MediWound Reports First Quarter 2019 Financial Results

May 21, 2019

Met Primary and All Secondary Endpoints in Pivotal Phase 3 DETECT Study; NexoBrid BLA Filing Planned for Fourth Quarter of 2019

Signed Exclusive License Agreement with Vericel for Commercial Rights to NexoBrid® in North America

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

YAVNE, Israel, May 21, 2019 (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 quarter ended March 31, 2019.

First Quarter 2019 Business and Financial Highlights:

- Total revenues for the first quarter of 2019 were $0.5 million, flat versus the first quarter of 2018.
- Announced positive top-line results in January from the pivotal Phase 3 DETECT study in NexoBrid for eschar removal of severe thermal burns.
- Entered into exclusive license and supply agreements with Vericel Corporation in May to commercialize NexoBrid in North America for an upfront payment of $17.5 million, sales royalties, and up to $132.5 million in potential milestones.
- Announced Executive Leadership changes.

"We had a terrific start to 2019, highlighted by positive top-line results from our Phase 3 DETECT study of NexoBrid, in which we met primary and all secondary endpoints with statistical significance, as well as by the execution of license and supply agreements with Vericel to market NexoBrid in North America," said Sharon Malka, MediWound's Chief Executive Officer. "The results, which were robust across all endpoints, corroborate our previous positive European Phase 3 clinical study results and clearly demonstrate the significant beneficial impact NexoBrid has on burn patients as a new paradigm in burn care management. We plan to file the NexoBrid BLA in the fourth quarter of 2019, subject to FDA concurrence in a pre-BLA meeting. The Vericel deal – which includes a $17.5 million upfront payment, a $7.5 million payment contingent upon U.S. BLA approval, tiered royalty payments, and up to $125 million in annual sales milestones – provides both clinical and commercial validation for NexoBrid as an innovative solution for the U.S. burn care market."

Mr. Malka continued, "This collaboration provides us with an ideal commercial partner to maximize the medical and commercial potential of NexoBrid in North America and with the funds to advance and optimize the development of EscharEx, our topical biologic drug candidate for the debridement of chronic and other hard-to-heal wounds, through BLA filing. We expect to commence the next phase of our EscharEx clinical development program within the next few months."

Stephen T. Wills, MediWound's Active Chairman, added, "After a comprehensive strategic review process, we are excited to partner with Vericel in advancing NexoBrid towards U.S. market approval. We will continue to be opportunistic in seeking collaborations for NexoBrid in other markets and with the assessment of potential strategic opportunities for EscharEx as the development program advances towards regulatory approval."

First Quarter Financial Results
Revenues for the first quarter of 2019 were $0.5 million, which was flat versus the first quarter of 2018.

Gross profit for the first quarter of 2019 was $0.15 million, compared to a gross profit of $0.14 million for the prior-year period.

Research and development expenses for the first quarter of 2019, net of participations, were $1.3 million, compared with $1.2 million for the first quarter of 2018.

Selling, general and administrative expenses for the first quarter of 2019 were $2.4 million, compared with $2.1 million for the first quarter of 2018. The increase was primarily as a result of one-time management transition costs.

Operating loss for the first quarter of 2019 was $3.6 million, compared with $3.7 million in the first quarter of 2018.

The Company posted a net loss of $4.1 million, or ($0.15) per share, for the first quarter of 2019 compared with a net loss of $4.6 million, or ($0.17) per share, for the first quarter of 2018.

Adjusted EBITDA, as defined below, for the first quarter of 2019 was a loss of $2.9 million, compared with a loss of $2.8 million for the first quarter of 2018.

Balance Sheet Highlights
As of March 31, 2019, the Company had cash, cash equivalents and short-term bank deposits of $21.5 million, compared with $23.6 million at December 31, 2018. We believe that the existing cash combined with the proceeds generated from the collaboration with Vericel, will allow us to significantly advance the ongoing development of EscharEx through BLA filing.

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 for ongoing operating activities in 2019 to be in the range of $12.0 million to $14.0 million.

Conference Call
MediWound management will host a conference call for investors today, Tuesday, May 21, 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 7396504. The call also will be broadcast live on the Internet on the Company's website at http://ir.mediwound.com/events-and-presentations.

A replay of the call will be accessible two hours after its completion through June 4, 2019 by dialing 855-859-2056 (in the U.S.) or 404-537-3406 (outside the U.S.) and entering passcode 7396504. 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 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® 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 and Russian Ministries of Health. MediWound's second innovative product, EscharEx® is a topical biological drug 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 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 timing of regulatory filings and submissions, expected payments under the license and supply agreements; anticipated uses of such payments and 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 that we may not submit the BLA to FDA in the timeframe expected, or at all; FDA may not provide marketing approval for NexoBrid in the United States and, if such approval is obtained, Vericel may not be able to successfully commercialize NexoBrid in the United States; and the risks discussed under the heading "Risk Factors" in our annual report on Form 20-F for the year ended December 31, 2018 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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MediWound Ltd.
CONDENSED CONSOLIDATED BALANCE SHEETS
U.S. dollars in thousands

	March 31,		December 31,
	2019	2018	2018
	Un-audited		Audited
Cash, cash equivalents and short term deposits	21,517	32,903	23,633

Accounts and other receivable	6,738	3,282	7,400
Inventories	1,472	2,020	1,680
Total current assets	**29,727**	**38,205**	**32,713**
Long term deposits	17	54	48
Property, plant and equipment, net	2,151	1,949	2,020
Right of use assets	2,418	-	-
Intangible assets, net	479	592	495
Total long term assets	**5,065**	**2,595**	**2,563**
Total assets	**34,792**	**40,800**	**35,276**
Current maturities of long-term liabilities	2,018	710	146
Trade payables and accrued expenses	2,996	3,380	2,715
Other payables	2,438	2,204	2,036
Total current liabilities	**7,452**	**6,294**	**4,897**
Deferred revenues	1,145	1,349	1,158
Liabilities in respect of Israeli Innovation Authority grants net of current maturities	7,497	7,577	7,568
Contingent consideration for the purchase of shares net of current maturities	5,186	14,208	6,330
Liability in respect of discontinued operation	6,003	6,003	6,003
Lease liability, net of current maturities	2,043	-	-
Severance pay liability, net	325	341	348
Total long term liabilities	**22,199**	**29,478**	**21,407**
Shareholders' equity	5,141	5,028	8,972
Total liabilities & shareholder equity	**34,792**	**40,800**	**35,276**

MediWound Ltd.
CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE LOSS (UNAUDITED)
U.S. dollars in thousands

	Three months ended March 31,	
	2019	**2018**
Revenues	461	520
Cost of revenues	307	381
Gross profit	**154**	**139**
Operating expenses:		
Research and development, gross	4,182	4,040
Participation by BARDA & IIA	(2,903)	(2,847)
Research and development, net of participations	1,279	1,193
Selling, general and administrative	2,365	2,060
Other (income) expenses	89	600
Operating loss	**(3,579)**	**(3,714)**
Financial income	61	67
Financial expense	(642)	(904)
Loss from continuing operations	**(4,160)**	**(4,551)**
Profit from discontinued operation	**50**	**-**
Loss for the period	**(4,110)**	**(4,551)**
Foreign currency translation adjustments	4	(10)

Total comprehensive loss	**(4,106)**	**(4,561)**
Basic and diluted loss per share:		
Loss from continuing operations	(0.15)	(0.17)
Profit from discontinued operation	0.00	0.00
Net loss per share	(0.15)	(0.17)
Weighted average number of ordinary shares used in the computation of basic and diluted loss per share:	27,179	27,048

ADJUSTED EBITDA
U.S. dollars in thousands

	Three months ended March 31,	
	2019	**2018**
Loss for the period	(4,110)	(4,551)
Adjustments:		
Financial (expenses) income, net	(581)	(837)
Profit from discontinued operation	50	-
Other expenses	(89)	(600)
Depreciation and amortization	(274)	(135)
Share-based compensation expenses	(275)	(218)
Total adjustments	(1,169)	(1,790)
Adjusted EBITDA	**(2,941)**	**(2,761)**

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

	Three months ended March 31,	
	2019	**2018**
Cash Flows from Operating Activities:		
Net loss	**(4,110)**	**(4,551)**
Adjustments to reconcile net loss to net cash used in continuing operating activities:		
Adjustments to profit and loss items:		
Profit from discontinued operation	(50)	-
Depreciation and amortization	274	135
Share-based compensation	275	218
Revaluation of liabilities in respect of IIA grants	74	186
Revaluation of contingent consideration for the purchase of shares	241	543
Revaluation of lease liabilities	103	-
Increase (decrease) in severance liability, net	(23)	11
Financing income	(62)	(67)
Unrealized foreign currency (gain) loss	(130)	41
	702	**1,067**
Changes in asset and liability items:		
Decrease in trade receivables	309	73
Decrease (increase) in inventories	208	(134)
Decrease in other receivables	262	118

Increase in trade payables & accrued expenses	281	125
Increase in other payables & deferred revenues	452	171
	1,512	**353**
Net cash used in continuing operating activities	**(1,896)**	**(3,131)**
Net cash provided by discontinued operating activities	**50**	**-**
Net cash used in operating activities	**(1,846)**	**(3,131)**
Cash Flows from Investment Activities:		
Purchase of property and equipment	(239)	(116)
Interest received	30	-
Proceeds from (investment in) short term bank deposits, net of investments	2,565	(22,845)
Net cash provided by (used in) investing activities	**2,356**	**(22,961)**
Cash Flows from Financing Activities:		
Repayment of lease liabilities	(155)	-
Net proceeds from IIA grants (repayment of IIA grants, net)	(55)	30
Net cash provided by financing activities	**(210)**	**30**
Exchange rate differences on cash and cash equivalent balances	118	(16)
Increase (decrease) in cash and cash equivalents from continuing activities	368	(26,078)
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
Balance of cash and cash equivalents at the end of the period	**7,134**	**9,991**

Source: MediWound Ltd.