MediWound Reports Second Quarter 2019 Financial Results

August 13, 2019

Total revenues of $20.7 million, driven primarily by the upfront payment from Vericel for NexoBrid® license agreement

BARDA committed additional $21 million to fund NexoBrid® expanded access treatment protocol

Confirmed BLA submission plans in a pre-BLA meeting with FDA

Company to initiate an adaptive design adequately-controlled study in 4Q 2019 comparing EscharEx to U.S. SOC and placebo control

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

YAVNE, Israel, Aug. 13, 2019 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq: MDWD), a fully-integrated biopharmaceutical company bringing innovative therapies to address unmet needs in severe burn and wound care management, today announced financial results for the quarter ended June 30, 2019.

Business and Financial Highlights for the Second Quarter 2019 and Recent Weeks include:

- Total revenues for the second quarter of 2019 were $20.7 million, driven primarily by $17.5 million upfront payment from Vericel for the NexoBrid license;
- As of June 30, 2019, the Company had $38.7 million in cash and short-term investments, compared to $23.6 million as of December 31, 2018;
- Entered into an exclusive commercial license and supply agreement with Vericel Corporation for NexoBrid in North America for an upfront payment of $17.5 million, an additional $7.5 million upon U.S. BLA approval, tiered sales royalties, and up to $125 million in potential sales-related milestones;
- The U.S. Biomedical Advanced Research and Development Authority (BARDA) upsized contract provides additional $21 million to fund primarily the NexoBrid expanded access treatment (NEXT) protocol planned to be initiated in the third quarter of 2019. Total non-dilutive funds for NexoBrid now valued at up to $196 million;
- Launched the EscharEx U.S. clinical development program and announced plans to initiate an adaptive designed adequately-controlled Phase 2 clinical study in the fourth quarter of 2019. Hosted an Analyst Day in New York to unveil the clinical development program;
- Confirmed plans in a pre-BLA meeting with the U.S Food and Drug Administration (FDA), for submission of a Biologics License Application (BLA) for NexoBrid in the second quarter of 2020.

"We are very pleased with the continued progress we have made this quarter following our terrific start to 2019, highlighted by the robust top-line results from our Phase 3 DETECT study of NexoBrid, in which we met primary and all secondary endpoints," said Sharon Malka, MediWound's Chief Executive Officer. "We continued being active in the second quarter and thereafter, with several significant milestones including signing commercial license and supply agreements with Vericel for NexoBrid in North America and confirming with the FDA in a pre-BLA meeting our BLA submission plans, which puts us on track to file a BLA for NexoBrid in the second quarter of 2020 and a clear path to the U.S. commercial market."

"The continued BARDA support provides us with an additional $21 million to fund the NexoBrid expanded access treatment (NEXT) protocol, which we plan to initiate in the third quarter of 2019," continued Mr. Malka. "The NEXT protocol allows U.S. burn centers to treat burn patients with NexoBrid prior to BLA approval and to use NexoBrid in non-declared emergency events. The NEXT protocol will result in an increased number of burn centers trained with the use of NexoBrid across the U.S. and thereby furthering the national preparedness for burn mass casualty incidences. In addition, this quarter NexoBrid received marketing authorization from Peru's Ministry of Health, in line with our global commercial strategy of expanding the use of NexoBrid in international markets through collaborations with local distributors."

"Following the North American commercial collaboration for NexoBrid, our primary focus turns to EscharEx. We plan to initiate an adequately-controlled, adaptive designed Phase 2 clinical study in the fourth quarter of 2019, with an interim assessment planned by year-end 2020. This study will compare EscharEx to a placebo control arm as well as head-to-head with the current non-surgical standard of care in the U.S, and if successfully completed, we believe it may serve as one of the two pivotal studies required for BLA submission. With adequate financial resources and a solid balance sheet, we are well positioned to support our development plans through our numerous upcoming milestones, and we look forward to making further progress during the second half of the year," concluded Mr. Malka.

Second Quarter Financial Results

Revenues for the second quarter of 2019 were $20.7 million, including $17.5 million upfront payment and $2.3 million revenues from development services derived by Vericel licensing agreement for NexoBrid, compared with the $1.0 million in the second quarter of 2018.

Cost of revenues for the second quarter of 2019 were $3.5 million, compared to $0.6 million in the second quarter of 2018. The increase was primarily driven by $2.2 million cost of development services and $0.7 million royalties attributed to the upfront license payment.

Gross profit for the second quarter of 2019 was $17.3 million, compared to a gross profit of $0.4 million for the second quarter of 2018.

Research and development expenses, net of participations, were $0.2 million for the second quarter of 2019 compared with $1.5 million of the second quarter of 2018.The decrease in research and development, net, was a result of a decrease in clinical trials cost of $3.1 million and a decrease of $1.7 million in participation by BARDA and the Israeli innovation authority grant.

Selling, general and administrative expenses for the second quarter of 2019 were $2.3 million, compared with $2.1 million for the second quarter of 2018.

Operating profit for the second quarter of 2019, which includes the $17.5 million upfront license payment, net of royalty payment of $0.7 million and $0.8 million of other expenses, was $13.9 million. Excluding the upfront license payment, net of deal related expenses, operating loss for the second quarter of 2019 was $2.1 million, an improvement of 37% from the $3.3 million in the second quarter of 2018, primarily due to the decrease in research and development costs, net of participation.

The Company net profit for the second quarter of 2019, which includes the $17.5 million upfront license payment, net of royalty payment of $0.7 million and $0.8 million of other expenses, was $12.7 million, or $0.47 per share. Excluding the net upfront license payment, net loss for the second quarter of 2019 was $3.3 million, or $(0.12) per share, compared with a net loss of $4.2 million, or $(0.15) per share, in the second quarter of 2018.

Adjusted EBITDA, as defined below, for the second quarter of 2019, was a profit of $15.4 million, compared with a loss of $2.9 million for the second quarter of 2018.

Year-to-Date 2019 Financial Results
Revenues for the first half of 2019 were $21.2 million, including $17.5 million upfront payment and $2.3 million revenues from development services derived by Vericel licensing agreement for NexoBrid, compared with the $1.6 million in the first half of 2018.

Cost of revenues for the first half of 2019 were $3.8 million compared to $1.0 million in the first half of 2018. The increase was primarily driven by $2.2 million cost of development services and $0.7 million royalties attributed to the upfront license payment.

Gross profit for the first half of 2019 was $17.4 million, compared to a gross profit of $0.5 million in the first half of 2018.

Research and development expenses, net of participations, were $1.5 million for the first half of 2019 compared with $2.7 million in first half of 2018. The decrease in research and development, net, was primarily driven by decrease in clinical trials costs of $3.0 million and a decrease of $1.7 million in participation by BARDA and the Israeli innovation authority.

Selling, general and administrative expenses for the first half of 2019 were $4.7 million, compared with $4.2 million for the first half of 2018. The increase was primarily as a result of one-time management transition costs.

Operating profit for the first half of 2019, which includes the $17.5 million upfront license payment, net of royalty payment of $0.7 million and $0.9 million of other expenses, was $10.4 million. Excluding the upfront license payment, net of deal related expenses, operating loss for the first half of 2019 was $5.5 million, an improvement of 21% from the $7.0 million in the first half of 2018, primarily due to the decrease in research and development net of participation.

The Company net profit for the first half of 2019, which includes the $17.5 million upfront license payment, net of royalty payment of $0.7 million and $0.9 million of other expenses, was $8.6 million, or a profit of $0.32 per share. Excluding the upfront license payment net of deal related costs, net loss was $7.3 million, or $(0.27) per share, compared with a net loss of $8.7 million, or $(0.32) per share, in the first half of 2018.

Adjusted EBITDA, for the first half of 2019, was a profit of $12.4 million, compared with a loss of $5.7 million for the first half of 2018.

Balance Sheet Highlights
As of June 30, 2019, the Company had cash, cash equivalents and short-term bank deposits of $38.7 million, compared with $23.6 million at December 31, 2018. The company remained on budget, utilizing $6.4 million in the first half of 2019.

Throughout 2019, the Company will continue to invest primarily in research and development efforts for EscharEx, while NexoBrid research and development programs will be funded by BARDA. As a result, the Company expects cash use in the second half of 2019 to be in the range of $6.0 million to $8.0 million, including NexoBrid license related payments and repayment of contingent liabilities.

Conference Call
MediWound management will host a conference call for investors today, Tuesday, August 13, 2019 beginning at 8:30 a.m. Eastern Time to discuss these results and answer questions. Shareholders and other interested parties may participate in the conference call by dialing 877-602-7189 (in the U.S.), 1809 315 362 (Israel), or 678-894-3057 (outside the U.S. & Israel), and entering passcode 2158065. The call will also be broadcast live on the Internet on the Company's website at https://edge.media-server.com/mmc/p/yyne5t8t.

An archived version of the webcast will be available 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 share-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® has demonstrated in clinical trials, with statistical significance the ability to non-surgically and rapidly remove the eschar earlier and without harming viable tissue. The product has received marketing authorization from the European Medicines Agency as well as the Israeli, Argentinian, South Korean, Russian and Peruvian Ministries of Health. MediWound's second innovative product, EscharEx® is a topical biological drug candidate for the debridement of chronic and other hard-to-heal wounds using the same proteolytic enzyme technology as NexoBrid. In two Phase 2 studies, EscharEx has demonstrated safety and efficacy in the debridement of various 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 content of the BLA filing package, the timeline for the BLA filing; FDA acceptance of the BLA,; the ability to fund the development of NexoBrid until BLA submission; the ability to successfully complete the development and commercialize NexoBrid, expected funding from BARDA; our ability to meet the timeline for the initiation of the NEXT treatment protocol, results of the NEXT treatment protocol and Vericel's ability to commercialize NexoBrid, the design of the Phase 2 study, the timeline for the Phase 2 study and the interim assessment; the ability of the Phase 2 study to serve as one of the two adequately-controlled studied required for BLA submission our development plan for EscharEx; expected revenues from Vericel and the ability to fund the development of EscharEx until BLA submission; the ability to fit EscharEx into treatment workflow and reimbursement programs; our expectations regarding the wound care market; and the ability to successfully develop and commercialize. 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 important factors. In particular, you should consider that the FDA may not accept part or all of our BLA; FDA may require additional information, which we may or may not able to provide; FDA may not provide marketing approval for NexoBrid in the United States; we may not submit the BLA to FDA in the timeframe expected; risks related to our collaboration with Vericel; our ability to obtain marketing approval of NexoBrid or EscharEx in the U.S.; the clinical utility, potential advantages and timing or likelihood of regulatory filings and approvals of NexoBrid and EscharEx; our commercialization, marketing and manufacturing capabilities and strategy; risks related to our contract with the U.S. Biomedical Advanced Research and Development Authority; the impact of government laws and regulations; and the additional risks discussed under the heading "Risk Factors" in our annual report on Form 20-F for the year ended December 31, 2018 as well as 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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MediWound, Ltd.
CONDENSED CONSOLIDATED BALANCE SHEETS
U.S. dollars in thousands

	June 30,		December 31,
	2019	2018	2018
	Un-audited		Audited
Cash, cash equivalents and short term deposits	38,712	27,004	23,633
Accounts and other receivables	4,649	5,224	7,400

Inventories	1,535	1,871	1,680
Total current assets	**44,896**	**34,099**	**32,713**
Long term deposits and prepaid expenses	19	65	48
Property, plant and equipment, net	2,183	2,051	2,020
Right of use assets	2,315	-	-
Intangible assets, net	462	528	495
Total long term assets	**4,979**	**2,644**	**2,563**
Total assets	**49,875**	**36,743**	**35,276**
Current maturities of long-term liabilities	896	514	146
Trade payables and accrued expenses	4,073	3,327	2,715
Other payables	5,889	1,825	2,036
Total current liabilities	**10,858**	**5,666**	**4,897**
Deferred revenues	1,144	1,178	1,158
Liabilities in respect of Israeli Innovation Authority grants net of current maturities	6,919	7,793	7,568
Contingent consideration for the purchase of shares net of current maturities	4,412	14,737	6,330
Liability in respect of discontinued operation	6,003	6,003	6,003
Lease liability, net of current maturities	2,022	-	-
Severance pay liability, net	338	336	348
Total long term liabilities	**20,838**	**30,047**	**21,407**
Shareholders' equity	18,179	1,030	8,972
Total liabilities & shareholder equity	**49,875**	**36,743**	**35,276**

MediWound, Ltd.

CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE PROFIT (LOSS) (UNAUDITED)

U.S. dollars in thousands

	Six months ended June 30,		Three months ended June 30,	
	2019	**2018**	**2019**	**2018**
Revenues	21,207	1,551	20,746	1,031
Cost of revenues	3,788	1,010	3,481	629
Gross profit	**17,419**	**541**	**17,265**	**402**
Operating expenses:				
Research and development, gross	6,075	9,027	1,893	4,987
Participation by BARDA & IIA	(4,624)	(6,298)	(1,721)	(3,451)
Research and development, net	1,451	2,729	172	1,536
Selling, general & administrative	4,708	4,150	2,343	2,090
Other expenses	901	662	812	62
Operating profit (loss)	**10,359**	**(7,000)**	**13,938**	**(3,286)**
Financial expenses, net	(1,803)	(1,716)	(1,222)	(879)
Profit (loss) from continuing operations	**8,556**	**(8,716)**	**12,716**	**(4,165)**
Profit from discontinued operation	50	0	0	0
Profit (loss) for the period	**8,606**	**(8,716)**	**12,716**	**(4,165)**
Foreign currency translation adjustments	2	8	(2)	18
Total comprehensive profit (loss)	**8,608**	**(8,708)**	**12,714**	**(4,147)**
Net Profit (loss) per share	0.32	(0.32)	0.47	(0.15)

Weighted average number of ordinary shares used in the computation of basic and diluted profit (loss) per share:	27,179	27,050	27,179	27,052

ADJUSTED EBITDA

U.S. dollars in thousands

	Six months ended June 30,		Three months ended June 30,	
	2019	**2018**	**2019**	**2018**
Profit (loss) for the period	8,606	(8,716)	12,716	(4,165)
Adjustments:				
Financial expenses, net	(1,803)	(1,716)	(1,222)	(879)
Profit from discontinued operation	50	-	-	-
Other expenses	(901)	(662)	(812)	(62)
Depreciation and amortization	(552)	(305)	(278)	(170)
Share-based compensation expenses	(599)	(367)	(324)	(149)
Total adjustments	(3,805)	(3,050)	(2,636)	(1,260)
Adjusted EBITDA	**12,411**	**(5,666)**	**15,352**	**(2,905)**

MediWound, Ltd.

CONDENSED CONSOLIDATED STATEMENT OF CASH FLOW (UNAUDITED)

U.S. dollars in thousands

	Six months ended June 30,		Three months ended June 30,	
	2019	**2018**	**2019**	**2018**
	Unaudited		**Unaudited**	
Cash Flows from Operating Activities:				
Net profit (loss)	8,606	(8,716)	12,716	(4,165)
Adjustments to reconcile net profit (loss) to net cash used in continuing operating activities:				
Adjustments to profit and loss items:				
Profit from discontinued operation	(50)	-	-	-
Depreciation and amortization	552	305	278	170
Share-based compensation	599	367	324	149
Revaluation of liabilities in respect of IIA grants	(392)	404	(466)	218
Revaluation of contingent consideration for the purchase of shares	1,322	1,112	1,081	569
Other income				
Revaluation of lease liabilities	194	-	91	-
Increase (decrease) in severance liability, net	(10)	6	13	(5)
Financing income	(149)	(182)	(87)	(115)
Unrealized foreign currency (gain) loss	(70)	126	60	85
	1,996	2,138	1,294	1,071
Changes in asset and liability items:				
Increase in trade receivables	(9)	(421)	(318)	(494)
Decrease (increase) in inventories	146	15	(62)	149
Decrease (increase) in other receivables	2,744	(1,572)	2,482	(1,690)

Increase (decrease) in trade payables and prepaid expenses	1,357	74	1,076	(51)
Increase (decrease) in other payables & deferred revenues	529	(336)	77	(507)
	4,767	(2,240)	3,255	(2,593)
Net cash provided by (used in) continuing operating activities	15,369	(8,818)	17,265	(5,687)
Net cash provided by discontinued operating activities	50	-	-	-
Net cash provided by (used in) operating activities	15,419	(8,818)	17,265	(5,687)

MediWound, Ltd.
CONDENSED CONSOLIDATED STATEMENT OF CASH FLOW (UNAUDITED)
U.S. dollars in thousands

	Six months ended June 30,		Three months ended June 30,	
	2019	**2018**	**2019**	**2018**
	Unaudited		**Unaudited**	
Cash Flows from Investment Activities:				
Purchase of property and equipment	(433)	(313)	(194)	(197)
Purchase of intangible assets	-	(13)	-	(13)
Interest received	44	2	14	2
Proceeds from (investment in) short term bank deposits, net of investments	2,977	(21,165)	412	1,680
Net cash provided by (used in) investing activities	**2,588**	**(21,489)**	**232**	**1,472**
Cash Flows from Financing Activities:				
Proceeds from exercise of options	-	*	-	*
Repayment of lease liabilities	(312)	-	(157)	-
Proceeds from IIA grants, net of repayments	193	30	248	-
Net cash (used in) provided by financing activities	**(119)**	**30**	**91**	**0**
Exchange rate differences on cash and cash equivalent balances	63	(133)	(55)	(117)
Increase (decrease) in cash and cash equivalents from continuing activities	17,901	(30,410)	17,533	(4,332)
Increase in cash and cash equivalents from discontinued activities	50	-	-	-
Balance of cash and cash equivalents at the beginning of the period	6,716	36,069	7,134	9,991
Balance of cash and cash equivalents at the end of the period	**24,667**	**5,659**	**24,667**	**5,659**

Source: MediWound Ltd.