November 14, 2016

MediWound Reports Third Quarter 2016 Financial Results

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

YAVNE, Israel, Nov. 14, 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 and nine months ended September 30, 2016.

Highlights of the third quarter of 2016 include:

- Third quarter 2016 Revenue of $518,000 compared with $102,000 in the prior year's third quarter, underscoring the Company's progress growing NexoBrid® sales;
- U.S. Phase 3 clinical trial protocol for NexoBrid to debride severe burns amended to increase the Total Body Surface Area (TBSA) of burn patients eligible for the study from 15% to 30%; and
- Multiple oral and poster presentations highlighting EscharEx® and NexoBrid's innovative, effective and fast enzymatic debriding of severe burns and chronic wounds presented at the 18th Congress of the International Society for Burn Injuries (ISBI).

Management Commentary

"Our third quarter financial performance demonstrates progress in converting NexoBrid use into revenues. The presentation of positive data at major burn meetings such as the ISBI continues to enhance interest as we work to transition NexoBrid to the standard-of-care for the debridement of severe burns," stated Gal Cohen, President and Chief Executive Officer of MediWound. "Following discussions with U.S. Food and Drug Administration (FDA), we amended the protocol for our U.S. Phase 3 study of NexoBrid, to increase the TBSA of patients eligible for inclusion from 15% to 30%. This amendment will allow for the inclusion of patients with larger TBSA and should support a broader marketing label. With the expansion of TBSA, we are required to collect additional data on this cohort of patients, which will require implementation of certain study adjustments. As a result, we now expect to have the acute top-line data in the first half of 2018.

"Earlier this year we were delighted to report compelling clinical efficacy and safety data from our Phase 2 study of EscharEx for the debridement of chronic and hard-to-heal wounds, particularly in diabetic foot ulcers and venous leg ulcers. We plan to submit our data package to the FDA by year-end, and expect to meet with the Agency in early 2017 to discuss a pivotal program for EscharEx in the U.S. We are excited to be advancing our clinical plan forward with the goal of making EscharEx available for the treatment of these indications.

"We continued to make progress across all key areas of our business, including growing revenues and advancing our clinical studies, all while maintaining financial discipline. We look forward to advancing our programs during the balance of 2016 and expect to build upon these achievements throughout 2017," added Mr. Cohen.

Third Quarter Financial Results

Revenues for the third quarter of 2016 were $518,000 compared with $102,000 for the third quarter of 2015.

Net research and development expenses for the third quarter of 2016 of $2.4 million compare with $0.8 million for the third quarter of 2015. The increase was primarily due to an incremental $1.2 million related to NexoBrid clinical trials and $0.8 million related to EscharEx and MWPC003 development, partially offset by $0.5 million of additional participation by the U.S. Biomedical Advanced Research and Development Authority (BARDA) and the Israeli Office of the Chief Scientist.

Sales, marketing and G&A expenses were $2.6 million for the third quarter of 2016 compared with $2.8 million for the third quarter of 2015.

For the third quarter of 2016, the Company posted a net loss of $5.7 million, or $0.26 per share, compared with a net loss of $3.8 million, or $0.17 per share, for the third quarter of 2015. The increase was primarily due to higher net research and development expenses of $1.5 million.

Adjusted EBITDA, as defined below, for the third quarter of 2016 was a loss of $4.2 million, compared with a loss of $3.6 million for the third quarter of 2015.

Nine Months Financial Results

Revenues for the first nine months of 2016 were $1.1 million compared with $0.3 million for the same period of 2015.

Operating expenses for the first nine months of 2016 were $15.5 million, in line with the Company's budget, and compare with $12.9 million for the same period of 2015. The increase was primarily due to higher net research and development expenses of $2.3 million and a $0.3 million increase in non-cash share-based compensation expense. The increase in net research and development expenses was primarily due to an increase of $3.7 million related to NexoBrid clinical trials, as well as $2.4 million related to EscharEx and MWPC003 development, which was partially offset by $3.6 million of additional participation from BARDA.

For the nine months ended September 30, 2016, the Company posted a net loss of $17.0 million, or $0.78 per share, compared with a net loss of $14.3 million, or $0.66 per share, for the same period in 2015.

Adjusted EBITDA, as defined below, for the first nine months of 2016 was a loss of $12.9 million, compared with a loss of $12.1 million for the first nine months of 2015.

Balance Sheet Highlights

As of September 30, 2016 the Company had cash and short-term deposits of $34.0 million and working capital of $32.6 million. The Company remained on budget and utilized $12.2 million in cash to fund operating activities during the first nine months of 2016.

During the remainder of 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, which is supported by BARDA funding, as well as to advance the development of EscharEx for chronic wounds and other pipeline product candidates.

The Company expects cash use for operating activities for the year ended December 31, 2016 to be in the range of $17 million to $20 million.

Conference Call

MediWound management will host a conference call for investors today, November 14, 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 90184006. The call also will be broadcast live on the Internet on the Company's website at www.mediwound.com.

A replay of the call will be accessible two hours after its completion through November 21, 2016 by dialing (855) 859-2056 (domestic) or (404) 537-3406 (international) and entering passcode 90184006. The call will also be archived on the Company website 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 its 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, 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 Israel and Argentina. 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 tissue.

MediWound's second innovative product, EscharEx®, is a topical biological drug being developed for debridement of chronic and other hard-to-heal wounds and is complementary to the large number of existing wound healing products, which require a clean wound bed in order to heal the wound. EscharEx contains the same proteolytic enzyme technology as NexoBrid, and benefits from the wealth of existing development data on NexoBrid. In two Phase 2 studies, EscharEx demonstrated safety and efficacy in the debridement of chronic and other hard-to-heal wounds, within a few daily applications.

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.

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CONDENSED CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands

	September 30,		December 31,
	2016	2015	2015
	Unaudited		Audited

CURRENT ASSETS:			
Cash, cash equivalents and short term deposits	33,956	49,948	45,768
Accounts and other receivable	2,606	2,009	2,912
Inventories	1,063	1,639	1,715
	37,625	**53,596**	**50,395**
LONG-TERM ASSETS:			
Long term deposits and deferred costs	103	234	192
Property, plant and equipment, net	1,362	1,096	1,040
Intangible assets, net	831	887	896
	2,296	**2,217**	**2,128**
	39,921	**55,813**	**52,523**
CURRENT LIABILITIES:			
Trade payables	1,031	1,253	1,123
Accrued expenses and other payables	3,950	2,121	4,083
	4,981	**3,374**	**5,206**
LONG-TERM LIABILITIES:			
Deferred revenues	1,067	-	-
Liabilities in respect of Chief Scientist government grants net of current maturities	7,637	6,161	7,275
Contingent consideration for the purchase of treasury shares net of current maturities	17,265	15,721	16,475
Severance pay liability, net	99	7	97
	26,068	**21,889**	**23,847**
SHAREHOLDERS' EQUITY	8,872	30,550	23,470
	39,921	**55,813**	**52,523**

CONDENSED CONSOLIDATED UNAUDITED STATEMENTS OF COMPREHENSIVE LOSS

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

	Nine months ended September 30,		Three months ended September 30,	
	2016	**2015**	**2016**	**2015**
Revenues	1,128	334	518	102
Cost of revenues	1,303	1,830	474	824
Gross loss	**(175)**	**(1,496)**	**44**	**(722)**
Operating expenses:				
Research and development, gross	11,420	5,295	3,947	1,944
Participation by OCS & others	(5,135)	(1,568)	(1,592)	(1,108)
Research and development, net	6,285	3,727	2,355	836
Selling, general & administrative	9,188	9,174	2,633	2,805
Total operating expenses	**15,473**	**12,901**	**4,988**	**3,641**
Operating loss	**(15,648)**	**(14,397)**	**(4,944)**	**(4,363)**
Financial income (expenses), net	(1,348)	506	(767)	597
Loss from continuing operations	**(16,996)**	**(13,891)**	**(5,711)**	**(3,766)**
Loss from discontinued operation	-	(417)	-	-
Loss for the period	**(16,996)**	**(14,308)**	**(5,711)**	**(3,766)**
Foreign currency translation adjustments	(4)	1	(1)	-
Total comprehensive loss	**(17,000)**	**(14,307)**	**(5,712)**	**(3,766)**
Basic and diluted loss per share:				
Loss from continuing operations	(0.78)	(0.64)	(0.26)	(0.17)
Loss from discontinued operation	-	(0.02)	-	-
Net loss per share	**(0.78)**	**(0.66)**	**(0.26)**	**(0.17)**
Weighted average number of ordinary shares used in the computation of basic and diluted loss per share:	21,853	21,674	21,857	21,801

CONDENSED CONSOLIDATED UNAUDITED STATEMENTS OF CASH FLOWS

U.S. dollars in thousands

	Nine months ended September 30,		Three months ended September 30,	
	2016	2015	2016	2015
	Unaudited		Unaudited	
Cash Flows from Operating Activities:				
Net loss	**(16,996)**	**(14,308)**	**(5,711)**	**(3,766)**
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	386	350	133	120
Share-based compensation	2,400	1,960	613	657
Revaluation of liabilities in respect of Chief Scientist government grants	(190)	(944)	(167)	(894)
Revaluation of contingent consideration for the purchase of treasury shares	1,180	(1,361)	641	(870)
Net financing (income) expenses	(367)	(10)	(107)	(63)
	3,409	**412**	**1,113**	**(1,050)**
Changes in asset and liability items:				
Increase in trade receivables	(245)	(47)	(90)	16
Increase in other receivables	425	110	754	121
Decrease (increase) in inventories	642	(357)	96	139
Increase (decrease) in trade payables	(97)	48	(539)	256
Increase in other payables	647	(572)	7	(980)
	1,372	**(818)**	**228**	**(448)**
Net cash flows used in operating activities	**(12,215)**	**(14,714)**	**(4,370)**	**(5,264)**
Cash Flows from Investment Activities:				
Purchase of property and equipment	(642)	(298)	(202)	(129)
Interest received	45	84	4	58
Proceeds from (investment in) short term bank deposits, net of investments	(25,239)	14,176	(1,505)	16,072
Net cash (used in) provided by investing activities	**(25,836)**	**13,962**	**(1,703)**	**16,001**
Cash Flows from Financing Activities:				
Proceeds from exercise of options	2	26	2	6
Proceeds from the Chief Scientist government grants, net of repayments	658	109	658	34
Net cash provided by financing activities	**660**	**135**	**660**	**40**
Increase in cash and cash equivalents	(37,391)	(617)	(5,413)	10,777
Exchange rate differences on cash and cash equivalent balances	71	(255)	1	(4)
Balance of cash and cash equivalents at the beginning of the period	42,502	25,422	10,594	13,777
Balance of cash and cash equivalents at the end of the period	**5,182**	**24,550**	**5,182**	**24,550**

ADJUSTED EBITDA

U.S. dollars in thousands

	Nine months ended September 30,		Three months ended September 30,	
	2016	2015	2016	2015
Loss for the period	(16,996)	(14,308)	(5,711)	(3,766)
Adjustments:				
Financial (expenses) income, net	(1,348)	506	(767)	597
Loss from discontinued operation	0	(417)	0	0
Depreciation and amortization	(386)	(350)	(133)	(120)
Share-based compensation expenses	(2,400)	(1,960)	(613)	(657)
Total adjustments	(4,134)	(2,221)	(1,513)	(180)
Adjusted EBITDA	**(12,862)**	**(12,087)**	**(4,198)**	**(3,586)**

Share-based compensation expenses:				
Cost of revenues	391	271	131	68
Research and development	579	375	194	128
Selling, general and administrative	1,430	1,314	288	461
Total share-based compensation expenses	**2,400**	**1,960**	**613**	**657**


Primary Logo

Source: MediWound Ltd.

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