MediWound Reports 2015 Fourth Quarter and Full Year Financial Results

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

YAVNE, Israel, Jan. 25, 2016 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq:MDWD), a fully integrated biopharmaceutical company bringing innovative therapies to address unmet needs in severe burn and wound management, reports financial results for the three and 12 months ended December 31, 2015.

Highlights of the fourth quarter of 2015 and recent weeks include:

- Provided NexoBrid[®] as humanitarian aid for a mass casualty incident (MCI) in Romania
- Highlighted <u>NexoBrid's potential role in managing MCIs in several presentations at the 4th International Conference on Healthcare System Preparedness and Response to Emergencies and Disasters
 </u>
- Appointed Aharon Yaari as Chairman of the Board of Directors and Dr. Roland Frosing as European Medical Director
- Received authorization from the Ministry of Health in Argentina to market and distribute NexoBrid for the removal of dead or damaged tissue in adults with deep partial and full-thickness thermal burns
- Expanded Latin American distribution of NexoBrid through agreement with Avalon Pharmaceutical S.A

Management Commentary

"Throughout 2015 we made significant progress increasing awareness of and interest in NexoBrid throughout Europe as evidenced by more than 90 clinical presentations at premier medical meetings by numerous burn specialists highlighting NexoBrid's merits in a number of severe burn applications. We have trained more than 75% of the European burn centers while more than half of the burn centers in Europe have treated an increasing number of patients with NexoBrid every quarter. Internationally, we obtained marketing authorization for NexoBrid in Argentina, submitted registration files in Mexico, Russia and South Korea and expended the reach of NexoBrid to most of South America with the recent distribution agreement with Avalon. In addition, we made meaningful progress with our clinical development programs including the initiation of our U.S. Phase 3 study of NexoBrid to treat severe burns and the completion of enrollment in our second Phase

2 study of EscharEx[®] for the treatment of chronic and hard-to-heal wounds," stated Gal Cohen, President and Chief Executive Officer of MediWound.Â

"Importantly, we entered a new market for NexoBrid in the preparedness for Mass Casualty Incidences (MCI) with the signing of a strategic agreement valued at up to \$112 million with the U.S. Biomedical Advanced Research and Development Authority (BARDA) in late September. This agreement provides non-dilutive funding for our NexoBrid U.S. development program and also has procurement commitments and options. We were particularly pleased to provide NexoBrid as humanitarian aid to victims of a MCI in Romania, where approximately 40 severe burn patients were treated with NexoBrid in less than 3 days, providing a real-world demonstration of the important role NexoBrid can play in such events where physician and surgical capacity are a bottleneck in saving patients' lives. We believe this is an important market where we can jointly work with governments and militaries in an effort to better prepare for such inevitable occurrences.

"We were particularly pleased to complete our second Phase 2 study with EscharEx for the treatment of chronic and hardto-heal wounds and we look forward to reporting top-line data in early February. We are excited about the potential for EscharEx in these indications based on a comprehensive market study we performed with more than 200 healthcare professionals and our U.S. advisory board, both indicating the huge commercial potential for an approved product that meets this target product profile. As EscharEx is based on the same technology as NexoBrid, we believe that the wealth of existing development data for NexoBrid, as well as clinical data from our first Phase 2 feasibility study, de-risks EscharEx's development as EscharEx benefits from the data developed for the European approval of NexoBrid including preclinical, toxicology, manufacturing and control data.

"The progress we made throughout 2015 puts us in a strong position to achieve a number of value-creating milestones during 2016, including the readout of top-line data from our Phase 2 study of EscharEx, the continued adoption of NexoBrid in Europe, the ongoing enrollment in our U.S. Phase 3 study of NexoBrid, expansion of NexoBrid as an important tool in managing MCIs and further commercialization of NexoBrid in international markets," concluded Mr. Cohen.

Fourth Quarter Financial Results

Revenues for the fourth quarter of 2015 increased to \$267,000 compared with \$124,000 for the same quarter last year, primarily due to sales of NexoBrid associated with the MCI in Romania, which were ordered in addition to the Company's donation of product.

Operating expenses for the fourth quarter of 2015 were \$6.4 million, in line with the Company's expectations, compared with \$5.6 million for the fourth quarter of 2014. The increase was primarily due \$0.8 million of research and development activities related to clinical development and \$0.5 million of general and administrative expense, offset by a \$0.5 million decrease in non-cash stock-based compensation expense.

For the fourth quarter of 2015, the Company reported a net loss of \$7.8 million, or \$0.36 per share, compared with a net loss of \$7.1 million, or \$0.33 per share, in the fourth quarter of 2014.

Adjusted EBITDA, as defined below, for the fourth quarter of 2014 was a loss \$6.0 million compared with a loss of \$5.3 million for the same quarter last year.

Full year Financial Results

For the 12 months ended December 31, 2015, revenues were \$601,000, compared with \$259,000 for the same period in 2014, representing primarily sales of NexoBrid in Europe and Israel in both periods.

Operating expenses for 2015 were \$19.3 million, in line with expectations, compared with \$18.9 million for 2014. The increase was primarily due to \$1.2 million of commercial activities associated with the European marketing infrastructure and \$0.8 million due to research and development activities related to clinical development, offset by a \$1.7 million decrease in non-cash stock-based compensation expense.

The Company reported a net loss for 2015 of \$22.1 million, or \$1.02 per share, compared with a loss for 2014 of \$18.9 million, or \$0.95 per share in the prior year. The increase in net loss was primarily due to one-time net financial income recognized in 2014, which was largely comprised of non-cash revaluation of warrants.

Adjusted EBITDA, as defined below, for 2015 was a loss of \$18.1 million, compared with a loss of \$16.1 million for 2014.

Balance Sheet Highlights

As of December 31, 2015, the Company had cash and short-term deposits of \$45.8 million, and working capital of \$45.2 million. The Company used \$19.1 million to fund ongoing activities during 2015, which was in line with its guidance of \$20.0 million.

During 2016 the Company will continue to invest primarily in its marketing infrastructure in Europe to advance the commercialization of NexoBrid and in research and development efforts of NexoBrid supported by BARDA funding as well as amplify the development of EscharEx for chronic wounds and other pipeline product candidates. As a result, cash use for the year is expected to be in the range of \$20.0 million to \$22.0 million.

Conference Call

MediWound management will host a conference call for members of the investment community today beginning at 8:30 a.m. Eastern time to discuss these results and answer questions. Â Shareholders and other interested parties may participate in the call by dialing (877) 280-2296 (domestic) or (1809) 212-925 (Israel) and entering passcode 8854485. The call also will be broadcast live on the Internet on the Company's website at www.mediwound.com.

A replay will be available beginning two hours after the completion of the live call through February 1, 2016 by dialing (866) 932-5017 (domestic) or (800) 358-7735 (UK) and entering passcode 8854485. The call will also be archived for 90 days on the Company's website at <u>www.mediwound.com</u>.

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 is defined as earnings before interest, taxes, depreciation and amortization, impairment, one-time expenses, restructuring and stock-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, as well as chronic and other hard-to-heal wounds. MediWound's first innovative biopharmaceutical product, NexoBrid, received marketing authorization from the European Medicines Agency for removal of dead or damaged tissue, known as eschar, in adults with deep partial- and full-thickness thermal burns and has been launched in Europe. 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. 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 financial results forecast, commercial results, clinical trials and the regulatory authorizations. 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 including, but not limited to, unexpected results of clinical trials, delays or denial in the FDA or the EMA regulatory approval process or additional competition in the market. 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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- Financial Tables to Follow -

CONDENSED CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands	
Â	
Â	December 31,
Â	2015 2014
CURRENT ASSETS:	ÂÂÂÂÂ
Cash, cash equivalents and short term deposits	45,768 64,853
Accounts and other receivable	2,912 2,223
Inventories	1,715 1,421
Â	50,395 68,497
LONG-TERM ASSETS:	ÂÂÂÂ
Long term deposits	192 168
Property, plant and equipment, net	1,040 1,088
Intangible assets, net	896 951
Other assets	- 417
Â	52,523 71,121

CURRENT LIABILITIES:	ÂÂ ÂÂ
Trade payables	1,123 1,214
Accrued expenses and other payables	4,083 2,683
Â	5,206 3,897
LONG-TERM LIABILITIES:	Â
Liabilities in respect of Chief Scientist government grants net of current maturities	7,275 6,985
Contingent consideration for the purchase of treasury shares net of current maturiti	ies 16,475 17,361
Severance pay liability, net	97 7
Â	23,847 24,353
Â	Â
SHAREHOLDERS' EQUITY	<u>23,470</u> <u>42,871</u>
Â	52,523 71,121

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

U.S. dollars in thousands (except share and per share data)	
Â	Â
Â	Year ended Three months ende
Â	December 31, December 31,
Â	<mark> 2015 2014 Â</mark> <mark> 2015 2014</mark>
Â	Audited Unaudited
Â	Â
Revenues	601 259 267 124
Cost of revenues	<u> 2,519Â</u> <u> 2,785Â</u> <u> 689Â</u> <u> 1,142</u>
Gross loss	(1,918) (2,526) (422) (1,018
Operating expenses:	ÂÂ ÂÂ ÂÂ ÂÂ
Research and development, net	6,021 5,349 2,294 1,496
Selling, general & administrative	<u> 13,288 13,552 4,114 4,072</u>
Total operating expenses	<mark> 19,309 18,901 </mark> <mark> 6,408</mark> 5,568
Operating loss	(21,227) (21,427) (6,830) (6,586
Financial income (expenses), net	(444) 2,552 (950) (508
Loss from continuing operations	<mark> (21,671)</mark> (18,875) (7,780) (7,094
Loss from discontinued operation	ÂÂ (417) ÂÂ -ÂÂÂ -ÂÂÂ ·
Loss for the period	<mark> (22,088)</mark> (18,875) (7,780) (7,094
Â	Â
Foreign currency translation adjustments	2 14 1 (27
Total comprehensive loss	(22,086) (18,861) (7,779) (7,121
Â	Â
Basic and diluted loss per share:	ÂÂ ÂÂ ÂÂ ÂÂ
Loss from continuing operations	(1.00) (0.95) (0.36) (0.33
Loss from discontinued operation	(0.02) 0.00 0.00 0.00
Net loss per share	$\hat{A} = \hat{A} = $
Weighted average number of ordinary shares used in the computation of basic a	and
diluted loss per share:	<u> 21,674 19,940 </u> <u> 21,801Â</u> <u> 21,298</u>

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. dollars in thousands					
Â	Â		Â	Â	
Â		Year ended		Three month	ns ended
Â		December 31,	Â	Decembe	er 31,
Â	Â	2015 Â Â Â 2014	ÂÂ	2015 Â	à 2014 Â
Â		Audited	Â	Unaudi	ted
Cash Flows from Operating Activities:	Â	ÂÂ	Â	ÂÂÂÂ	i.
Net loss	Â	(22,088) Â Â (18,87	5) Â	(7,780) Â	(7,094)
Â	Â	ÂÂ	Â	ÂÂÂÂ	ί.
Adjustments to reconcile net loss to net cash used in continuing operating activitie	s: Â	ÂÂ	Â	ÂÂÂÂ	ί.
Adjustments to profit and loss items:	Â	ÂÂ	Â	ÂÂÂÂ	ί.
Loss from discontinued operation	Â	417Â Â Â	-ÂÂ	ÂÂ-ÂÂÂ	À -Â

Depreciation and amortization	А	503A A A	492A A A	153A A A	88A
Revaluation of warrants to shareholders	Â	-ÂÂÂ	-	· · · · · ·	-Â
Share-based compensation	Â	2,659Â Â Â	(.)		
Revaluation of liabilities in respect of Chief Scientist government grants	Â	(474) Â Â	,		55Â
Revaluation of contingent consideration for the purchase of treasury shares	Â	(764) Â Â			55Â
Increase in severance liability, net	Â	90Â Â Â			-Â
Net financing expenses (income)	Â	(219) Â Â			(52)
Â	Â	2,212 Â Â Â		<u> </u>	<u> </u>
Changes in asset and liability items:	Â	2,2120 0 0			1,550A
Increase in trade receivables	Â	(181) Â Â			(46)
Decrease (increase) in other receivables	Â	(556) Â Â			(40) 103Â
Decrease (increase) in inventories	Â	(273) Â Â		· · · · ·	161Â
Increase (decrease) in trade payables	Â	(76) Â Â	(.)		301Â
Increase in other payables	Â	· · ·	1,909Â Â Â	()	844Â
Â	<u>Λ</u> Δ	275 Â Â Â		1,093 Â Â Â	
	<u>^</u>		(16,493) Â Â		
Net cash flows used in operating activities					(4,301)
Cash Flows from Investment Activities:	Â	ÂÂ			
Purchase of property and equipment	Â	(376) Â Â	()		61Â
Purchase of intangible assets	Â	(30) Â Â	()	. ,	(30)
Interest received	Â	287Â Â Â	173ÂÂÂ	203Â Â Â	128Â
Interest received Proceeds from (investment in) short term bank deposits, net of investments	Â Â	287Â Â Â 36,165Â Â Â	173ÂÂÂÂ (36,931) ÂÂ	203Â Â Â 21,989Â Â Â	128Â 10,643Â
Interest received	Â Â Â	287Â Â Â <u>36,165Â</u> Â <u>Â</u> 36,046 Â Â Â	173Â Â Â (36,931) Â Â (37,154) Â Â	203Â Â Â 21,989Â Â 22,084 Â Â	128Â 10,643Â
Interest received Proceeds from (investment in) short term bank deposits, net of investments	Â Â	287Â Â Â 36,165Â Â Â	173ÂÂÂÂ (36,931) Â <u>Â</u> (37,154) Â <u>Â</u>	203Â Â Â 21,989Â Â 22,084 Â Â	128Â 10,643Â
Interest received Proceeds from (investment in) short term bank deposits, net of investments Net cash provided by (used in) investing activities	Â <u>Â</u> Â Â	287Â Â Â <u>36,165Â Â Â 36,046Â Â Â Â</u>	173Â Â Â (36,931) Â Â (37,154) Â Â Â Â Â	203Â Â Â 21,989Â Â Â 22,084 Â Â Â	128Â 10,643Â
Interest received Proceeds from (investment in) short term bank deposits, net of investments Net cash provided by (used in) investing activities Â	Â <u>Â</u> Â	287Â Â Â <u>36,165Â</u> Â Â 36,046 Â Â Â Â	173Â Â Â (36,931) Â Â (37,154) Â Â Â Â Â	203Â Â Â <u>21,989Â</u> Â Â 22,084 Â Â Â Â Â Â Â	128Â 10,643Â
Interest received Proceeds from (investment in) short term bank deposits, net of investments Net cash provided by (used in) investing activities Â Cash Flows from Financing Activities:	Â <u>Â</u> Â Â	287Â Â Â <u>36,165Â</u> Â Â <u>36,046Â</u> Â Â Â Â Â Â Â Â Â	173Â Â Â (36,931) Â Â (37,154) Â Â Â Â Â	203Â Â Â 21,989Â Â Â 22,084 Â Â Â Â Â Â -Â Â Â	128Â 10,643Â 10,802 Â
Interest received Proceeds from (investment in) short term bank deposits, net of investments Net cash provided by (used in) investing activities Â <u>Cash Flows from Financing Activities:</u> Proceeds from exercise of options	Â Â Â Â Â Â	287Â Â Â <u>36,165Â</u> Â Â <u>36,046Â</u> Â Â Â Â Â Â Â Â Â	A 173Â Â Â A (36,931) Â Â A (37,154) Â Â A Â Â A Â Â A 306Â Â Â A 71,824Â Â Â	203Â Â Â 21,989Â Â <u>Â</u> 22,084 Â Â <u>Â</u> Â Â Â -Â Â Â -Â Â Â	128Â 10,643Â 10,802 Â 98Â
Interest received Proceeds from (investment in) short term bank deposits, net of investments Net cash provided by (used in) investing activities Â <u>Cash Flows from Financing Activities:</u> Proceeds from exercise of options Proceeds from issuance of shares and warrants, net	Â <u>Â</u> Â Â Â	287Â Â Â 36,165Â Â Â 36,046 Â Â Â Â Â 26Â Â Â -Â Â Â 752Â Â Â	A 173Â Â Â A (36,931) Â Â A (37,154) Â Â A Â Â A Â Â A 306Â Â Â A 71,824Â Â Â	203Â Â Â 21,989Â Â Â 22,084 Â Â Â Â Â Â -Â Â Â -Â Â Â 643Â Â Â	128Â 10,643Â 10,802 Â 98Â -Â
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Interest received Proceeds from (investment in) short term bank deposits, net of investments Net cash provided by (used in) investing activities Â <u>Cash Flows from Financing Activities:</u> Proceeds from exercise of options Proceeds from issuance of shares and warrants, net Proceeds from the Chief Scientist government grants, net of repayments Net cash provided by financing activities	Â Â Â Â Â Â Â	287Â Â Â 36,165Â Â Â 36,046 Â Â Â Â Â Â Â Â Â Â Â Â Â Â Â 752Â Â Â 778 Â Â Â (143) Â Â	$\begin{array}{c} & 173\hat{A} & \hat{A} & \hat{A} \\ \hline (36,931) & \hat{A} & \hat{A} \\ \hline (37,154) & \hat{A} & \hat{A} \\ \hline (37,1524\hat{A} & \hat{A} & \hat{A} \\ \hline (345\hat{A} & \hat{A} & \hat{A} \\ \hline \hline \hline (345\hat{A} & \hat{A} & \hat{A} \\ \hline \hline \hline (345\hat{A} & \hat{A} & \hat{A} \\ \hline \hline \hline (345\hat{A} & \hat{A} & \hat{A} \\ \hline \hline (345\hat{A} & \hat{A} & \hat{A} \\ \hline \hline \hline (345\hat{A} & \hat{A} & \hat{A} \\ \hline \hline \hline \hline (345\hat{A} & \hat{A} & \hat{A} \\ \hline \hline \hline \hline $	203Â Â Â 21,989Â Â Â 22,084 Â Â Â Â Â Â -Â Â Â -Â Â Â 643Â Â Â 112Â Â Â	128Â 10,643Â 10,802Â 98Â -Â 66Â 164Â (96)
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RECONCILIATION OF NET LOSS TO ADJUSTED EBITDA

U.S. dollars in thousands									
Â	Â		Â		Â			Â	
Â		Year	end	led	Â	TI	nree mo	ont	hs ended
Â	Â	Decer	nber	·31,	Â		Dece	mb	er 31,
Â	Â	2015 Â	ÂÂ	2014 Â	Â	Â	2015 Â	Â	2014 Â
Loss for the period	Â	(22,088)	ÂÂ	(18,875)	Â	Â(7,780)	Â	(7,094)
Adjustments:	Â	Â	ÂÂ		Â	Â		Â	Â
Financial (expenses) income, net	Â	(444)	ÂÂ	2,552Â	Â	Â	(950)	Â	(508)
Loss from discontinued operation	Â	(417)	ÂÂ	-Â	Â	Â	-Â	Â	-Â
Depreciation and amortization	Â	(503)	ÂÂ	(492)	Â	Â	(153)	Â	(88)
Share-based compensation expenses	Â	(2,659)	ÂÂ	(4,827)	Â	Â	(699)	Â	(1,204)
Total adjustments	Â	(4,023)	ÂÂ	(2,767)	Â	(1,802)	Â	(1,800)
Adjusted EBITDA from continuing operation	Â	(18,065)	ÂÂ	(16,108)	Â	(5,978)	Â	(5,294)
Â	Â	Â	ÂÂ		Â	Â		Â	Â
Share-based compensation and options expenses	s:Â/	Â	ÂÂ		Â	Â		Â	Â
Cost of revenues	Â		ÂÂ	763Â	Â	Â	101Â	Â	188Â
Research and development	Â	511Â	ÂÂ	657Â	Â	Â	136Â	Â	163Â
Selling and marketing	Â	669Â	ÂÂ	1,430Â	Â	Â	189Â	Â	351Â
General and administrative	Â	1,107Â	ÂÂ	1,977Â	Â	Â	273Â	Â	502Â
Total share-based compensation expenses	Â	2,659 Â	ÂÂ	4,827 Â	Â	Â	699 Â	Â	1,204 Â
	-				-				



Source: MediWound Ltd.

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