MediWound Reports Third Quarter 2020 Financial Results

November 10, 2020

Total Third Quarter Revenues of $6.6 Million Increased 29% Year-over-Year

Assigned PDUFA Goal Date of June 29, 2021 for NexoBrid BLA

YAVNE, Israel, Nov. 10, 2020 (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 third quarter ended September 30, 2020.

Third Quarter Business and Financial Highlights:

- Revenues for the third quarter of 2020 were $6.6 million, an increase of 29% compared with the third quarter of 2019, primarily driven by the procurement of NexoBrid® by the Biomedical Advanced Research and Development Authority (BARDA)
- Cash and short term investments of $25.0 million as of September 30, 2020, compared with $29.5 million as of December 31, 2019
- Announced the U.S. Food and Drug Administration (FDA) accepted for review the Biologics License Application (BLA) for NexoBrid and assigned a Prescription Drug User Fee Act (PDUFA) goal date of June 29, 2021
- Delivered the first shipment of NexoBrid to BARDA for emergency response preparedness
- Completed enrollment stage of the NexoBrid Phase 3 Children Innovation Debridement Study (CIDS). Top-line data anticipated in the second half of 2021
- Completed U.S Phase 3 (DETECT) including patient long-term safety follow-up; The twenty-four-month safety data of cosmesis and function was comparable across all study arms with no new safety signals observed
- Continue to address challenges associated with the COVID-19 pandemic, while prioritizing the health and safety of our workforce and maintaining operational efficiency and flexibility

“We generated strong revenue growth in the third quarter, driven by the first delivery of NexoBrid emergency stock to BARDA,” said Sharon Malka, Chief Executive Officer of MediWound. “The quarter was highlighted by several important milestones that bring us closer to our goal of providing a new standard of care for eschar removal in patients with severe burns. Our NexoBrid BLA was accepted for review, we successfully completed the long-term safety patient follow-up stage of our U.S Phase 3 DETECT study, which showed comparable results across all arms, we completed the enrollment stage of our NexoBrid pediatric Phase 3 study and we continue to enroll patients under the NEXT protocol. In addition, we are actively recruiting patients in our U.S. EscharEx® Phase 2 study. While the COVID-19 pandemic continues to cause considerable uncertainty, we expect to maintain growth and are optimistic that we remain on track to strengthen our company further.”

Third Quarter Financial Results

Revenues for the quarter ended September 30, 2020 were $6.6 million, compared with $5.1million for the third quarter of 2019, an increase of 29%. Revenues from products for the quarter ended September 30, 2020, were $3.2 million, an increase of 189% in comparison to the third quarter of 2019, primarily driven by the procurement of NexoBrid by BARDA for emergency response preparedness.

Gross profit for the quarter ended September 30, 2020 was $2.8 million, compared with $1.2 million for the third quarter of 2019. Gross margin increased from 23% of revenues in the third quarter of 2019 to 42% in the third quarter of 2020.

Research and development expenses for the quarter ended September 30, 2020, were $2.1 million, compared with $1.6 million for the third quarter of 2019. The increase was a result of EscharEx clinical development.

Selling, general and administrative expenses for the quarter ended September 30, 2020 were $2.2 million, in line with the third quarter of 2019.

Operating loss for the quarter ended September 30, 2020 was $1.5 million, compared with a loss of $2.7 million in the third quarter of 2019.

MediWound’s loss for the quarter ended September 30, 2020 was $1.9 million, or $0.07 per share, compared with a loss of $0.2 million, or $0.01 per share, for the third quarter of 2019, which included one-time profit from discontinued operations of $2.8 million.

Adjusted EBITDA, as defined below, for the quarter ended September 30, 2020, was a loss of $0.8 million, compared with a loss of $2.0 million for the third quarter of 2019.

Year-to-Date 2020 Financial Results

Revenues for the nine months ended September 2020 were $15.1 million, compared with $26.3 million in the first nine months of 2019, which included a $17.5 million upfront payment from the Vericel licensing agreement for NexoBrid.

Operating loss for the nine months ended September 2020 was $6.5 million, compared with a profit of $7.6 million in the comparable period, which includes a $17.5 million upfront license payment and $1.7 million of NexoBrid licensing related expenses. Excluding the upfront license payment, net of deal related costs, operating loss for the first nine months of 2019 was $8.2 million.

MediWound's loss for the nine months ended September 2020 was $7.5 million, or $0.28 per share, compared with net profit of $8.4 million, or $0.31 per share, for the first nine months of 2019, which included the $17.5 million upfront license payment, $1.7 million licensing deal related expenses and discontinued operating profit of $2.8 million. Excluding the upfront license payment, net of deal related costs, and discontinued profit, net loss for the first nine months of 2019 was $10.2 million, or $0.37 per share.

Adjusted EBITDA, for the nine months ended September 2020, was a loss of $4.7 million, compared with a profit of $10.5 million for the first nine months of 2019, which included the upfront payment of $17.5 million from the Vericel licensing agreement, net of royalty payment of $0.7 million.

Balance Sheet Highlights

As of September 30, 2020, MediWound had $25.0 million in cash and short-term investments, compared with $29.5 million as of December 31, 2019, and no debt. MediWound remained on budget, utilizing $4.5 million in the first nine months of 2020 for its operational activities. MediWound reiterates its expectations of cash use for operating activities in 2020 to be in the range of $8 to $10 million.

Conference Call

MediWound management will host a conference call for investors today, Tuesday, November 10, 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 6997223. The call also will be webcast live on the MediWound's website at http://ir.mediwound.com/events-and-presentations.

A replay of the call will be accessible two hours after its completion through November 24, 2020 by dialing 855-859-2056 (in the U.S.) or 404-537-3406 (outside the U.S.) and entering passcode 6997223. The call will also be archived on MediWound's 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 for eschar removal (debridement) in adults with deep partial-thickness and/or full-thickness thermal burns. On June 29, 2020, a biological license application (BLA) was submitted to the U.S. FDA and was assigned a Prescription Drug User Fee Act (PDUFA) target date of June 29, 2021. 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; timeline of the 12- and 24-month top-line data in the CIDS; 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 Corporation; 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, its ability to monitor our clinical trials, and/or conduct necessary reviews or inspections any or all of which may result in timelines being materially delayed, which could affect the development and ultimate commercialization of NexoBrid and EscharEx. 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.

Contacts:	**Jeremy Feffer**
Boaz Gur-Lavie	Jeremy Feffer
Chief Financial Officer	Managing Director, LifeSci Advisors
MediWound Ltd.	212-915-2568
ir@mediwound.com	jeremy@lifesciadvisors.com

MediWound, Ltd.
CONDENSED CONSOLIDATED BALANCE SHEETS
U.S. dollars in thousands

	Sep 30,		Dec 31,
	2020	2019	2019
	Un-audited		Audited
Cash, cash equivalents and short term deposits	25,023	32,856	29,458
Accounts and other receivable	3,495	5,170	4,557
Inventories	1,805	1,419	1,613
Total current assets	30,323	39,445	35,628
LONGTERM ASSETS:			
Property, plant and equipment, net	2,448	2,169	2,304
Right of use assets, net	2,170	2,254	2,229
Intangible assets, net	380	446	429
Total long term assets	4,998	4,869	4,962
Total assets	**35,321**	**44,314**	**40,590**
CURRENT LIABILITIES:			
Current maturities of long-term liabilities	1,081	810	569
Trade payables and accrued expenses	3,155	2,863	4,067
Liability in respect of discontinued Operations	-	2,240	-
Other payables	7,394	4,898	5,737
Total current liabilities	11,630	10,811	10,373
Deferred revenues	1,283	1,134	1,135
Liabilities in respect of Israeli Innovation Authority grants net of current maturities	7,157	7,099	6,811
Contingent consideration for the purchase of shares net of current maturities	4,408	4,621	4,853
Lease liabilities net of current maturities	1,942	2,015	2,006
Severance pay liability, net	284	316	243
Total long term liabilities	15,074	15,185	15,048
Shareholders' equity	8,617	18,318	15,169
Total liabilities & shareholder equity	**35,321**	**44,314**	**40,590**

MediWound, Ltd.
CONDENSED CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME (LOSS) (UNAUDITED)

U.S. dollars in thousands

	Nine months ended Sep 30,		Three months ended Sep 30,	
	2020	2019	2020	2019
Revenues	15,090	26,347	6,625	5,140
Cost of revenues	9,873	7,489	3,855	3,969
Gross profit	5,217	18,858	2,770	1,171
Operating expenses:				
Research and development, gross	5,473	7,861	2,142	1,574
Participation by BARDA & IIA	-	(4,568)	-	-
Research and development, net	5,473	3,293	2,142	1,574
Selling, general & administrative	6,198	6,887	2,170	2,179
Other expenses, net	-	1,041	-	140
Total operating expenses	11,671	11,221	4,312	3,893
Operating profit (loss)	(6,454)	7,637	(1,542)	(2,722)
Financial expenses, net	(1,093)	(2,045)	(448)	(242)
Profit (loss) from continuing operations	(7,547)	5,592	(1,990)	(2,964)
Profit from discontinued operation	83	2,806	83	2,756
Profit (loss) for the period	(7,464)	8,398	(1,907)	(208)
Foreign currency translation adjustments	(11)	17	(12)	15
Total comprehensive income (loss)	(7,475)	8,415	(1,919)	(193)
Basic and diluted loss per share:				
Profit (loss) from continuing operations	(0.28)	0.21	(0.07)	(0.11)
Profit from discontinued operation	(*)	0.10	(*)	0.10
Net profit (loss) per share	(0.28)	0.31	(0.07)	(0.01)
Weighted average number of ordinary shares used in the computation of basic and diluted profit /loss per share:	27,206	27,179	27,179	27,179

(*) Represents less than $ 1

MediWound, Ltd.

ADJUSTED EBITDA

U.S. dollars in thousands

	Nine months ended Sep 30,		Three months ended Sep 30,	
	2020	2019	2020	2019
	Un-audited		Un-audited	
Profit (loss) for the period	(7,464)	8,398	(1,907)	(208)
Adjustments:				
Financial expenses, net	(1,093)	(2,045)	(448)	(242)
Profit from discontinued operation	83	2,806	83	2,756
Other expenses	-	(1,041)	-	(140)
Depreciation and amortization	(866)	(848)	(327)	(296)

Share-based compensation expenses	(923)	(931)	(404)	(332)
Total adjustments	(2,799)	(2,059)	(1,096)	1,746
Adjusted EBITDA	(4,665)	10,457	(811)	(1,954)

MediWound, Ltd.

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

	Nine months ended Sep 30,		Three months ended Sep 30,	
	2020	**2019**	**2020**	**2019**
Net profit (loss)	(7,464)	8,398	(1,907)	(208)
Adjustments to reconcile net profit (loss) to net cash used in continuing operating activities:				
Adjustments to profit and loss items:				
Profit from discontinued operation	(83)	(2,806)	(83)	(2,756)
Depreciation and amortization	866	848	327	296
Share-based compensation	923	931	404	332
Revaluation of liabilities in respect of IIA grants	692	(99)	268	293
Revaluation of contingent consideration for the purchase of shares	558	1,519	210	197
Revaluation of lease liabilities	127	(291)	63	(485)
Increase (decrease) in severance liability, net	35	(32)	(5)	(22)
Financing income, net	(244)	(295)	(53)	(146)
Unrealized foreign currency (gain) loss	(8)	(52)	(36)	18
	2,866	(277)	1,095	(2,273)
Changes in asset and liability items:				
Decrease (Increase) in trade receivables	1,477	(3,955)	136	(3,946)
Decrease (increase) in inventories	(231)	260	95	114
Decrease (increase) in other receivables	(397)	5,198	(113)	2,454
Increase (decrease) in trade payables and prepaid expenses	(925)	150	724	(1,207)
Increase in other payables & deferred revenues	1,288	810	1,202	281
Net cash provided by (used in)	1,212	2,463	2,044	(2,304)
continuing operating activities	(3,386)	10,584	1,232	(4,785)
Net cash provided by discontinued operating activities	(192)	-	(192)	-
Net cash provided by (used in) operating activities	**(3,578)**	**10,584**	**1,040**	**(4,785)**

MediWound, Ltd.

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

	Nine months ended Sep 30,		Three months ended Sep 30,	
	2020	**2019**	**2020**	**2019**
Cash Flows from Investment Activities:				
Purchase of property and equipment	(480)	(463)	(236)	(30)
Interest received	43	104	1	60
Proceeds from short term bank deposits, net of investments	8,136	(8,005)	(2,459)	(10,982)
Net cash provided by (used in) continuing investing activities	**7,699**	**(8,364)**	**(2,694)**	**(10,952)**

Net cash used in discontinued investing activities	-	**(957)**	-	**(1,007)**
Net cash provided by investing activities	**7,699**	**(9,321)**	**(2,694)**	**(10,952)**
Cash Flows from Financing Activities:				
Repayment of lease liabilities	(533)	99	(220)	411
Proceeds from IIA grants, net of repayments	(121)	(376)	(55)	(569)
Net cash used in financing activities	**(654)**	**(277)**	**(275)**	**(158)**
Exchange rate differences on cash and cash equivalent balances	32	41	58	(22)
Increase (decrease) in cash and cash equivalents from continuing activities	3,691	1,984	(1,679)	(15,917)
Decrease in cash and cash equivalents from discontinued activities	(192)	(957)	(192)	(1,007)
Balance of cash and cash equivalents at the beginning of the period	7,242	6,716	12,612	24,667
Balance of cash and cash equivalents at the end of the period	**10,741**	**7,743**	**10,741**	**7,743**

Source: MediWound Ltd.