May 8, 2017

MediWound Reports First Quarter 2017 Financial Results

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

YAVNE, Israel, May 08, 2017 (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 months ended March 31, 2017.

Highlights of the first quarter of 2017 and recent weeks include:

- Total revenues for the first quarter of 2017 were $0.54 million, a 113% increase from $0.25 million in the first quarter of 2016, underscoring the continuous growth of NexoBrid® sales;
- Obtained U.S. Food and Drug Administration (FDA) concurrence that complete debridement will be the primary endpoint of the U.S. pivotal program for EscharEx®;
- An independent cost analysis review utilizing NexoBrid in severe burn management was published in *BioMed Research International* and showed that NexoBrid reduced average treatment costs per patient by more than €5,000 compared with standard-of-care (SOC);
- Multiple presentations at the American Burn Association (ABA) Annual Meeting highlighted the positive results achieved by clinicians using NexoBrid as an enzymatic debridement for severe burns and EscharEx for debridement of chronic wounds;
- A "Meet the Expert" panel comprised of seven leading burn specialists from across Europe and the U.S. was convened at the ABA and shared outcomes from their use of NexoBrid for the debridement of severe burns and provided insight into the role of NexoBrid as a potential part of the U.S. SOC;
- Multiple presentations at the Symposium on Advanced Wound Care (SAWC) Spring 2017 highlighted the positive results achieved by clinicians using NexoBrid as an enzymatic debridement for severe burns and EscharEx for debridement of chronic wounds; and
- Successful completion of a Good Manufacturing Practice (GMP) audit of the Company's facility in Yavne, Israel by the Israeli Ministry of Health (IMOH) granting a compliance certificate for additional three years.

Management Commentary

"We continued to make progress with our commercial strategy to increase NexoBrid revenue in Europe and promote NexoBrid globally through distribution agreements while advancing our clinical programs for NexoBrid and EscharEx in the U.S.," stated Gal Cohen, President and Chief Executive Officer of MediWound. "We are pleased to report revenue growth that more than doubled compared with the 2016 first quarter and to have an independent cost analysis published that showed NexoBrid significantly reduces the average cost of treatment per patient by more than €5,000 compared with SOC. These data, along with other independent cost effectiveness studies being conducted, strongly support our goal to turn NexoBrid into the new SOC in severe burn treatment. Moreover, published data such as these highlight our value proposition and support our reimbursement efforts worldwide.

"We were delighted to report final results from our Phase 2 EscharEx study in chronic wounds and to have the data presented at this year's SAWC. These highly encouraging results reinforce our belief that EscharEx has the potential to become a first-in-class topical debridement pharmaceutical product. There is a great unmet medical need to effectively debride chronic wounds in a non-surgical and prompt manner, as debriding is a critical first step for subsequent wound management. In tandem, we advanced the second cohort of patients in the study to demonstrate safety over extended periods of application to enhance convenience and compliance and plan to report top-line data from this cohort around mid-2017. Based on the compelling clinical activity and safety data EscharEx demonstrated, particularly in diabetic foot ulcers (DFUs) and venous leg ulcers (VLUs), and the magnitude of the commercial opportunity as affirmed by extensive market research conducted with more than 200 healthcare professionals, we look forward to advancing the clinical development of EscharEx.

"Following discussions with the FDA regarding the pivotal program for EscharEx to treat chronic and hard-to-heal wounds, we were able to obtain FDA concurrence that complete debridement will be the primary endpoint of the studies and wound closure will be measured as a safety outcome to document that EscharEx has no deleterious effect on wound closure. This design was used in our recently reported successful second Phase 2 study as well as in our on-going NexoBrid U.S. Phase 3 study. Following this meeting with the Agency, we are working to finalize and initiate our U.S. pivotal program.

"Once again, the ABA was an outstanding venue for further enhancing the awareness of NexoBrid and increasing the interest in NexoBrid among US and international burn care specialists. In addition to more than a dozen poster presentations highlighting the merits of NexoBrid, the 'Meet the Experts' panel provided great insight into the use of NexoBrid in Europe, its potential role in the management of burn mass casualty events and the future integration of NexoBrid as part of the U.S. SOC for severe burns.

"As a fully integrated company, manufacturing is a core competency of MediWound and is critical for our R&D and commercial success. We take great pride in maintaining the highest quality standards and are particularly pleased that the IMOH is granting us a compliance certificate for sterile manufacturing for three years rather than the customary two years for the second consecutive time. This underscores the viability, quality and high standards MediWound upholds in the manufacture of our proteolytic enzyme therapeutics for commercial and clinical use in compliance with rigorous international standards," concluded Mr. Cohen.

First Quarter Financial Results

Revenues for the first quarter of 2017 were $540,000, more than double revenues of $254,000 for the first quarter of 2016.

Operating loss for the first quarter of 2017 was $3.7 million, down 9% from $4.0 in the first quarter of 2016. The decrease was primarily due to gross profit generated in 2017 of $0.2 million compared with gross loss of $0.2 in the first quarter of 2016.

Research and development expenses, net of participation, for the first quarter of 2017 were $1.8 million, in line with the Company's budget, compared with $1.0 million for the first quarter of 2016. The increase was primarily due to an increase of $0.2 million related to NexoBrid and EscharEx clinical trials and a decrease of $0.5 million of participation from the Israeli Innovation Authority, which resulted from revaluation of a contingent liability in 2016.

Selling, general and administrative expenses in the first quarter of 2017 decreased $0.8 million to $2.1 million from $2.9 million in the first quarter of 2016.

For the first quarter of 2017, the Company's net loss was $4.3 million, or $0.20 per share, compared with a net loss of $3.8 million, or $0.17 per share, for the first quarter of 2016. The increase was primarily due to net financial expenses, which were largely comprised of non-cash revaluation of contingent liabilities and changes in foreign currency exchange rates.

Adjusted EBITDA, as defined below, for the first quarter of 2017 was a loss of $3.2 million, compared with a loss of $3.0 million for the first quarter of 2016.

Balance Sheet Highlights

As of March 31, 2017 the Company had cash and short-term deposits of $25.2 million, compared with cash and short-term deposits of $30.0 million as of December 31, 2016. The Company remained on budget and utilized $4.8 million in cash to fund operating activities during the first quarter of 2017.

Throughout 2017, the Company will continue to invest primarily in research and development efforts for NexoBrid, which is predominantly funded by the Biomedical Advanced Research and Development Agency (BARDA), and EscharEx for chronic wounds, as well as in our commercialization efforts. As a result, cash use for 2017 is expected to remain within our guidance for 2017 in the range of $15.0 million to $17.0 million.

Conference Call

MediWound management will host a conference call for investors May 8, 2017 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 4551719. 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 May 14, 2017 by dialing (855) 859-2056 (domestic and international) or and entering passcode 4551719. 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 the Company's 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 and Israel, with plans for a launch in 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 tissues.

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® has 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, 2016 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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Tables to Follow

CONDENSED CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands

	March 31,		December 31,
	2017	2016	2016
	Unaudited		
Cash, cash equivalents and short term deposits	25,229	41,591	30,029
Accounts and other receivable	3,276	3,283	2,739
Inventories	991	1,534	844
	29,496	**46,408**	**33,612**
Long term deposits	44	135	103
Property, plant and equipment, net	1,357	1,267	1,276
Intangible assets, net	729	874	773
	2,130	**2,276**	**2,152**
	31,626	**48,684**	**35,764**
Trade payables and accrued expenses	2,732	2,666	3,320
Other payables	2,355	2,293	2,060
	5,087	**4,959**	**5,380**
Deferred revenues	995	-	1,023
Liabilities in respect of Israeli Innovation Authority grants net of current maturities	6,997	7,019	6,839
Contingent consideration for the purchase of shares net of current maturities	14,540	16,041	14,533
Severance pay liability, net	226	101	219
	22,758	**23,161**	**22,614**
SHAREHOLDERS' EQUITY	**3,781**	**20,564**	**7,770**
	31,626	**48,684**	**35,764**

CONDENSED CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE LOSS (UNAUDITED)

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

	Three months ended March 31,	
	2017	2016
Revenues	540	254
Cost of revenues	340	404
Gross profit (loss)	**200**	**(150)**
Operating expenses:		
Research and development, gross	3,441	3,230
Participation by BARDA & IIA	(1,670)	(2,237)
Research and development, net of participations	1,771	993
Selling, general & administrative	2,092	2,861
Operating loss	**(3,663)**	**(4,004)**
Financial income (expenses), net	(651)	230
Loss for the period	**(4,314)**	**(3,774)**
Foreign currency translation adjustments	(3)	(6)
Total comprehensive loss	**(4,317)**	**(3,780)**
Net loss per share	**(0.20)**	**(0.17)**
Weighted average number of ordinary shares used in the computation of basic and diluted loss per share:	**21,930**	**21,850**

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

U.S. dollar in thousands

	Three months ended March 31,	
	2017	**2016**
Cash Flows from Operating Activities:		
Net loss	**(4,314)**	**(3,774)**
Adjustments to profit and loss items:		
Depreciation and amortization	156	123
Share-based compensation	328	874
Revaluation of liabilities in respect of IIA grants	181	(228)
Revaluation of contingent consideration for the purchase of shares	550	(76)
Increase in severance liability, net	8	-
Net financing expenses (income)	(138)	(229)
	1,085	**464**
Changes in asset and liability items:		
Increase in trade receivables	(40)	(143)
Decrease (increase) in inventories	(147)	169
Increase in other receivables	(555)	(149)
Increase in trade payables	1,277	1,536
Decrease in other payables & deferred revenues	(2,065)	(2,204)
	(1,530)	**(791)**
Net cash flows used in operating activities	**(4,759)**	**(4,101)**
Cash Flows from Investment Activities:		
Purchase of property and equipment	(196)	(327)
Interest received	15	9
Investment in short term bank deposits, net	(19,844)	(29,211)
Net cash used in investing activities	**(20,025)**	**(29,529)**
Cash Flows from Financing Activities:		
Proceeds from the IIA grants, net of repayments	28	-
Net cash provided by financing activities	**28**	**-**
Exchange rate differences on cash and cash equivalent balances	**41**	**154**
Increase in cash and cash equivalents	(24,715)	(33,476)
Balance of cash and cash equivalents at the beginning of the period	28,866	42,502
Balance of cash and cash equivalents at the end of the period	**4,151**	**9,026**

RECONCILIATION OF NET LOSS TO ADJUSTED EBITDA (UNAUDITED)

U.S. dollars in thousands

	March 31,	
	2017	**2016**
Loss for the period	(4,314)	(3,774)
Adjustments:		
Financial (expenses) income, net	(651)	230
Depreciation and amortization	(156)	(123)
Share-based compensation expenses	(328)	(874)
Total adjustments	(1,135)	(767)
Adjusted EBITDA	**(3,179)**	**(3,007)**

Primary Logo

Source: MediWound Ltd.