

MediWound Reports Second Quarter 2014 Financial Results

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

YAVNE, Israel, July 31, 2014 (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 and six months ended June 30, 2014.

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

- Completed recruitment of a commercial management team in Europe to support the planned commercial launch in Europe
- Expanded global distribution of NexoBrid® through agreements in Russia and in South Korea
- Received marketing approval for NexoBrid in Israel from the Israel Ministry of Health (IMOH)
- Successfully completed a Good Manufacturing Practice (GMP) audit of the Company's facility in Yavne, Israel by IMOH
- Initiated a second Phase 2 clinical trial of EscharEx™ to treat chronic and other harto-heal wounds

Management Commentary

"We made continued progress with our strategic plan throughout the second quarter of 2014 in key areas including commercial, manufacturing, clinical development and corporate leadership," stated Gal Cohen, President and Chief Executive Officer of MediWound.

"Our commercial launch in Europe continues to proceed on plan, initially in Germany, where we have completed the clinical training of all major burn centers and our awareness and educational programs are producing results. Plans for expansion into other European countries in the second half of 2014 are on track, with experienced country managers hired in each geography. We continue to enhance awareness of NexoBrid and build enthusiasm by participating in regional and national medical conferences where we showcase compelling clinical data that demonstrate NexoBrid's ability to promptly and effectively remove the eschar from severe burns, thereby allowing clinicians to visually assess burn severity.

"International expansion progressed as we signed distribution agreements for NexoBrid in Russia and South Korea. We intend to build upon this foundation with additional distributors serving other countries in Latin America, CIS and Asia-Pacific with the goal of driving NexoBrid sales and creating value for our stakeholders. In addition, we were very pleased with our recent marketing approval from the Israeli Ministry of Health for NexoBrid and look forward to a commercial launch in the coming quarter.

"We made further progress with our U.S. Phase 3 trial of NexoBrid to treat severe burns and submitted the final protocol to the Investigational Review Board (IRB) at clinical trial sites. We believe these protocols will be reviewed and approved in the third quarter and that we can initiate the study soon thereafter. We have also submitted the final protocol to the IRBs for our post-marketing pediatric study of NexoBrid to treat severe burns in children in Europe, and expect to begin that study in the third quarter as well.

"We advanced our product pipeline during the quarter with the initiation of a second Phase 2 trial with EscharExTM to treat chronic and other hard-to-heal wounds. This study is expected to build upon and support the earlier feasibility study that demonstrated efficacy in debriding various wound etiologies such as diabetic foot ulcers, venous ulcers, pressure sores and other post-surgical or post-trauma hard-to-heal wounds. We believe this program offers tremendous opportunity in a multibillion-dollar market with significant unmet medical need.

"Our team continues to execute on our work plan and we believe the progress we've made combined with the significant opportunities ahead, allow MediWound to build value for our shareholders throughout the second half of 2014 and beyond," concluded Mr. Cohen.

Second Quarter Financial Results

Revenue for the second quarter of 2014 were de minimis, as the Company initially launched NexoBrid in Germany, with efforts focused on preliminary onsite training and hands-on demonstrations in burn centers throughout Germany.

Operating expenses for the second quarter of 2014 were \$4.5 million compared with \$1.7 million in the second quarter of 2013. The increase was primarily due to \$1.4 million of commercial activities associated with building the European marketing infrastructure and a \$1.0 million increase in non-cash share based compensation expenses.

For the second quarter of 2014, the Company posted a net loss of \$6.0 million, or \$0.28 per share.

Adjusted EBITDA, as defined below, for the second quarter of 2014 was (\$3.9) million compared with (\$1.5) million for the same quarter last year.

Six Month Financial Results

The Company generated initial insignificant revenues from sales of NexoBrid in the first half of 2014.

Operating expenses for the first six months of 2014 were \$8.8 million compared with \$3.1 million in the first half of 2013. The increase was primarily due to \$2.5 million of commercial activities associated with building the European marketing infrastructure and a \$2.2 million increase in non-cash share based compensation expenses.

For the first six months ended June 30, 2014, the Company posted a net loss of \$6.8 million, or \$0.37 per share.

Adjusted EBITDA, as defined below, for the first six months of 2014 was (\$6.6) million compared with (\$2.8) million for the same period last year.

Balance Sheet Highlights

As of June 30, 2014, the Company had \$73.6 million in cash and cash equivalents and working capital of \$74.4 million. The Company used \$7.6 million in cash during the first six months of 2014 to fund ongoing operating activities.

During 2014, the Company plans to continue to build its marketing infrastructure in Europe, fund further clinical development of NexoBrid, support efforts to obtain regulatory approvals worldwide and initiate plans to scale up manufacturing capabilities.

Conference Call

MediWound management will host a conference call for investors 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 72748741. The call also will be broadcast live on the Internet at www.mediwound.com.

A replay of the call will be accessible two hours after its completion through August 6, 2014 by dialing (855) 859-2056 (domestic) or (404) 537-3406 (international) and entering passcode 72748741. The call will also be archived for 90 days at www.streetevents.com and 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 that 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, 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 -

June 20 December 21

CONDENSED CONSOLIDATED UNAUDITED BALANCE SHEETS

U.S. dollars in thousands

	June 30,	December 31,
	2014	2013
CURRENT ASSETS:		
Cash, cash equivalents and short term deposits	73,578	9,553
Accounts receivable	2,564	2,512
Inventories	1,311	
	77,453	12,065
LONG-TERM ASSETS:		
Long term deposits and deferred costs	161	204
Property, plant and equipment, net	1,204	1,136
Intangible assets, net	966	1,004
Derivative instruments		
Other assets	417	417
	80,201	14,826
CURRENT LIABILITIES:		
Current maturities of Financials Liabilities	305	
Accounts payables and accruals	2,798	2,023
	3,103	2,023
LONG-TERM LIABILITIES:		
Liabilities in respect of Chief Scientist government grants net of current maturities	6,914	6,604
Contingent consideration for the purchase of treasury shares net of current maturities	17,753	16,800

Warrants to shareholders		9,200
Severance pay liability, net	3	3
	24,670	32,607
SHAREHOLDERS' EQUITY (DEFICIT)	52,428	(19,804)
	80,201	14,826
Working capital, net	74,350	10,042

CONDENSED CONSOLIDATED UNAUDITED STATEMENTS OF COMPREHENSIVE INCOME

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

	Six months ended June 30,		Three months ended June 30,	
	2014	2013	2014	2013
Revenues	89		39	
Cost of revenues	893		723	
Gross loss	(804)		(684)	
Operating expenses:				
Research and development, net	2,826	1736	1,361	979
Selling and marketing	3,725	552	2,110	312
General and administrative	2,263	819	996	408
Total operating expenses	8,814	3,107	4,467	1,699
Operating loss	(9,618)	(3,107)	(5,151)	(1,699)
Financial income	4,552		58	
Financial expense	(1,698)	(2,438)	(936)	(1,553)
Loss from continuing operations	(6,764)	(5,545)	(6,029)	(3,252)
Income (loss) from discontinued operation		(1,928)	14	(1,083)
Loss for the period	(6,764)	(7,473)	(6,015)	(4,335)
Foreign currency translation adjustments	7		17	
Total comprehensive loss	(6,757)	(7,473)	(5,998)	(4,335)
Basic and diluted loss per share:				
Loss from continuing operations	(0.37)	(0.36)	(0.28)	(0.21)
Loss from discontinued operation		_(0.12)_	(*)	(0.07)
Net loss per share	(0.37)	(0.48)	(0.28)	(0.28)
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Weighted average number of ordinary shares used in the computation of basic and diluted loss per share:	18,524	15,729	21,298	15,751

(*)Represents less than \$0.01.

CONDENSED CONSOLIDATED UNAUDITED STATEMENTS OF CASH FLOWS

U.S. dollars in thousands

	June 30,		June 30,	
	2014	2013	2014	2013
Cash Flows from Operating Activities:	_	_	_	_ _
Net loss	(6,764)	(7,473)	(6,015)	(4,335)
Adjustments to reconcile net loss to net cash used in continuing operating activities:				
Adjustments to profit and loss items:				
Loss (income) from discontinued operation		1,928	(14)	1,083
Depreciation and amortization	254	124	137	59
Revaluation of warrants to shareholders	(4,491)			
Share-based compensation	2,377	193	1,116	134
Revaluation of liabilities in respect of Chief Scientist government grants	326	447	185	225
Revaluation of contingent consideration for the purchase of treasury shares	1,234	700	648	200
Accrued interest in respect of financial loans		1,284		1,116
Net financing expenses	(18)	(8)	(4)	(2)
	(318)	4,668	2,068	2,815
Changes in asset and liability items:				
Increase in trade receivables	(14)		2	
Decrease (increase) in other receivables	(126)	155	(134)	130
Increase in inventories	(1,312)		(503)	
Increase in trade payables	89	16	448	214
Increase (decrease) in other payables	682	(323)	(410)	(542)
	(681)	(152)	(597)	(198)
Net cash used in continuing operating activities	(7,763)	(2,957)	(4,544)	(1,718)
Net cash used in (provided by) discontinued operating activities		(1,077)	14	(655)
Net cash flows used in operating activities	(7,763)	(4,034)	(4,530)	(2,373)
Cash Flows from Investing Activities:				
Purchase of property and equipment	(284)	(117)	(210)	(92)
Interest received	29		26	
Proceeds from (investment in) short term bank deposits, net of investments	(50,262)		(52,762)	
Net cash provided by (used in) investing activities	(50,517)	(117)	(52,946)	(92)
Cash Flows from Financing Activities:				
Proceeds from exercise of options	208	279		
Proceeds from issuance of shares and warrants, net	71,824		(2,258)	
Proceeds from shareholders' loans		3,930		2,485
Proceeds from the Chief Scientist government grants	27		15	
Net cash provided by (used in) financing activities	72,059	4,209	(2,243)	2,485
Exchange rate differences on cash and cash equivalent balances	(16)	8	(35)	2
Increase in cash and cash equivalents from continuing activities	13,763	1,143	(59,768)	677
Decrease in cash and cash equivalents from discontinued activities		(1,077)	14	(655)
Balance of cash and cash equivalents at the beginning of the period	7,053	337	80,570	381
Balance of cash and cash equivalents at the end of the period	20,816	403	20,816	403
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Exercise of cashless warrants into shares	4,709			
	34,600		34,600	
Treasury shares cancellation against ordinary shares and share premium	- 7,000			

ADJUSTED EBITDA

Six months ended Three months ended

	June 30,		June 30,	
	2014	2013	2014	2013
Loss for the period	(6,764)	(7,473)	(6,015)	(4,335)
Adjustments:				
Financial (expenses) income, net	2,854	(2,438)	(878)	(1,553)
Other (expenses) income *		(1,928)	14	(1,083)
Depreciation and amortization	(254)	(124)	(137)	(59)
Share-based compensation expenses	(2,377)	(193)	(1,116)	(134)
One-time IPO related expenses	(400)			
Total adjustments	(177)	(4,683)	(2,117)	(2,829)
Adjusted EBITDA from continuing operation	(6,587)	(2,790)	(3,898)	(1,506)
Stock-based compensation and options expenses:				
Cost of revenues	379		190	
Research and development	323	115	34	95
Selling and marketing	708		406	
General and administrative	967	78	486	39
Share-based compensation continuing operations	2,377	193	1,116	134
Discontinuing operation Equity-based compensation		38		4
Total share-based compensation expenses	2,377	231	1,116	138

^{*} Loss from discontinued operation