



MediWound Reports Third Quarter 2017 Financial Results

November 16, 2017

NexoBrid[®] sales grow 74% year-to-date

Raised gross proceeds of \$25.2 million through public equity offering

Awarded additional \$32 million from BARDA to support NexoBrid R&D programs

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

YAVNE, Israel, Nov. 16, 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, today announced financial results for the three and nine months ended September 30, 2017.

Third Quarter 2017 Operational and Financial Highlights

- Total revenues for the third quarter of 2017 were \$0.74 million, a 43% increase from \$0.52 million in the third quarter of 2016, underscoring the continued growth of NexoBrid[®] sales.
- Raised total gross proceeds of \$25.2 million through a public offering of 5.04 million shares, which included the exercise of the underwriters' option to purchase additional shares.
- BARDA upsized contract with MediWound, committing an additional \$32 million to support R&D activities, bringing total non-dilutive funding to up to \$132 million.
- Successfully completed the second cohort of the Phase 2 study evaluating EscharEx, MediWound's topical biologic drug for the debridement of dead or damaged tissue in diabetic foot ulcers and venous leg ulcers. The study achieved its primary objective of demonstrating EscharEx's safety over extended periods of application with no material safety concerns identified.
- Awarded Best Poster Presentation in the 17th Annual European Burns Association (EBA) Congress. Overall 43 presentations of burn experts from across Europe on NexoBrid at the EBA conference.
- New distribution agreement in Taiwan with Holy Stone Healthcare further expands NexoBrid's[®] global reach.
- Appointed Stephen T. Wills as Chairman of the Company's Board of Directors and Assaf Segal as a new Board member.
- Tel Aviv district court ordered MediWound to purchase approximately \$1.5 million of PolyHeal shares; MediWound weighing an appeal.
- Positive decision of European Commission on a five-year renewal of NexoBrid's Marketing Authorization.

"We continue to see growing enthusiasm among burn specialists for the benefits of NexoBrid and its place as the standard-of-care for debridement of severe burns. This is evidenced by increased demand for NexoBrid, by the 43 presentations from burn experts from across Europe on NexoBrid at the EBA conference, and by the endorsement of the European Burn Association granting the best poster award to a presentation of European consensus for 62 statements on the benefits of NexoBrid," said Gal Cohen, MediWound's President and Chief Executive Officer.

"We remain excited about the commercial opportunity for EscharEx being developed for a large and growing market where enzymatic debridement is being used, sold and reimbursed for hundreds of millions of dollars every year. We were pleased to have successfully completed the second cohort of our Phase 2 study in EscharEx, which included 38 diabetic foot ulcer and venous leg ulcer patients treated over extended periods of application. Our recent successful public equity offering of \$25.2 million in gross proceeds, combined with the recent increase of \$32 million of non-dilutive financing from BARDA to support our NexoBrid R&D activities, provide us with the financial resources needed for the execution of our EscharEx pivotal program," added Mr. Cohen.

"Following the November 12, 2017, ruling of the Tel Aviv District Court regarding certain PolyHeal shareholders claim, we are evaluating the court ruling and its implications and our options going forward, including a potential appeal," added Mr. Cohen.

Third Quarter Financial Results

Revenues for the third quarter of 2017 were \$0.74 million, up 43% from the \$0.52 million in revenues for the third quarter of 2016.

Gross profit for the third quarter of 2017 was \$0.40 million, compared to a gross profit of \$0.04 million in the prior year period.

Research and development expenses, net of participations, for the third quarter of 2017 were \$0.8 million, compared with \$2.4 million for the third quarter of 2016. The decrease in net research and development expenses was primarily due to a decrease of \$0.5 million related to EscharEx clinical trials and non-clinical development and an increase of \$1.0 million in participation by BARDA and Israeli Innovation Authority.

Selling, and general and administrative expenses decreased to \$2.4 million for the third quarter of 2017 from \$2.6 million for the third quarter of 2016.

Operating loss for the third quarter of 2017 was \$2.8 million, down 43% from \$4.9 million in the third quarter of 2016. The decrease was primarily due to improvements in gross margins and a decrease of about \$1.8 million in operating expenses compared to the third quarter of 2016.

The Company posted a net loss of \$11.0 million, or \$0.49 per share, for the third quarter of 2017 compared with a net loss of \$5.7 million, or \$0.26 per share, for the third quarter of 2016. The increase in net loss was as a result of a full provision for the PolyHeal's shares purchase price plus the accrued interest, in the amount of \$7.5 million that was recorded within the loss from discontinued operation as a result of the district court ruling. This was offset by a decrease of \$2.2 million in net loss from continuing operation, primarily due to the decrease of \$1.8 million in operating expenses.

Adjusted EBITDA, as defined below, for the third quarter of 2017 was a loss of \$2.3 million, compared with a loss of \$4.2 million for the third quarter of 2016.

Year-to-Date 2017 Financial Results

Total revenue for the first nine months of 2017 was \$2.0 million compared with \$1.1 million for the first nine months of 2016, an increase of 74%.

Gross profit for the first nine months of 2017 was \$0.8 million, compared with a gross loss of \$0.2 million in the prior year period, an improvement of approximately \$1.0 million.

Research and development expenses, net of participations, were \$4.3 million for the first nine months of 2017, compared with \$6.3 million for the first nine months of 2016. The decrease was primarily due to a decrease of \$1.3 million related to EscharEx clinical trials and non-clinical development, and an increase of \$0.7 million in participation by BARDA and the Israeli Innovation Authority.

Selling, general and administrative expenses in the first nine months of 2017 decreased \$2.5 million to \$6.7 million from \$9.2 million during the same period in 2016, primarily due to a reduction of \$1.6 million related to marketing expenses associated with launch activities and a \$0.9 decrease in non-cash share based compensation.

Operating loss for the first nine months of 2017 was \$10.2 million, an improvement of 35% versus an operating loss of \$15.6 million in the first nine months of 2016. The decrease was primarily due to the positive change in gross profit in the first nine months of 2017 and the decrease in operating expenses compared to the prior year period.

For the nine months ended September 30, 2017, the Company posted a net loss of \$19.8 million, or \$0.90 per share, compared with a net loss of \$17.0 million, or \$0.78 per share, for the same period in 2016. The change in net loss comprised of: (i) a decrease in net loss from continuing operation, primarily due to a \$5.5 million decrease in operating loss which was offset by an increase of \$0.8 million net financial expenses, largely comprised of non-cash revaluation of contingent liabilities; and (ii) a loss from discontinued operation of \$7.5 million, following a full provision for the shares purchase price plus the accrued interest, that was recorded as a result of the district court ruling.

Adjusted EBITDA, as defined below, for the first nine of 2017 was a loss of \$8.7 million, compared with a loss of \$12.9 million for the first nine months of 2016.

Balance Sheet Highlights

As of September 30, 2017, the Company had cash and short-term deposits of \$40.6 million, which includes the \$22.8 million of net proceeds generated from the Company's recent public offering. The Company remained on budget and utilized \$13.1 million in cash to fund operating activities during the first nine months of 2017.

For the remainder of 2017, the Company intends to allocate its cash resources to advance the development of EscharEx while the NexoBrid development plans are fully funded by BARDA. We currently anticipate that existing cash resources, together with BARDA's funding and procurement, will be sufficient to enable us to complete our ongoing Phase 3 clinical program for NexoBrid and our planned Phase 3 clinical program for EscharEx.

Expected cash use to support ongoing operating activities in 2017 will remain toward the lower end of the Company's guidance range for 2017 of \$15.0 million to \$17.0 million. The Company may bear an additional \$1.5 million expense to purchase shares of PolyHeal pursuant to the District Court ruling in the fourth quarter of 2017.

Conference Call

MediWound management will host a conference call for investors today, November 16, 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 (888) 715-1402 (domestic) or (719) 325-2204 (international) and entering passcode 7237105. 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 30, 2017 by dialing (844) 512-2921 (domestic) or (412) 317-6671 (international) and entering passcode 7237105. 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, 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 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 U.S. 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

	September 30,		December 31,
	2017	2016	2016
	Unaudited		
Cash, cash equivalents and short term deposits	40,593	33,956	30,029
Accounts and other receivable	4,238	2,606	2,739
Inventories	1,637	1,063	844
Total current assets	46,468	37,625	33,612
Long term deposits	60	103	103
Property, plant and equipment, net	1,834	1,362	1,276
Intangible assets, net	649	831	773
Total long term assets	2,543	2,296	2,152
Total assets	49,011	39,921	35,764
Trade payables and accrued expenses	3,289	2,505	3,320
Other payables	2,190	2,476	2,060
Other payables from discontinued operation	7,500	-	-

Total current liabilities	12,979	4,981	5,380
Deferred revenues	937	1,067	1,023
Liabilities in respect of Israeli Innovation Authority grants net of current maturities	7,395	7,637	6,839
Contingent consideration for the purchase of shares net of current maturities	15,673	17,265	14,533
Severance pay liability, net	242	99	219
Total long term liabilities	24,247	26,068	22,614
Shareholders' equity	11,785	8,872	7,770
Total liabilities & shareholder equity	49,011	39,921	35,764

CONDENSED CONSOLIDATED UNAUDITED STATEMENTS OF COMPREHENSIVE LOSS (UNAUDITED)

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

	Nine months ended		Three months ended	
	September 30,		September 30,	
	2017	2016	2017	2016
Revenues	1,966	1128	739	518
Cost of revenues	1,162	1,303	338	474
Gross profit (loss)	804	(175)	401	44
Operating expenses:				
Research and development, gross	10,068	11,420	3,446	3,947
Participation by IIA & BARDA	(5,789)	(5,135)	(2,602)	(1,592)
Research and development, net	4,279	6,285	844	2,355
Selling, general & administrative	6,688	9,188	2,354	2,633
Total operating expenses	10,967	15,473	3,198	4,988
Operating loss	(10,163)	(15,648)	(2,797)	(4,944)
Financial income (expenses), net	(2,117)	(1,348)	(707)	(767)
Loss from continuing operations	(12,280)	(16,996)	(3,504)	(5,711)
Loss from discontinued operation	(7,500)	-	(7,500)	-
Loss for the period	(19,780)	(16,996)	(11,004)	(5,711)
Foreign currency translation adjustments	(19)	(4)	(2)	(1)
Total comprehensive loss	(19,799)	(17,000)	(11,006)	(5,712)
Basic and diluted loss per share:				
Loss from continuing operations	(0.56)	(0.78)	(0.16)	(0.26)
Loss from discontinued operation	(0.34)	0.00	(0.33)	0.00
Net loss per share	(0.90)	(0.78)	(0.49)	(0.26)
Weighted average number of ordinary shares used in the computation of basic and diluted loss per share:	22,105	21,853	22,438	21,857

CONDENSED CONSOLIDATED UNAUDITED STATEMENTS OF CASH FLOWS (UNAUDITED)

U.S. dollars in thousands

	Nine months ended		Three months ended	
	September 30,		September 30,	
	2017	2016	2017	2016
Cash Flows from Operating Activities:				
Net loss	(19,780)	(16,996)	(11,004)	(5,711)
Adjustments to reconcile net loss to net cash used in continuing operating activities:				
Adjustments to profit and loss items:				
Loss from discontinued operation	7,500	-	7,500	-
Depreciation and amortization	430	386	128	133
Share-based compensation	1,013	2,400	348	613
Revaluation of liabilities in respect of IIA grants	351	(190)	(51)	(167)
Revaluation of contingent consideration for the purchase of shares	1,672	1,180	552	641
Increase in severance liability, net	23	-	3	-
Net financing expenses (income)	(319)	(367)	(54)	(107)
	10,670	3,409	8,426	1,113
Changes in asset and liability items:				
Decrease (increase) in trade receivables	(225)	(245)	16	(90)
Decrease (increase) in inventories	(793)	642	(514)	96
Decrease (increase) in other receivables	(1,548)	425	(1,271)	754
Increase (decrease) in trade payables	(46)	1,377	1,164	935
Increase (decrease) in other payables & deferred revenues	(328)	(827)	131	(1,467)
	(2,940)	1,372	(474)	228
Net cash flows used in operating activities	(12,050)	(12,215)	(3,052)	(4,370)
Cash Flows from Investment Activities:				
Purchase of property and equipment	(864)	(642)	(499)	(202)
Interest received	52	45	25	4
Proceeds from (investment in) short term bank deposits, net of investments	(13,837)	(25,239)	3,000	(1,505)
Net cash provided by (used in) investing activities	(14,649)	(25,836)	2,526	(1,703)
Cash Flows from Financing Activities:				
Proceeds from exercise of options	7	-	5	-
Proceeds from issuance of shares, net	22,794	2	22,794	2
Proceeds from IIA grants, net of repayments	328	658	365	658
Net cash provided by financing activities	23,129	660	23,164	660
Exchange rate differences on cash and cash equivalent balances	106	71	(11)	1
Increase (decrease) in cash and cash equivalents	(3,464)	(37,320)	22,627	(5,412)
Balance of cash and cash equivalents at the beginning of the period	28,866	42,502	2,775	10,594
Balance of cash and cash equivalents at the end of the period	25,402	5,182	25,402	5,182

ADJUSTED EBITDA

U.S. dollars in thousands

	Nine months ended		Three months ended	
	September 30,		September 30,	
	2017	2016	2017	2016
Loss for the period	(12,280)	(16,996)	(3,504)	(5,711)

Adjustments:

Financial (expenses) income, net	(2,117)	(1,348)	(707)	(767)
Loss from discontinued operation	(7,500)	-	(7,500)	-
Depreciation and amortization	(430)	(386)	(128)	(133)
Share-based compensation expenses	(1,012)	(2,401)	(347)	(614)
Total adjustments	<u>(11,059)</u>	<u>(4,135)</u>	<u>(8,682)</u>	<u>(1,514)</u>
Adjusted EBITDA	<u>(8,721)</u>	<u>(12,861)</u>	<u>(2,322)</u>	<u>(4,197)</u>

Source: MediWound Ltd.