



May 4, 2015

## MediWound Reports First Quarter 2015 Financial Results

### Conference Call Begins Today at 8:30 a.m. Eastern Time

YAVNE, Israel, May 4, 2015 (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 reported financial results for the three months ended March 31, 2015.

#### Highlights of the first quarter of 2015 and recent weeks include:

- Initiated U.S. Phase 3 clinical trial of NexoBrid<sup>®</sup> to treat severe burns
- NexoBrid highlighted in award-winning poster presentation at the American Burn Association (ABA) Annual Meeting
- NexoBrid featured at the International Conference on Minimally Invasive Medicine
- Expanded global distribution of NexoBrid through agreement in Mexico

#### Management Commentary

"Throughout the first quarter of 2015, we made progress on a number of important initiatives that support MediWound's long-term growth strategy," stated Gal Cohen, President and Chief Executive Officer of MediWound. "We continued to advance the commercial launch of NexoBrid in targeted European countries, initiated our U.S. Phase 3 clinical trial of NexoBrid to treat severe burns, expanded our distribution for NexoBrid in international markets and made good progress with the enrollment of our Phase 2 clinical trial with EscharEx<sup>™</sup> to treat chronic wounds."

"We are particularly pleased to have initiated our U.S. Phase 3 clinical trial with NexoBrid to treat patients with severe thermal burns, especially as the streamlined study protocol evaluates NexoBrid on a singular primary endpoint of eschar removal compared with vehicle, rather than on three co-primary endpoints as in the previous version of the study protocol. The other two primary endpoints of reduction in surgical burden and long term cosmesis are now a secondary endpoint and a safety endpoint, respectively. As a result of this efficient protocol and in light of the significant positive results in eschar removal vs. vehicle in our past clinical studies, we were able to reduce the number of patients to be enrolled in the study to 175.

"Since long-term cosmesis after a 12-month and 24-month follow up is no longer a primary endpoint, we now expect to have top-line results on the acute primary and secondary endpoints in the first half of 2017 and to have the results of the long-term 12- and 24-month follow-up in the first half of 2018 and 2019, respectively. Subject to positive acute results, we can discuss with the U.S. Food and Drug Administration the potential for submitting a Biologics License Application after completion of the acute phase of the study, with plans to supplement the application with the long-term follow up data, when it is available."

"While product revenues during this early phase of our European launch remains modest, we made significant progress in integrating NexoBrid use in Europe throughout the first quarter, as evidenced by the growing number of patients treated and the number of burn centers that have started to use NexoBrid. To date in 2015, burn specialists in Europe treated nearly as many patients with NexoBrid as were treated during all of 2014 and the number of treating centers has more than doubled. We have trained more than half of our target burn centers in Europe and will continue this effort to further expand the use of NexoBrid throughout Europe. We believe this growing patient experience and the increasing number of medical reference points in burn centers throughout Europe will further increase physician confidence and use, and supports our aim to assimilate NexoBrid as standard-of-care. We understand that reimbursement in the different markets in Europe will enable us to convert increasing use into revenues. Toward this end, we have submitted the locally required reimbursement dossiers in target European markets and expect that the compelling clinical and pharmacoeconomic benefits of NexoBrid will provide the basis for favorable payment determinations in these territories.

"We continue to build strong clinical support among burn specialists as evidenced by the number and quality of the papers presented on the benefits of NexoBrid as a non-surgical debridement for severe burns at the recent ABA meeting. We continue to encourage such sharing of evidenced-based data and will maintain a major presence in the burn conferences on a national and European level. We are confident that the work we are undertaking to increase awareness, interest and hands-on experience with NexoBrid will establish a strong foundation, from which to integrate NexoBrid into standard-of-care treatment for severe burns.

"Our Phase 2 clinical study with EscharEx for debridement of chronic wounds has enrolled more than half the patients required and we expect to report top-line results from this study in the second half of 2015. EscharEx represents a significant

opportunity for MediWound due to the prevalence of patients and the remaining unmet medical need despite the billions of dollars spent on currently available treatments," concluded Mr. Cohen.

## **First Quarter Financial Results**

Revenues for the first quarter of 2015 totaled \$67,000 compared with \$50,000 for the same quarter last year.

Operating expenses for the first quarter of 2015 totaled \$4.4 million, in line with our budget, compared with \$4.3 million in the first quarter of 2014. The increase was primarily due to an increase of \$0.6 million in commercial activities associated with the European marketing infrastructure, offset by a \$0.5 million decrease in non-cash share-based compensation expense.

For the first quarter of 2015, the Company posted a net loss of \$6.4 million, or \$0.30 per share, compared with a loss of \$0.8 million, or \$0.05 per share, in the first quarter of 2014. The increase was primarily due to net financial expenses, which was largely comprised of non-cash revaluation of contingent liabilities and exchange rate differences.

Adjusted EBITDA, as defined below, for the first quarter of 2015 was a loss of \$3.7 million, compared with a loss of \$3.1 million for the same quarter last year.

## **Balance Sheet Highlights**

As of March 31, 2015 the Company had cash and short-term deposits of \$59.4 million and working capital of \$59.6 million. The Company remained on budget and utilized \$4.8 million in cash during this quarter to fund operating activities.

During 2015 the Company will continue to mainly invest in its sales and marketing activities to advance the commercialization of NexoBrid across Europe and in research and development efforts to develop products for additional territories and indications. As a result, cash usage for the year is expected to remain as communicated in the range of \$20 million to \$22 million.

## **Conference Call**

MediWound management will host a conference call for investors May 4, 2015 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) 280-2296 (domestic) or (809) 212-923 (Israel) and entering passcode 3015886. The call also will be broadcast live on the Internet at [www.streetevents.com](http://www.streetevents.com) and [www.mediwound.com](http://www.mediwound.com).

A replay of the call will be accessible two hours after its completion until 5:00 p.m. Eastern time May 10, 2015 by dialing (866) 932-5017 and entering passcode 3015886. The call will also be archived for 90 days at [www.streetevents.com](http://www.streetevents.com) and [www.mediwound.com](http://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 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](http://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, ability to recruit patients, low recruitment rate, 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.

**Contacts:** Anne Marie Fields  
 Sharon Malka Senior Vice President  
 Chief Financial & Operation Officer **LHA**  
**MediWound Ltd.** 212-838-3777  
[ir@mediwound.co.il](mailto:ir@mediwound.co.il) [afields@lhaj.com](mailto:afields@lhaj.com)

### Financial Tables to Follow

#### CONDENSED CONSOLIDATED UNAUDITED BALANCE SHEETS

U.S. dollars in thousands

	<b>March 31, December 31,</b>	
	<b>2015</b>	<b>2014</b>
<b>CURRENT ASSETS:</b>		
Cash, cash equivalents and short term deposits	59,427	64,853
Accounts and other receivable	2,081	2,223
Inventories	1,997	1,421
	<b>63,505</b>	<b>68,497</b>
<b>LONG-TERM ASSETS:</b>		
Long term deposits and deferred costs	151	168
Property, plant and equipment, net	1,050	1,088
Intangible assets, net	930	951
Other assets	--	417
	<b>65,636</b>	<b>71,121</b>
<b>CURRENT LIABILITIES:</b>		
Trade payables	1,096	1,214
Accrued expenses and other payables	2,859	2,683
	<b>3,955</b>	<b>3,897</b>
<b>LONG-TERM LIABILITIES:</b>		
Liabilities in respect of Chief Scientist government grants net of current maturities	7,140	6,985
Contingent consideration for the purchase of treasury shares net of current maturities	17,385	17,361
Severance pay liability, net	7	7
	<b>24,532</b>	<b>24,353</b>

## SHAREHOLDERS' EQUITY (DEFICIENCY)

37,149	42,871
<u>65,636</u>	<u>71,121</u>

**CONDENSED CONSOLIDATED UNAUDITED STATEMENTS OF COMPREHENSIVE INCOME**

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

	Three months ended	
	March 31,	
	<u>2015</u>	<u>2014</u>
Revenues	67	50
Cost of revenues	175	170
<b>Gross loss</b>	<b>(108)</b>	<b>(120)</b>
Operating expenses:		
Research and development, net	1397	1465
Selling, general & administrative	2,963	2,882
<b>Total operating expenses</b>	<b>4,360</b>	<b>4,347</b>
<b>Operating loss</b>	<b>(4,468)</b>	<b>(4,467)</b>
Financial income (expenses), net	(1,525)	3,732
<b>Loss from continuing operations</b>	<b>(5,993)</b>	<b>(735)</b>
Loss from discontinued operation	(417)	(14)
<b>Loss for the period</b>	<b>(6,410)</b>	<b>(749)</b>
Foreign currency translation adjustments	1	(10)
<b>Total comprehensive loss</b>	<b>(6,409)</b>	<b>(759)</b>
<b>Basic and diluted loss per share:</b>		
Loss from continuing operations	(0.28)	(0.05)
Loss from discontinued operation	(0.02)	0.00
Net loss per share	(0.30)	(0.05)
Weighted average number of ordinary shares used in the computation of basic and diluted loss per share:	<u>21,550</u>	<u>15,749</u>

**CONDENSED CONSOLIDATED UNAUDITED STATEMENTS OF CASH FLOWS**

U.S. dollars in thousands

	Three months ended	
	March 31,	
	<u>2015</u>	<u>2014</u>
<b>Cash Flows from Operating Activities:</b>		
Net loss	<b>(6,410)</b>	<b>(749)</b>
Adjustments to reconcile net income (loss) to net cash used in continuing operating activities:		
Adjustments to profit and loss items:		
Loss from discontinued operation	417	14
Depreciation and amortization	115	117
Revaluation of warrants to shareholders	0	(4,491)
Share-based compensation	687	1,261
Revaluation of liabilities in respect of Chief Scientist government grants	202	141
Revaluation of contingent consideration for the purchase of treasury shares	641	586

Net financing expenses (income)	504	(14)
	<b>2,566</b>	<b>(2,386)</b>
Changes in asset and liability items:		
Increase in trade receivables	30	(16)
Decrease in other receivables	90	8
Increase in inventories	(783)	(809)
Increase in trade payables	(105)	(359)
(Decrease) increase in other payables	(157)	1,092
	<b>(925)</b>	<b>(84)</b>
Net cash used in continuing operating activities	<u>(4,769)</u>	<u>(3,219)</u>
Net cash used in discontinued operating activities	<u>0</u>	<u>(14)</u>
<b>Net cash flows used in operating activities</b>	<b><u>(4,769)</u></b>	<b><u>(3,233)</u></b>
<b>Cash Flows from Investing Activities:</b>		
Purchase of property and equipment	(61)	(74)
Interest received	7	3
Proceeds from (investment in) short term bank deposits, net of investments	(2,897)	2,500
<b>Net cash provided by (used in) investing activities</b>	<b><u>(2,951)</u></b>	<b><u>2,429</u></b>
<b>Cash Flows from Financing Activities:</b>		
Proceeds from exercise of options	--	208
Proceeds from issuance of shares and warrants, net	--	74,082
Proceeds from the Chief Scientist government grants	--	12
<b>Net cash provided by financing activities</b>	<b><u>0</u></b>	<b><u>74,302</u></b>
Exchange rate differences on cash and cash equivalent balances	(603)	19
<b>Increase in cash and cash equivalents from continuing activities</b>	<b>(7,720)</b>	<b>73,512</b>
Decrease in cash and cash equivalents from discontinued activities	--	(14)
Balance of cash and cash equivalents at the beginning of the period	<u>25,422</u>	<u>7,053</u>
<b>Balance of cash and cash equivalents at the end of the period</b>	<b><u>17,099</u></b>	<b><u>80,570</u></b>

## ADJUSTED EBITDA

U.S. dollars in thousands

	Three months ended	
	March 31,	
	2015	2014
Loss for the period	(6,410)	(749)
Adjustments:		
Financial (expenses) income, net	(1,525)	3,732
Other expenses *	(417)	(14)
Depreciation and amortization	(115)	(117)
Share-based compensation expenses	(687)	(1,261)
Total adjustments	<u>(2,744)</u>	<u>2,340</u>
Adjusted EBITDA from continuing operation	<b><u>(3,666)</u></b>	<b><u>(3,089)</u></b>
* Loss from discontinued operation		
Share-based compensation and options expenses:		
Cost of revenues	101	132
Research and development	122	346
Selling, general & administrative	464	783
Equity-based compensation continuing operations	<b><u>687</u></b>	<b><u>1,261</u></b>



Source: MediWound

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