

MediWound Reports Fourth Quarter and Year End 2014 Financial Results

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

YAVNE, Israel--(BUSINESS WIRE)-- 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 and 12 months ended December 31, 2014.

Highlights of the fourth quarter of 2014 and recent weeks include:

- Completed recruitment of the Company's commercial team to support the ongoing commercial launch of NexoBrid[®] in Europe
- Launched NexoBrid in the U.K., Italy, Poland and Belgium
- Expanded the global distribution channels of NexoBrid through an agreement in Mexico

Management Commentary

"2014 was a transformational year for MediWound as we advanced from a privately held, development-stage company to a publicly traded commercial enterprise with operations across Europe and distribution agreements in Latin America, Russia and Asia," stated Gal Cohen, President and Chief Executive Officer of MediWound.

"We are pleased with the meaningful commercial and clinical progress in the fourth quarter and throughout the year. Our commercial activities in Europe are on plan with recent product launches of NexoBrid in the U.K, Italy, Poland and Belgium. We completed recruitment of our European commercial team and are training clinical staff at major burn centers. Our on-site training programs are resulting in continued success with increasing awareness of NexoBrid and use of the product. Experience with NexoBrid among the growing number of medical reference points will further increase physician confidence and use, and supports accelerated adoption.

"We have achieved many milestones during 2014, including the build out of a full-blown commercial organization and the launch of NexoBrid in nearly all our target markets in Europe. We also expanded NexoBrid's global reach with four new distribution agreements and obtained marketing authorization in Israel. In addition, we initiated our NexoBrid phase 3 study in pediatric patients in Europe and our EscharEx phase 2 study. Importantly, we received a 3 year extension of our cGMP accreditation for our production site following a successful inspection by the Israeli Ministry of Health.

"We look forward to achieving a number of value-creating milestones during 2015, as our launches in Europe and our clinical studies continue to gain traction. Throughout the coming year, we look forward to expanding our launch in Europe, as well as to initiating the U.S. phase 3 study and reporting top line results from our EscharEx phase 2 study," concluded Mr. Cohen.

Fourth Quarter Financial Results

Revenues for the fourth quarter of 2014 of \$124,000 substantively increased compared to the previous nine months of 2014, primarily from sales of NexoBrid in Germany.

Operating expenses for the fourth quarter of 2014 were \$5.6 million, in line with our expectations, compared with \$2.2 million for the fourth quarter of 2013. The increase was primarily due to \$1.5 million of commercial activities associated with building the European marketing infrastructure, \$0.8 million of research and development activities related to clinical development and a \$1.0 million increase in non-cash stock-based compensation expense.

For the fourth quarter of 2014, the Company reported a net loss of \$7.1 million, or \$0.33 per share.

Adjusted EBITDA, as defined below, for the fourth quarter of 2014 was (\$5.3) million compared with (\$1.9) million for the same quarter last year.

Full year Financial Results

The Company generated initial revenues from sales of NexoBrid in 2014 of \$259,000, the majority of which was generated from sales of NexoBrid in Germany.

Operating expenses for the year ended December 31, 2014 were \$18.9 million, in line with our expectations, compared with \$7.6 million for the same period of 2013. The increase was primarily due to \$5.1 million of commercial activities associated with building the European marketing infrastructure, \$4.3 million increase in non-cash stock-based compensation expense and \$1.3 million due to expenses related to being a public company in the United States (including \$0.6 million of one-time expenses in connection with our initial public offering).

For the year ended December 31, 2014, the Company reported a net loss of \$18.9 million, or \$0.95 per share.

Adjusted EBITDA, as defined below, for the year ended December 31, 2014 was (\$15.5) million compared with (\$6.7) million for the same period last year.

Balance Sheet Highlights

As of December 31, 2014, the Company had \$64.9 million in cash and short term deposits, and working capital of \$64.6 million. The Company remains on track with regard to cash use and used \$16.5 million in cash during the full year ended December 31, 2014 to fund ongoing operating activities.

During 2015, the Company will continue to primarily invest in its marketing infrastructure in Europe, to advance the commercialization of NexoBrid across Europe and in research and development efforts to develop our products for additional territories and indications. As a result, cash use for the year is expected to be in the range of \$20 million to \$22 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 (domestic) or (678) 894-3057 (international) and entering passcode 72940579. The call also will be broadcast live on the Internet at <u>www.streetevents.com</u> and <u>www.mediwound.com</u>.

A replay will be available beginning two hours after the completion of the live call through February 18, 2015 by dialing (855) 859-2056 (domestic) or (404) 537-3406 (international) and entering passcode 72940579. The call will also be archived for 90 days at <u>www.streetevents.com</u> and <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

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.

- Financial Tables to Follow -

U.S. dollars in thousands		
	Decem	ber 31,
	2013	2014
	Audited	Audited
CURRENT ASSETS:		
Cash, cash equivalents and short term deposits	9,553	64,853
Accounts and other receivable	2,512	2,223
Inventories		1,421
	12,065	68,497
LONG-TERM ASSETS:		
Long term deposits and deferred costs	204	168
Property, plant and equipment, net	1,136	1,088
Intangible assets, net	1,004	951
Other assets	417	417
	14,826	71,121
CURRENT LIABILITIES:		
Trade payables	1,180	1,214
Accrued expenses and other payables	843	2,683
Total current liabilities	2,023	3,897
LONG-TERM LIABILITIES:		
Liabilities in respect of Chief Scientist government grants net of current maturities	6,604	6,985
Contingent consideration for the purchase of treasury shares net of current maturities	16,800	17,361
Warrants to shareholders	9,200	-
Severance pay liability, net	3	7
SHAREHOLDERS' EQUITY (DEFICIENCY)	(19,804)	42,871
	14,826	71,121

CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME

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

		Year ended December 31,		nths ended ber 31,
	2013	2013 2014		2014
	Audited	Audited	Unaudited	Unaudited
Revenues		259		124
Cost of revenues		2785		1142

Gross loss		(2,526)		(1,018)
Operating expenses:				
Research and development, net	3,635	5,349	726	1,496
Selling and marketing	2,259	8,829	1,005	2,852
General and administrative-	1,687	4,723	441	1,220
Total operating expenses	7,581	18,901	2,172	5,568
Operating loss	(7,581)	(21,427)	(2,172)	(6,586)
Financial income	2,401	4,665	2,401	54
Financial expense	(3,321)	(2,113)	(761)	(562)
Loss from continuing operations	(8,501)	(18,875)	(532)	(7,094)
Loss from discontinued operation	(6,850)		(180)	0
Loss for the period	(15,351)	(18,875)	(712)	(7,094)
Foreign currency translation adjustments	(32)	14	(24)	(27)
Total comprehensive loss	(15,383)	(18,861)	(736)	(7,121)
Basic and diluted loss per share:				
Loss from continuing operations	(0.54)	(0.95)	(0.04)	(0.33)
Loss from discontinued operation	(0.44)	-	(0.01)	-
Net loss per share	(0.98)	(0.95)	(0.05)	(0.33)

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS

U.S. dollars in thousands

	Year ended December 31,		three months ended December 31,		
	2013 2014		2013	2014	
	Audited	Audited	Unaudited	Unaudited	
Operating Activities:					
Net Income (loss)	(15,351)	(18,875)	(712)	(7,094)	
Adjustments to reconcile net income (loss) to net cash used in continuing operating activities:					
Loss from discontinued operation	6,850	-	180	-	
Depreciation and amortization	336	492	81	88	
Revaluation of warrants to shareholders	820	(4,491)	760	-	
Share-based compensation	531	4,827	228	1,204	
Revaluation of liabilities in respect of Chief Scientist government grants	(106)	87	(466)	55	
Revaluation of contingent consideration for the purchase of treasury shares	(2,400)	612	(2,600)	55	
Accrued interest in respect of financial loans	1,669	-	-	-	
Net financing expenses (income)	(35)	226	5	(52)	
Changes in asset and liability items:					
Increase in trade receivables	-	(67)	-	(46)	
Decrease (increase) in other receivables	(532)	186	(328)	103	
(Increase) decrease in inventories	-	(1,421)	(349)	161	
Increase in trade payables	405	22	604	301	
(Decrease) increase in other payables	(262)	1,909	(262)	844	
Net cash used in continuing operating activities	(8,075)	(16,493)	(2,859)	(4,381)	
Net cash used in discontinued operating activities	(1,665)		(1,886)		
Net cash flows used in operating activities	(9,740)	(16,493)	(4,745)	(4,381)	

Purchase of property and equipment	(268)	(366)	(33)	61 (20)
Purchase of intangible assets Interest received	(90) 3	(30) 173	(90) 3	(30) 128
Proceeds from (investment in) short term bank deposits, net of investments	(2,500)	(36,931)	(2,500)	10,643
Net cash provided by (used in) investing activities	,	(37,154)	(2,620)	10,802
	(2,000)	(37,134)	(2,020)	10,002
Financing Activities:				
Proceeds from exercise of options	279	306	-	98
Proceeds from issuance of shares and warrants, net	15,800	71,824	-	-
Proceeds from shareholders' loans	3,930	-	-	-
Repayment of shareholders' loans	(915)	-	-	-
Deferred issuance costs	(129)	-	(129)	-
Proceeds from the Chief Scientist government grants	276	345	258	66
Net cash provided by financing activities	19,241	72,475	129	164
Exchange rate differences on cash and cash equivalent balances	70	(459)	8	(96)
Increase (decrease) in cash and cash equivalents from continuing				
activities	8,311	18,828	(5,350)	6,585
(Decrease) increase in cash and cash equivalents from discontinued activities	(1,665)	-	221	-
Balance of cash and cash equivalents at the beginning of the period	337	7,053	12,174	18,933
Balance of cash and cash equivalents at the end of the period	7,053	25,422	7,053	25,422

RECONCALIATION OF NET LOSS TO ADJUSTED EBITDA U.S. dollars in thousands

	Year ended		Three months ended		
	December 31,		Decem	nber 31,	
	2013	2014	2013	2014	
Loss for the period	(15,351)	(18,875)	(712)	(7,094)	
Adjustments:					
Financial (expenses) income, net	(920)	2,552	1,640	(508)	
Loss from discontinued operation	(6,850)	-	(180)		
Depreciation and amortization	(335)	(492)	(80)	(88)	
Share-based compensation expenses	(531)	(4,827)	(228)	(1,204)	
One-time IPO related expenses	-	(567)	-	(56)	
Total adjustments	(8,636)	(3,334)	1,152	(1,856)	
Adjusted EBITDA from continuing operation	(6,715)	(15,541)	(1,864)	(5,238)	

Share-based compensation expenses:

Cost of revenues	-	763	-	188
Research and development	315	657	129	163
Selling and marketing	24	1,430	24	351
General and administrative	192	1,977	75	502
Share-based compensation	531	4,827	228	1,204

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