MediWound Reports Second Quarter 2020 Financial Results and Provides Corporate Update

August 6, 2020

Submitted Biological License Application to the FDA for NexoBrid
EscharEx U.S. Phase 2 Study Resumed Patient Screening

YAVNE, Israel, Aug. 06, 2020 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq: MDWD) (the "Company"), a fully-integrated biopharmaceutical company bringing innovative therapies to address unmet needs in severe burn and wound management, today announced financial results for the second quarter ended June 30, 2020 and provided business and financial updates related to the COVID-19 pandemic.

Second Quarter Business and Financial Highlights:

- Revenues for the second quarter of 2020 were $4.0 million, compared with $20.7 million for the second quarter of 2019, which included the upfront payment of $17.5 million from the Vericel licensing agreement
- The Company had $24.4 million in cash and short-term investments as of June 30, 2020, compared with $29.5 million as of December 31, 2019
- Resumed patient screening and randomization in U.S. EscharEx® phase 2 adaptive design study for the treatment of venous leg ulcers ("VLU's"); Interim assessment is anticipated in the first half of 2021
- Submitted Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) for NexoBrid® for the treatment of severe thermal burns in adults
- Instituted a series of measures to address challenges associated with the COVID-19 pandemic, while maintaining workforce and operational capacity and flexibility

"We are pleased to have submitted the BLA for NexoBrid on schedule despite the disruptions of the COVID-19 pandemic. This submission is a major milestone in our long-term partnership with BARDA, and we are actively preparing for the commercial launch with our partner, Vericel, upon approval," said Sharon Malka, Chief Executive Officer of MediWound. "In addition, we are actively recruiting and enrolling patients in our U.S. EscharEx phase 2 study, and we are encouraged to see progress in moving this trial forward."

Mr. Malka concluded, "In recent months, humanity is facing tremendous challenges with a great deal of uncertainty. We are privileged to be among those tasked with improving patients' quality of care and impacting their lives. Our solid balance sheet continues to support our growth as we execute on our strategic plans, and we are optimistic that we will continue to successfully strengthen our Company."

Corporate Update

MediWound has implemented several measures to safeguard the health and well-being of its employees, their families, and healthcare providers. The Company has reduced expenses to minimize impact to operations while ensuring full compliance with all necessary regulations. Management continues to assess the impact of the pandemic, the potential implications to business continuity, and necessary remedies and will adjust accordingly to the challenges created by any directives from regulatory authorities.

The Company continues to manufacture and supply NexoBrid to patients with severe burn injuries, including manufacturing NexoBrid and building an emergency stockpile for the U.S. Biomedical Advanced Research and Development Authority (BARDA), while the first delivery to BARDA is planned in the third quarter of 2020. The Company maintains a significant safety stock of all key raw materials and NexoBrid inventory to meet expected demand over the next several quarters. At this time, the Company does not expect any disruptions to its manufacturing operations and global supply chain.

The Company submitted a BLA to the U.S. FDA seeking the approval of NexoBrid for eschar removal (debridement) in adults with deep partial-thickness and full-thickness thermal burns. The BLA submission is based on multiple preclinical and clinical studies including the pivotal Phase 3 U.S. clinical study (DETECT) of NexoBrid in adult patients with severe thermal burns. Vericel Corporation (NASDAQ: VCEL) holds an exclusive license for North American commercial rights of NexoBrid. MediWound is eligible to receive a $7.5 million milestone payment from Vericel upon BLA approval.

On the clinical front, the Company has resumed new patients' screening and randomization in its U.S. EscharEx phase 2 adaptive design study for the treatment of VLU's and expects to achieve the pre-defined interim assessment in the first half of 2021. In addition, enrollment in the NexoBrid expanded access (NEXT) program continues with enhanced safety measures, such as remote visits and virtual tools.

The Company had $24.4 million in cash and short-term investments as of June 30, 2020, compared with $29.5 million as of December 31, 2019, with no debt. The Company reiterates its expectations of cash use for operating activities in 2020 to be in the range of $8 to $10 million. At this time, the Company cannot predict the extent or duration of the impact of the COVID-19 outbreak on its ongoing financial and operational results.

Second Quarter Financial Results

Revenues for the second quarter of 2020 were $4.0 million, compared with $20.7 million for the second quarter of 2019, which included the upfront

payment of $17.5 million from the Vericel licensing agreement. Revenues from product in the second quarter of 2020 were $1.1 million, reflecting an increase of 17% in comparison to the second quarter of 2019, excluding the one-time upfront payment.

Gross profit for the second quarter of 2020 was $1.2 million, compared to a gross profit of $17.5 million for the second quarter of 2019, which included $16.8 million from the Vericel licensing agreement.

Research and development expenses for the second quarter of 2020, net of participations, were $1.6 million, compared with $0.4 million for the second quarter of 2019. The increase was primarily due to decrease of participation by BARDA and Israeli Innovation Authority (IIA).

Selling, general and administrative expenses for the second quarter of 2020 were $2.3 million, in line with the second quarter of 2019.

Operating loss for the second quarter of 2020 was $2.7 million, compared with an operating profit of $13.9 million in the second quarter of 2019, which included the upfront payment of $17.5 million from the Vericel licensing agreement, net of royalty payment of $0.7 million and $0.8 million of other expenses.

The Company posted a net loss of $3.1 million, or $0.11 per share, for the second quarter of 2020 compared with a net profit of $12.7 million, or $0.47 per share, for the second quarter of 2019, which included the $17.5 million upfront license payment, net of royalty payment of $0.7 million and $0.8 million of other expenses. Excluding the upfront license payment net of deal related costs, net loss for the second quarter of 2019 was $3.3 million, or $0.12 per share.

Adjusted EBITDA, as defined below, for the second quarter of 2020 was a loss of $2.1 million, compared with a profit of $15.4 million for the second quarter of 2019, which included the upfront payment of $17.5 million from the Vericel licensing agreement, net of royalty payment of $0.7 million.

Year-to-Date 2020 Financial Results

Revenues for the first half of 2020 were $8.5 million compared with $21.2 million in the first half of 2019, which included the $17.5 million upfront payment from the Vericel licensing agreement for NexoBrid.

The Company's net loss for the first half of 2020 was $5.6 million or $0.20 per share compared with net profit of $8.6 million or $0.32 per share for the first half of 2019, which included the $17.5 million upfront license payment, net of royalty payment of $0.7 million and $0.9 million of other expenses. Excluding the upfront license payment net of deal related costs, net loss for the first half of 2019 was $7.3 million, or $0.27 per share.

Adjusted EBITDA, for the first half of 2020, was a loss of $3.9 million, compared with a profit of $12.4 million for the first half of 2019, which included the upfront payment of $17.5 million from the Vericel licensing agreement, net of royalty payment of $0.7 million.

Conference Call

MediWound management will host a conference call for investors today, Thursday, August 6, 2020 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 3176168. The call also will be webcast live 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 August 27, 2020 by dialing 855-859-2056 (in the U.S.) or 404-537-3406 (outside the U.S.) and entering passcode 3176168. The call will also be archived on the Company website for 90 days at www.mediwound.com.

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, non-surgically and rapidly removes burn eschar 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.

About BARDA

The Biomedical Advanced Research and Development Authority (BARDA), part of the Office of the Assistant Secretary for Preparedness and Response within the U.S. Department of Health and Human Services, provides an integrated, systematic approach to the development and purchase of the necessary vaccines, drugs, therapies and diagnostic tools for public health medical emergencies. For more information, refer to www.phe.gov/about/BARDA. Funding and technical support for development of NexoBrid to obtain marketing approval in the U.S. including the expanded access treatment protocol (NEXT), the pivotal U.S. Phase 3 clinical study (DETECT) and the marketing approval registration process for NexoBrid in the U.S. is provided by BARDA, under the Assistant Secretary for Preparedness and Response (ASPR), within the U.S. Department of Health and Human Services (HHS), under ongoing USG Contract No. HHSO100201500035C. Additional projects for evaluation of NexoBrid funded under the BARDA contract include randomized, controlled pivotal clinical trial for use in pediatric population, establishment of a pre-emergency use data package and development of the health economic model to evaluate the cost savings impact to enable market adoption in the United States.

Cautionary Note Regarding Forward-Looking Statements

MediWound caution you that all statements other than statements of historical fact included in this press release that address activities, events, or developments that we expect, believe or anticipate will or may occur in the future are forward-looking statements. Although we believe that we have a reasonable basis for the forward-looking statements contained herein, they are based on current expectations about future events affecting us and are subject to risks, assumptions, uncertainties and factors, all of which are difficult to predict and many of which are beyond our control. Actual results may differ materially from those expressed or implied by the forward-looking statements in this press release. These statements are often, but are not always, made through the use of words or phrases such as "anticipates," "intends," "estimates," "plans," "expects," "continues," "believe," "guidance,"

"outlook," "target," "future," "potential," "goals" and similar words or phrases, or future or conditional verbs such as "will," "would," "should," "could," "may," or similar expressions.

Specifically, this press release contains forward-looking statements concerning the anticipated progress, development, objectives, expectations, and commercial potential of NexoBrid and EscharEx. Among the factors that may cause results to be materially different from those stated herein are the inherent uncertainties associated with the timing and conduct of clinical trial and product development activities; the timing or likelihood of regulatory approvals; the ability to successfully develop and commercialize NexoBrid, including its commercial growth potential and the market demand for the product; the availability of funding from BARDA under its agreement with MediWound for use in connection with NexoBrid development activities; the timing of the NexoBrid delivery to BARDA, expected payments under the license agreement with Vericel; competitive developments; whether FDA will accept all or part of the BLA and provide marketing approval for NexoBrid in the United States; the risks related to the timing and conduct of NEXT Study; the ability to successfully develop and commercialize EscharEx, the design of the Phase 2 study, the timing of the interim assessment, the impact of applicable laws and regulations; and the uncertainties associated with the scope, scale and duration of the impact of the COVID-19 pandemic. For example, we are unable to predict how the pandemic will affect the overall healthcare infrastructure, including the pace with which governmental agencies, such as the FDA, will review and approve regulatory submissions. Additional government-imposed quarantines and requirements to "shelter at home" or other incremental mitigation efforts also may impact our ability to source supplies for our operations or our ability or capacity to manufacture, sell and support the use of NexoBrid in the future.

These and other significant factors are discussed in greater detail in MediWound's annual report on Form 20-F for the year ended December 31, 2019, filed with the Securities and Exchange Commission ("SEC") on February 25, 2020, Quarterly Reports on Form 6-K and other filings with the SEC from time-to-time. These forward-looking statements reflect MediWound's current views as of the date hereof and MediWound undertakes, and specifically disclaims, any obligation to update any of these forward-looking statements to reflect a change in their respective views or events or circumstances that occur after the date of this release except as required by law.

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MediWound, Ltd.

CONDENSED CONSOLIDATED BALANCE SHEETS

U.S. dollars in thousands

	June 30,		December 31,
	2020	2019	2019
	Un-audited		Audited
Cash, cash equivalents and short term deposits	24,382	38,712	29,458
Accounts and other receivable	3,492	4,668	4,557
Inventories	1,934	1,535	1,613
Total current assets	**29,808**	**44,915**	**35,628**
Property, plant and equipment, net	2,326	2,183	2,304
Right of use assets, net	2,086	2,315	2,229
Intangible assets, net	396	462	429
Total long-term assets	**4,808**	**4,960**	**4,962**
Total assets	**34,616**	**49,875**	**40,590**
Current maturities of long-term liabilities	1,321	896	569
Trade payables and accrued expenses	2,423	4,073	4,067
Other payables	6,040	5,889	5,737
Total current liabilities	**9,784**	**10,858**	**10,373**
Deferred revenues	1,174	1,144	1,135
Liability in respect of Israeli Innovation Authority grants net of current maturity	7,130	6,919	6,811
Contingent consideration for the purchase of shares net of current maturity	4,249	4,412	4,853

Liability in respect of discontinued operation	-	6,003	-
Lease liabilities, net of current maturity	1,866	2,022	2,006
Severance pay liabilities, net	281	338	243
Total long-term liabilities	**14,700**	**20,838**	**15,048**
Shareholders' equity	10,132	18,179	15,169
Total liabilities & shareholder equity	**34,616**	**49,875**	**40,590**

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

U.S. dollars in thousands

	Six months ended June 30,		Three months ended June 30,	
	2020	**2019**	**2020**	**2019**
Revenues	8,465	21,207	4,027	20,746
Cost of revenues	6,018	3,788	2,809	3,481
Gross profit	**2,447**	**17,419**	**1,217**	**17,265**
Operating expenses:				
Research and development, gross	3,312	6,075	1,593	1,893
Participation by BARDA & IIA	19	-4,624	19	-1,721
Research and development, net	3,331	1,451	1,612	172
Selling, general & administrative	4,028	4,708	2,311	2,343
Other expenses	-	901	-	812
Operating profit (loss)	**(4,912)**	**10,359**	**(2,706)**	**13,938**
Financial expenses, net	(645)	(1,803)	(390)	(1,222)
Profit (loss) from continuing operations	**(5,557)**	**8,556**	**(3,096)**	**12,716**
Profit from discontinued operation	-	50	0	0
Profit (loss) for the period	**(5,557)**	**8,606**	**(3,096)**	**12,716**
Foreign currency translation adjustments	1	2	0	(2)
Total comprehensive profit (loss)	**(5,556)**	**8,608**	**(3,096)**	**12,714**
Net Profit (loss) per share	(0.20)	0.32	(0.11)	0.47
Weighted average number of ordinary shares used in the computation of basic and diluted profit (loss) per share:	27,207	27,179	27,211	27,179

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ADJUSTED EBITDA

U.S. dollars in thousands

	Six months ended June 30,		Three months ended June 30,	
	2020	**2019**	**2020**	**2019**
Profit (loss) for the period	(5,557)	8,606	(3,096)	12,716

Adjustments:				
Financial expenses, net	(645)	(1,803)	(390)	(1,222)
Profit from discontinued operation	-	50	-	-
Other expenses	-	(901)	-	(812)
Depreciation and amortization	(539)	(552)	(271)	(278)
Share-based compensation expenses	(519)	(599)	(346)	(324)
Total adjustments	(1,703)	(3,805)	(1,007)	(2,636)
Adjusted EBITDA	**(3,854)**	**12,411**	**(2,089)**	**15,352**

MediWound, Ltd.

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

	Six months ended June 30,		Three months ended June 30,	
	2020	**2019**	**2020**	**2019**
Cash Flows from Operating Activities:				
Net profit (loss)	(5,557)	8,606	(3,096)	12,716
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	539	552	271	278
Share-based compensation	519	599	346	324
Revaluation of liabilities in respect of IIA grants	424	(392)	226	(466)
Revaluation of contingent consideration for the purchase of shares	348	1,322	196	1,081
Revaluation of lease liabilities	64	194	100	91
Increase (decrease) in severance liability, net	40	(10)	19	13
Financing income	(191)	(149)	(81)	(87)
Unrealized foreign currency (gain) loss	28	(70)	(51)	60
	1,771	1,996	1,026	1,294
Changes in asset and liability items:				
Decrease (increase) in trade receivables	1,341	(9)	444	(318)
Decrease (increase) in inventories	(326)	146	65	(62)
Decrease (increase) in other receivables	(284)	2,744	(383)	2,482
Increase (decrease) in trade payables	(1,649)	1,357	(1,004)	1,076
Increase in other payables & deferred revenues	86	529	133	77
	(832)	4,767	(745)	3,255
Net cash provided by (used in) continuing operating activities	(4,618)	15,369	(2,815)	17,265
Net cash provided by discontinued operating activities	-	50		-
Net cash provided by (used in) operating activities	**(4,618)**	**15,419**	**(2,815)**	**17,265**

MediWound, Ltd.

CONDENSED CONSOLIDATED STATEMENT OF CASH FLOW
(UNAUDITED)-Cont.
U.S. dollars in thousands

	Six months ended June 30,		Three months ended June 30,	
	2020	**2019**	**2020**	**2019**
Cash Flows from Investment Activities:				
Purchase of property and equipment	(244)	(433)	(100)	(194)
Interest received	42	44	39	14
Proceeds from short term bank deposits, net of investments	10,595	2,977	7,603	412
Net cash provided by investing activities	**10,393**	**2,588**	**7,542**	**232**
Cash Flows from Financing Activities:				
Repayment of lease liabilities	(313)	(312)	(153)	(157)
Proceeds from IIA grants, net of repayments	(66)	193	-	248
Net cash (used in) provided by financing activities	**(379)**	**(119)**	**(153)**	**91**
Exchange rate differences on cash and cash equivalent balances	(26)	63	57	(55)
Increase in cash and cash equivalents from continuing activities	5,370	17,901	4,631	17,533
Increase in cash and cash equivalents from discontinued activities	-	50	-	-
Balance of cash and cash equivalents at the beginning of the period	7,242	6,716	7,981	7,134
Balance of cash and cash equivalents at the end of the period	**12,612**	**24,667**	**12,612**	**24,667**

Source: MediWound Ltd.