

MediWound Reports Third Quarter 2015 Financial Results

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

YAVNE, Israel, Oct. 27, 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 and nine months ended September 30, 2015.

Highlights of the third quarter of 2015 and recent weeks include:

- Awarded contract from the U.S. Biomedical Advanced Research and Development Authority (BARDA) valued at up to \$112 million for the development and procurement of NexoBrid for the U.S.
- Completed enrollment in second Phase 2 clinical trial with EscharEx® to treat chronic and other hard-to-heal wounds
- Received approval from Argentina's Ministry of Health for NexoBrid[®] to treat severe burns
- NexoBrid highlighted in more than two dozen clinical presentations at the 16th European Burns Association Congress

Management Commentary

"Throughout the third quarter we advanced our global commercial and clinical programs while significantly elevating the profile of both our lead product and our company. Our contract with BARDA provides up to \$24 million of non-dilutive funding for our ongoing U.S. development program for NexoBrid, along with an initial commitment to procure \$16 million of product for stockpiling and provides BARDA with options for additional funding of up to \$72 million. Importantly, this contract also highlights an additional opportunity to aid countries in their efforts for preparedness in advance of mass casualties, whether military or civilian," stated Gal Cohen, President and Chief Executive Officer of MediWound.

"We have completed enrollment in our second Phase 2 clinical study with EscharEx for the debridement of chronic wounds and are on track to report top-line results around the end of the year. We believe that since EscharEx is based on the same technology as NexoBrid, the wealth of development data supporting NexoBrid, which is an approved drug, as well as the clinical data from our first Phase 2 feasibility study in treating chronic and hard-to-heal wounds, de-risks EscharEx development. The enthusiasm for the potential of EscharEx to treat chronic and hard-to-heal wounds is supported by the results of the market study that surveyed more than 200 health care professionals as well as the feedback of a U.S. advisory board, both indicating that EscharEx represents a significant commercial opportunity within the multibillion-dollar chronic wound care market, where more than a million patients with diabetic foot ulcers and venous leg ulcers in the U.S. alone undergo debridement every year.

"Following the recent marketing authorization of NexoBrid in Argentina, we look forward to a commercial launch in 2016 by our exclusive distribution partner, Tuteur S.A. This approval supports our global commercial strategy to leverage our marketing authorization from the European Medicines Agency to expand NexoBrid into emerging markets mainly in Latin America, Asia Pacific and the CIS. We look forward to additional approvals in these regions while seeking to expand our distribution channels to other markets through ongoing business development efforts.

"The magnitude of positive NexoBrid data presented in dozens of clinical presentations by burn experts from numerous countries at the recent European Burns Association Congress underscores the growing interest in and adoption of NexoBrid for the treatment of severe burns throughout Europe. The breadth of clinical data presented clearly supports the transformation of NexoBrid from a novel therapy to standard-of-care treatment for severe burns. We look forward to amplifying the awareness and interest in NexoBrid among U.S. burn experts as we advance our U.S. Phase 3 clinical trial of NexoBrid, with plans to report top-line results on the acute primary and secondary endpoints in the first half of 2017," concluded Mr. Cohen.

Third Quarter Financial Results

Revenues for the third quarter of 2015 were \$102,000 compared with \$46,000 for the same quarter last year.

Operating expenses for the third quarter of 2015 were in line with the Company's budget at \$3.6 million, compared with \$4.5 million for the third quarter of 2014. The decrease was primarily due to \$0.6 million decrease in non-cash share-based compensation expense.

For the third quarter of 2015, the Company posted a net loss of \$3.8 million, or \$0.17 per share, compared with a loss of \$5.0

million, or \$0.24 per share, for the third quarter of 2014. The decrease was primarily due to net financial income, which was largely comprised of non-cash revaluation of contingent liabilities.

Adjusted EBITDA, as defined below, for the third quarter of 2015 was a loss of \$3.6 million, compared with a loss of \$3.7 million for the same quarter last year.

Nine Months Financial Results

Revenues for the first nine months of 2015 were \$334,000 compared with \$135,000 for the same period last year.

Operating expenses for the first nine months of 2015 were \$12.9 million, in line with the Company's budget, compared with \$13.3 million for the same period of 2014. The decrease was primarily due to a \$1.7 million decrease in non-cash share-based compensation expense offset by an increase of \$1.3 million in commercial activities associated with the continued build-out of the European marketing infrastructure.

For the nine months ended September 30, 2015, the Company posted a net loss of \$14.3 million, or \$0.66 per share, compared with a loss of \$11.7 million, or \$0.61 per share, for nine months ended September 30, 2014. The increase was primarily due to one-time net financial income recognized in 2014, which was largely comprised of non-cash revaluation of warrants.

Adjusted EBITDA for the nine months ended September 30, 2015 was a loss of \$12.1 million, compared with a loss of \$10.3 million for the same period last year.

Balance Sheet Highlights

As of September 30, 2015 the Company had cash and short-term deposits of \$49.9 million and working capital of \$50.2 million. The Company utilized \$14.7 million in cash during the period ended September 30, 2015 to fund operating activities, in line with the Company's budget and guidance.

MediWound now expects 2015 full-year cash use for ongoing operating activities will be approximately \$20 million, reflecting anticipated investment in its sales and marketing activities to advance the commercialization of NexoBrid across Europe and in research and development, net of participation by BARDA.

Conference Call

MediWound management will host a conference call for investors on October 28, 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 7048275. 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 until midnight November 4, 2015 Eastern time by dialing (866) 932-5017 or (800) 358-7735 (UK) and entering passcode 7048275. The call will also be archived for 90 days 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 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 expense.

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 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 and Israel. 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. 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, 2014 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.

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-Financial Tables to Follow-

CONDENSED CONSOLIDATED UNAUDITED BALANCE SHEETS

U.S. dollars in thousands			
	Septen	nber 30 <u>,</u>	December 31,
	2015	2014	2014
	Unaudited		Audited
CURRENT ASSETS:			
Cash, cash equivalents and short term deposits	49,948	69,007	64,853
Accounts and other receivable	2,009	2,356	2,223
Inventories	1,639	1,512	1,421
	53,596	72,875	68,497
LONG-TERM ASSETS:			
Long term deposits and deferred costs	234	151	168
Property, plant and equipment, net	1,096	1,209	1,088
Intangible assets, net	887	945	951
Other assets		417	417
	55,813	75,597	71,121

CURRENT LIABILITIES:

1,253	797	1,214
2,121	2,002	2,683
3,374	2,799	3,897
6,161	6,825	6,985
15,721	17,279	17,361
7	3	7
21,889	24,107	24,353
30,550	48,691	42,871
55,813	75,597	71,121
	2,121 3,374 6,161 15,721 7 21,889 30,550	2,121 2,002 3,374 2,799 6,161 6,825 15,721 17,279

CONDENSED CONSOLIDATED UNAUDITED STATEMENTS OF COMPREHENSIVE INCOME

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

	Nine months ended September 30,		Three months ended September 30,	
	2015	2014	2015	2014
Revenues	334	135	102	46
Cost of revenues	1,830	1,643	824	750
Gross loss	(1,496)	(1,508)	(722)	(704)
Operating expenses:				
Research and development, net	3,727	3,853	836	1,027
Selling, general & administrative	9,174	9,480	2,805	3,492
Total operating expenses	12,901	13,333	3,641	4,519
Operating loss	(14,397)	(14,841)	(4,363)	(5,223)
Financial income, net	506	3,060	597	206
Loss from continuing operations	(13,891)	(11,781)	(3,766)	(5,017)
Loss from discontinued operation	(417)			
Loss for the period	(14,308)	(11,781)	(3,766)	(5,017)
Foreign currency translation adjustments	1	41		34
Total comprehensive loss	(14,307)	(11,740)	(3,766)	(4,983)
Basic and diluted loss per share:				
Loss from continuing operations	(0.64)	(0.61)	(0.17)	(0.24)
Loss from discontinued operation	(0.02)			
Net loss per share	(0.66)	(0.61)	(0.17)	(0.24)
Weighted average number of ordinary shares used in the computation of basic and diluted loss per share:	21,674	19,448	21,801	21,298

CONDENSED CONSOLIDATED UNAUDITED STATEMENTS OF CASH FLOWS

	September 30,		September 30,	
	2015	2014	2015	2014
Cash Flows from Operating Activities:				
Net loss	(14,308)	(11,781)	(3,766)	(5,017)
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	350	404	120	150
Revaluation of warrants to shareholders		(4,491)		
Share-based compensation	1,960	3,623	657	1,246
Revaluation of liabilities in respect of Chief Scientist government grants	(944)	32	(894)	(294)
Revaluation of contingent consideration for the purchase of treasury shares	(1,361)	557	(870)	(677)
Net financing expenses (income)	(10)	278	(63)	296
	412	403	(1,050)	721
Changes in asset and liability items:				
Decrease (increase) in trade receivables	(47)	(21)	16	(7)
Decrease in other receivables	110	83	121	209
Decrease (increase) in inventories	(357)	(1,582)	139	(270)
Decrease in trade payables	48	(279)	(980)	(368)
Increase in other payables	(572)	1,065	256	383
	(818)	(734)	(448)	(53)
Net cash used in continuing operating activities	(14,714)	(12,112)	(5,264)	(4,349)
Cash Flows from Investment Activities:				
Purchase of property and equipment	(298)	(427)	(129)	(143)
Interest received	84	45	58	16
Proceeds from (investment in) short term bank deposits, net of investments	14,176	(47,574)	16,072	2,688
Net cash provided by (used in) investing activities	13,962	(47,956)	16,001	2,561
Cash Flows from Financing Activities:				
	26	208	6	
Proceeds from exercise of options				
Proceeds from exercise of options Proceeds from issuance of shares and warrants, net				
Proceeds from issuance of shares and warrants, net		71,824 279		 252
Proceeds from issuance of shares and warrants, net Proceeds from the Chief Scientist government grants, net of repayments	 109	71,824 		
Proceeds from issuance of shares and warrants, net Proceeds from the Chief Scientist government grants, net of repayments Net cash provided by financing activities	109 135	71,824 279 72,311	34 40	252
Proceeds from issuance of shares and warrants, net Proceeds from the Chief Scientist government grants, net of repayments Net cash provided by financing activities Exchange rate differences on cash and cash equivalent balances	109 135 (255)	71,824 279 72,311 (363)	34 40 (4)	252 (347)
Proceeds from issuance of shares and warrants, net Proceeds from the Chief Scientist government grants, net of repayments Net cash provided by financing activities	109 135	71,824 279 72,311	34 40	252

Nine months ended Three months ended

ADJUSTED EBITDA

U.S. dollars in thousands

 September 30,
 September 30,

 2015
 2014

 2015
 2014

Loss for the period	(14,308)	(11,781)	(3,766)	(5,017)
Adjustments:				
Financial (expenses) income, net	506	3,060	597	206
Loss from discontinued operation	(417)			
Depreciation and amortization	(350)	(404)	(120)	(150)
Share-based compensation expenses	(1,960)	(3,623)	(657)	(1,246)
One-time IPO related expenses		(511)		(111)
Total adjustments	(2,221)	(1,478)	(180)	(1,301)
Adjusted EBITDA from continuing operation	(12,087)	(10,303)	(3,586)	(3,716)
Share-based compensation and options expenses:				
Cost of revenues	271	575	68	196
Research and development	375	494	128	171
Selling and marketing	480	1,079	181	371
General and administrative	834	_1,475_	280	508
Total share-based compensation expenses	1,960	3,623	657	1,246