February 21, 2017

MediWound Reports 2016 Fourth Quarter and Full Year Financial Results

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

YAVNE, Israel, Feb. 21, 2017 (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, 2016.

Highlights of the fourth quarter of 2016 and recent weeks include:

- Revenue for the fourth quarter 2016 of $0.43 million increased 61% compared with revenue of $0.27 million in the prior year's fourth quarter, demonstrating continued growth in NexoBrid® sales;
- Reported final results of the Phase 2 clinical trial of EscharEx® for the debridement of chronic and hard-to-heal wounds, which support the previously reported positive top-line results;
- Reported favorable results from a NexoBrid Phase 2 pharmacokinetic (PK) clinical study that support treatment of severe burns covering up to 30% of total body surface area;
- Initiated the second stage of a European pediatric Phase 3 study of NexoBrid that expands treatment of severe burns to children age one to four, the age bracket representing the largest incidence of pediatric burns;
- Awarded "Best Poster" at the International Disaster and Military Medicine Conference (DiMiMED) for an abstract highlighting NexoBrid in burn mass casualties; and
- Granted a U.S. patent for MWPC003 for the treatment of connective tissue diseases.

Management Commentary

"2016 was an outstanding year for MediWound as we reported positive data from our second Phase 2 clinical trial of EscharEx to treat chronic and hard-to-heal wounds, made meaningful progress towards establishing NexoBrid as the standard of care in burn centers in Europe, extended NexoBrid's reach to emerging markets and advanced our clinical programs to include larger burns, younger pediatric patients and additional geographies," stated Gal Cohen, President and Chief Executive Officer of MediWound.

"We were very pleased to report final results from the first cohort of our second Phase 2 clinical trial of EscharEx to treat chronic and hard-to-heal wounds and to affirm the previously reported positive results. These final results reinforce our belief that EscharEx has the potential to become a first-in-class topical debridement treatment for chronic wounds, a large and growing market that represents a significant commercial opportunity. We plan to share these final data with the U.S. Food and Drug Administration (FDA) as part of our request for a meeting to discuss a U.S. pivotal clinical program for EscharEx. In tandem, we advanced a second cohort of patients in this study to demonstrate safety over extended periods of application to enhance convenience and compliance and plan to report top-line data from this cohort around mid-2017.

"We made great progress advancing NexoBrid towards becoming the standard of care in burn centers across Europe. This is evidenced by the growing number of patients treated with NexoBrid, the increasing number of centers treating and able to procure NexoBrid, additional countries establishing reimbursement for NexoBrid such as in Italy and Belgium, and the significant number of abstracts and award-winning presentations at premier burn conferences. The magnitude of these presentations illustrates the evolution taking place at European burn centers as NexoBrid is transitioning to become the new standard of care for severe burns. We continue to work with our partners in Latin America, Russia, South Korea, India and Japan and look forward to further expanding NexoBrid's global commercial reach.

"Through our dialog with the FDA and European Medicines Agency (EMA), we amended the U.S. phase 3 DETECT study protocol to allow inclusion of patients suffering from burns covering up to 30% of their total body surface area (TBSA). The collection of data in these larger burns in DETECT, along with the positive PK data from our recently completed phase 2 study in 36 patients, is aimed to generate data to support a request to FDA and EMA to extend the label for NexoBrid to larger TBSA burns. In addition, based on the recommendation of our pediatric phase 3 (CIDS) Data Safety Monitoring Board and the EMA endorsement, we initiated the second stage of the CIDS study that allows inclusion of pediatric burn patients ages one to four years, who represent the age bracket with the largest incidence of pediatric burns.

"We have a very productive year ahead as we continue to facilitate our pivotal program for EscharEx to treat chronic wounds. We look forward to further advancing NexoBrid as a new standard of care, to expanding its commercial reach to

important international markets and its potential use by countries for preparedness for mass-casualty events. In addition, we will continue to progress our ongoing NexoBrid phase 3 studies in the U.S. and in the pediatric population," concluded Mr. Cohen.

Fourth Quarter Financial Results

Revenues for the fourth quarter of 2016 increased 61% to $430,000 from $267,000 for the same quarter last year.

Operating expenses for the fourth quarter were $4.1 million, down $2.3 million from $6.4 million in the fourth quarter of 2015. The decrease was as a result of $1.5 million reduction in net research and development expense, primarily due to participation by BARDA and the Israeli Innovation Authority, and $0.8 million decrease in selling, general and administrative expenses.

For the fourth quarter of 2016, the Company reported a net loss of $1.9 million, or $0.09 per share, compared with a net loss of $7.8 million, or $0.36 per share, in the fourth quarter of 2015. The decrease in net loss was primarily as a result of non-cash financial income from revaluation of contingent liabilities recorded in 2016 and the aforementioned decrease in operating expenses.

Adjusted EBITDA, as defined below, for the fourth quarter of 2016 was a loss of $3.5 million compared with a loss of $6.0 million for the same quarter last year. A reconciliation of adjusted EBITDA to GAAP net loss is set forth below.

Full Year Financial Results

For the year ended December 31, 2016, revenues increased 159% to approximately $1.6 million from approximately $0.6 million for the year ended December 31, 2015.

Operating expenses for 2016 were $19.6 million, in line with the Company's budget and up slightly from $19.3 million for 2015.

Research and development expenses in 2016, net of participation, increased $1.1 million to $7.1 million from $6.0 million in 2015. The increase was primarily due to an increase of $3.8 million related to NexoBrid clinical trials, as well as $2.8 million related to EscharEx and MWPC003 development, which was partially offset by an increase of $5.6 million of participation from BARDA and the Israeli Innovation Authority.

Selling, general and administrative expenses in 2016 decreased $0.8 million to $12.5 million from $13.3 million in 2015.

The Company reported a net loss for 2016 of $18.9 million, or $0.86 per share, compared with a net loss of $22.1 million, or $1.02 per share, in 2015. The decrease in net loss was attributed to growth in revenues in 2016 and non-cash financial income recorded in 2016, from revaluation of contingent liabilities.

Adjusted EBITDA for 2016 was a loss of $16.4 million, compared with a loss of $18.1 million for 2015. A reconciliation of adjusted EBITDA to GAAP net loss is set forth below.

Balance Sheet Highlights

As of December 31, 2016, the Company had cash and short-term deposits of $30.0 million and had no debt. The Company used $15.7 million in cash to fund operations during 2016, which was below the Company's cash use guidance of $17.0 million.

Throughout 2017, the Company will continue to invest primarily in research and development efforts for NexoBrid, which is predominantly funded by BARDA, EscharEx for chronic wounds and other pipeline product candidates, as well as in sales and marketing activities to advance the adoption of NexoBrid in Europe. As a result, cash use for 2017 is expected to be in the range of $15.0 million to $17.0 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. Shareholders and other interested parties may participate in the call by dialing (877) 602-7189 (in the U.S.) or (678) 894-3057 (outside the U.S.) and entering passcode 43709562. 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 28, 2016 by dialing

(855) 859-2056 (in the U.S.) or 404-537-3406 (outside the U.S.) and entering passcode 43709562. The call will also be archived for 90 days on the Company's website 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 its performance. Management uses Adjusted EBITDA, which is defined 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, management believes the non-IFRS financial measures it presents provide meaningful supplemental information regarding operating results primarily because they exclude certain non-cash charges or items management does not believe are reflective of ongoing operating results when budgeting, planning and forecasting and determining compensation, and when assessing the performance of the business with 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. MediWound's second innovative product, EscharEx® is a topical biological drug being developed for debridement of chronic and other hard-to-heal wounds, a large and growing market. EscharEx® 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. 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.

CONDENSED CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands

	December 31,	
	2016	**2015**
CURRENT ASSETS:		
Cash, cash equivalents and short term deposits	30,029	45,768
Accounts and other receivables	2,739	2,912
Inventories	844	1,715

	33,612	**50,395**
LONG-TERM ASSETS:		
Long term deposits	103	192
Property, plant and equipment, net	1,276	1,040
Intangible assets, net	773	896
	2,152	**2,128**
	35,764	**52,523**
CURRENT LIABILITIES:		
Trade payables	1,456	1,123
Accrued expenses and other payables	3,924	4,083
	5,380	**5,206**
LONG-TERM LIABILITIES:		
Deferred revenues	1,023	-
Liabilities in respect of Israeli Innovation Authority grants, net of current maturities	6,839	7,275
Contingent consideration for the purchase of shares, net of current maturities	14,533	16,475
Severance pay liability, net	219	97
	22,614	**23,847**
SHAREHOLDERS' EQUITY	**7,770**	**23,470**
	35,764	**52,523**

CONDENSED CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE LOSS

U.S. dollars in thousands (except share and loss per share)

	Year ended December 31,		**Three months ended December 31,**	
	2016	**2015**	**2016**	**2015**
Revenues	1,558	601	430	267
Cost of revenues	2,158	2,519	855	689
Gross loss	**(600)**	**(1,918)**	**(425)**	**(422)**
Operating expenses:				
Research and development, gross	14,779	8,139	3,359	2,844
Participation by IIA & BARDA	(7,711)	(2,118)	(2,576)	(550)
Research and development, net	7,068	6,021	783	2,294
Selling, general & administrative	12,487	13,288	3,299	4,114
Total operating expenses	**19,555**	**19,309**	**4,082**	**6,408**
Operating loss	**(20,155)**	**(21,227)**	**(4,507)**	**(6,830)**
Financial income (expenses), net	1,270	(444)	2,621	(950)
Loss from continuing operations	**(18,885)**	**(21,671)**	**(1,886)**	**(7,780)**
Loss from discontinued operation	**-**	(417)	**-**	**-**
Loss for the period	**(18,885)**	**(22,088)**	**(1,886)**	**(7,780)**
Foreign currency translation adjustments	7	2	11	1
Total comprehensive loss	**(18,878)**	**(22,086)**	**(1,875)**	**(7,779)**
Net loss per share	**(0.86)**	**(1.02)**	**(0.09)**	**(0.36)**
Weighted average number of ordinary shares used in the computation of basic and diluted loss per share:	21,862,169	21,718,401	21,890,854	21,850,301

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. dollar in thousands

	Year ended December 31,		Three months ended December 31,	
	2016	2015	2016	2015
	Audited		Unaudited	
Cash Flows from Operating Activities:				
Net loss	**(18,885)**	**(22,088)**	**(1,886)**	**(7,780)**
Adjustments to reconcile net loss to net cash used in continuing operating activities:				
Adjustments to profit and loss items:				
Loss from discontinued operation	-	417	-	-
Depreciation and amortization	589	503	203	153
Share-based compensation	3,171	2,659	771	699
Revaluation of liabilities in respect of Israeli Innovation Authority grants	(1,298)	(474)	(1,108)	470
Revaluation of contingent consideration for the purchase of shares	(1,621)	(764)	(2,801)	597
Increase in severance liability, net	125	90	125	90
Net financing income	(508)	(219)	(144)	(209)
	458	**2,212**	**(2,954)**	**1,800**
Changes in asset and liability items:				
Decrease (increase) in trade receivables	(107)	(181)	138	(134)
Decrease (increase) in inventories	873	(273)	231	(383)
Decrease (increase) in other receivables	33	(556)	(392)	(199)
Increase (decrease) in trade payables	331	(76)	428	(124)
Increase in other payables	852	1,361	205	1,933
	1,982	**275**	**610**	**1,093**
Net cash flows used in operating activities	**(16,445)**	**(19,601)**	**(4,230)**	**(4,887)**
Cash Flows from Investment Activities:				
Purchase of property and equipment	(671)	(376)	(29)	(78)
Purchase of intangible assets	(30)	(30)	(30)	(30)
Interest received	407	287	362	203
Proceeds from short term bank deposits, net of investments	2,110	36,165	27,349	21,989
Net cash provided by investing activities	**1,816**	**36,046**	**27,652**	**22,084**
Cash Flows from Financing Activities:				
Proceeds from exercise of options	7	26	5	-
Proceeds from the IIA government grants, net of repayments	900	752	242	643
Net cash provided by financing activities	**907**	**778**	**247**	**643**
Increase (decrease) in cash and cash equivalents	(13,722)	17,223	23,669	17,840
Exchange rate differences on cash and cash equivalent balances	86	(143)	15	112
Balance of cash and cash equivalents at the beginning of the period	42,502	25,422	5,182	24,550
Balance of cash and cash equivalents at the end of the period	**28,866**	**42,502**	**28,866**	**42,502**

RECONCILIATION OF NET LOSS TO ADJUSTED EBITDA

U.S. dollars in thousands

	Year ended December 31,		Three months ended December 31,	
	2016	2015	2016	2015
Loss for the period	(18,885)	(22,088)	(1,886)	(7,780)
Adjustments:				
Financial (expenses) income, net	1,270	(444)	2,621	(950)
Loss from discontinued operation	-	(417)	-	-
Depreciation and amortization	(589)	(503)	(203)	(153)
Share-based compensation expenses	(3,171)	(2,659)	(771)	(699)
Total adjustments	(2,490)	(4,023)	1,647	(1,802)
Adjusted EBITDA (loss)	**(16,395)**	**(18,065)**	**(3,533)**	**(5,978)**

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