

MediWound Reports First Quarter 2016 Financial Results

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

YAVNE, Israel, April 21, 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 months ended March 31, 2016.

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

- Reported positive top-line results from the Company's Phase 2 clinical trial with EscharEx[®] for the debridement of chronic and hard-to-heal wounds, achieving the primary endpoint of incidence of complete debridement compared with patients treated with the hydrogel vehicle, with statistical significance;
- Expanded global access to NexoBrid[®] through distribution agreements for certain territories in Latin America and in India, Bangladesh and Sri Lanka;
- Presented positive EscharEx Phase 2 data at the "Late Breaker" session at the Symposium on Advanced Wound Care (SAWC) Spring 2016.

Management Commentary

"Throughout the first quarter of 2016 we made important clinical and operational progress that supports MediWound's growth strategy," stated Gal Cohen, President and Chief Executive Officer of MediWound. "We reported positive Phase 2 clinical trial data with EscharEx for the debridement of chronic and hard-to-heal wounds, continued to advance the adoption of NexoBrid in targeted European countries and expanded distribution for NexoBrid in important international markets.

"We were delighted to report the top-line data from our Phase 2 study of EscharEx and to have them presented at the 'Late Breaker' session at this year's SAWC. These highly encouraging results reinforce our belief that EscharEx has the potential to become a first-in-class topical debridement pharmaceutical product for the treatment of chronic wounds. There is a great unmet medical need to effectively debride chronic wounds in a non-surgical and prompt manner, as debriding is a critical first step for subsequent wound management and is complementary to the large number of existing wound healing products, which require a clean wound bed in order to heal the wound. Based on the safety data and the compelling clinical activity EscharEx demonstrated, particularly in diabetic foot ulcers and venous leg ulcers, we are moving forward with our clinical program with the goal of making EscharEx available for the treatment of these important indications.

"We look forward to continued progress throughout 2016 and to advancing our commercial and clinical programs to the benefit of patients suffering with severe burns and chronic wounds," concluded Mr. Cohen.

First Quarter Financial Results

Revenues for the first quarter of 2016 were \$254,000 compared with \$67,000 for the first quarter of 2015.

Research and Development expenses, gross, for the first quarter of 2016 were \$3.2 million, in line with the Company's budget, compared with \$1.4 million for the first quarter of 2015. The increase was primarily due to an increase of \$0.8 million related to expenses for NexoBrid clinical trials and \$0.8 million for EscharEx development. Research and development expenses gross, were offset by \$1.8 million participation by the U.S. Biomedical Advanced Research and Development Authority (BARDA) and \$0.4 million revaluation of the Office of the Chief Scientist (Israel) contingent liability. Sales, marketing and G&A expenses remained stable at \$2.9 million.

For the first quarter of 2016, the Company posted a net loss of \$3.8 million, or \$0.17 per share, compared with a loss of \$6.4 million, or \$0.30 per share, for the first quarter of 2015. The decrease was primarily due to a decrease in net research and development expenses of \$0.4 million, net financial expenses of \$1.5 million recorded in 2015, which was largely comprised of non-cash revaluation of contingent liabilities and changes in foreign currency exchange rates, and an impairment of discontinued operation of \$0.4 million recorded in the first quarter of 2015.

Adjusted EBITDA, as defined below, for the first quarter of 2016 was a loss of \$3.0 million, compared with a loss of \$3.7

million for the first quarter of 2015.

Balance Sheet Highlights

As of March 31, 2016 the Company had cash and short-term deposits of \$41.6 million and working capital of \$41.4 million. The Company remained on budget and utilized \$4.2 million in cash to fund operating activities during the first quarter of 2016.

During 2016 the Company will continue to invest primarily in its sales and marketing activities in Europe to advance the adoption of NexoBrid and in research and development efforts for 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 investors April 21, 2016 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 (domestic) or (678) 894-3057 (international) and entering passcode 84818465. The call also will be broadcast live on the Internet on the Company's website at <u>www.mediwound.com</u>.

A replay of the call will be accessible two hours after its completion through April 27, 2016 by dialing (855) 859-2056 (domestic) or (404) 537-3406 (international) and entering passcode 84818465. The call will also be archived on the Company website for 90 days 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 it defines 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 as well as the Israeli and Argentinian Ministries of Health, for removal of dead or damaged tissue, known as eschar, in adults with deep partial and full-thickness thermal burns and was launched in Europe and Israel, with plans for a launch in Argentina. MediWound has distribution agreements for NexoBrid in Latin America, Asia Pacific, India, Japan and CIS regions. 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 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, 2015 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.

Contacts: Sharon Malka Chief Financial and Operations Officer MediWound ir@mediwound.co.il Anne Marie Fields Senior Vice President LHA 212-838-3777 <u>afields@lhai.com</u>

Financial Tables to Follow

CONDENSED CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands

	March 31,	December 31,
	2016	2015
	Unaudited	Audited
CURRENT ASSETS:		
Cash, cash equivalents and short term deposits	41,591	45,768
Accounts and other receivable	3,283	2,912
Inventories	1,534	1,715
	46,408	50,395
LONG-TERM ASSETS:		
Long term deposits	135	192
Property, plant and equipment, net	1,267	1,040
Intangible assets, net	874	896
	48,684	52,523
CURRENT LIABILITIES:		
Trade payables	1,815	1,123
Accrued expenses and other payables	3,144	4,083
	4,959	5,206
LONG-TERM LIABILITIES:		
Liabilities in respect of Chief Scientist government grants net of current maturities	7,019	7,275
Contingent consideration for the purchase of treasury shares net of current maturities	16,041	16,475
Severance pay liability, net	101	97
	23,161	23,847
SHAREHOLDERS' EQUITY	20,564	23,470
	48,684	52,523

CONDENSED CONSOLIDATED UNAUDITED STATEMENTS OF COMPREHENSIVE LOSS

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

		Three months ended March 31,	
	2016	2015	
Revenues	254	67	
Cost of revenues	404	175	
Gross loss	(150)	(108)	

Operating expenses:		
Research and development, gross	3,230	1,397
Participation by OCS & BARDA	(2,237)	-
Research and development, net	993	1,397
Selling, general & administrative	2,861	2,963
Total operating expenses	3,854	4,360
Operating loss	(4,004)	(4,468)
Financial income (expenses), net	230	(1,525)
Loss from continuing operations	(3,774)	(5,993)
Loss from discontinued operation	-	(417)
Loss for the period	(3,774)	(6,410)
Foreign currency translation adjustments	(6)	1
Total comprehensive loss	(3,780)	(6,409)
Basic and diluted loss per share:		
Loss from continuing operations	(0.17)	(0.28)
Loss from discontinued operation	0.00	(0.02)
Net loss per share	(0.17)	(0.30)
Weighted average number of ordinary shares used in the computation of basic and diluted loss per share:	21,850	21,550

CONDENSED CONSOLIDATED UNAUDITED STATEMENTS OF CASH FLOWS

U.S. dollars in thousands

	Three months end	Three months ended March 31,		
	2016	2015		
Cash Flows from Operating Activities:				
Net loss	(3,774)	(6,410)		
Adjustments to reconcile net loss to net cash used in continuing operating activiti	les:			
Adjustments to profit and loss items:				
Loss from discontinued operation	-	417		
Depreciation and amortization	123	115		
Share-based compensation	874	687		
Revaluation of liabilities in respect of Chief Scientist government grants	(228)	202		
Revaluation of contingent consideration for the purchase of treasury shares	(76)	641		
Net financing (income) expenses	(229)	504		
	464	2,566		
Changes in asset and liability items:				
Increase in trade receivables	(143)	30		
Decrease (increase) in other receivables	(149)	90		
Decrease (increase) in inventories	169	(783)		
Increase (decrease) in trade payables	685	(105)		
Decrease in other payables	(1,353)	(157)		
	(791)	(925)		
Net cash flows used in operating activities	(4,101)	(4,769)		
Cash Flows from Investment Activities:				
Purchase of property and equipment	(327)	(61)		
Interest received	9	7		
Investment in short term bank deposits	(29,211)	(2,897)		
Net cash used in investing activities	(29,529)	(2,951)		
Increase in cash and cash equivalents	(33,630)	(7,720)		
Exchange rate differences on cash and cash equivalent balances	154	(603)		
Balance of cash and cash equivalents at the beginning of the period	42,502	25,422		
Balance of cash and cash equivalents at the end of the period	9,026	17,099		

ADJUSTED EBITDA

U.S. dollars in thousands

	Three months ended		
	March 31,		
	2016	2015	
Loss for the period	(3,774)	(6,410)	
Adjustments:			
Financial income (expenses), net	230	(1,525)	
Loss from discontinued operation	-	(417)	
Depreciation and amortization	(123)	(115)	
Share-based compensation expenses	(874)	(687)	
Total adjustments	(767)	(2,744)	
Adjusted EBITDA	(3,007)	(3,666)	

Share-based compensation expenses:

Cost of revenues	130	101
Research and development	193	122
Selling, general and administrative	551	464
Total share-based compensation expenses	874	687



Source: MediWound Ltd.

News Provided by Acquire Media