



MediWound Reports Third Quarter 2022 Financial Results and Provides Company Update

November 15, 2022

\$30.5 million in gross proceeds raised; operating cash runway through 2025

NexoBrid PDUFA date of January 1, 2023; Upon approval, NexoBrid expected to generate meaningful revenues

Company focused on the billion-dollar market opportunity with EscharEx Phase 3 clinical study to begin in first-half 2023

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

YAVNE, Israel, Nov. 15, 2022 (GLOBE NEWSWIRE) -- MediWound Ltd. (NASDAQ: MDWD), a fully integrated biopharmaceutical company focused on next-generation biotherapeutic solutions for tissue repair and regeneration, today announced financial results for the third quarter ended September 30, 2022 and provided a corporate update.

"We are approaching several significant inflection points for the Company," said Ofer Gonen, Chief Executive Officer of MediWound. "We believe, once approved, NexoBrid[®] is poised to generate meaningful revenues in 2023 and exponential growth going forward. Following the launch of NexoBrid, we will focus on the billion-dollar market opportunity presented to us with EscharEx[®], where we plan to initiate a Phase III study next year. We have all the essential elements aligned for success: a mature pipeline, favorable data, large addressable markets, an experienced operational team, tier-1 partners, and a strong balance sheet. We are strategically positioned to unlock additional opportunities that will improve patient lives and add value to our shareholders."

Third Quarter Highlights and Recent Developments:

- Raised \$30.5 million in gross proceeds in a concurrent Registered Direct and Private Placement offering with participation from current and new shareholders including Israel Biotech Fund, New Era Capital Partners, Discount Capital and Deep Insight, as well as members of the management team and board of directors. The Company intends to use the net proceeds primarily for the development of EscharEx[®], scale up of the manufacturing facility, and general corporate purposes.
- EscharEx's promising results from the completed Phase 2 trials featured in oral and poster presentations at the Symposium on Advanced Wound Care (SAWC) Fall 2022, in Las Vegas, Nevada. Pivotal Phase 3 clinical study of EscharEx for the debridement of venous leg ulcers (VLUs) is currently expected to start in the first-half of 2023.
- FDA's review of NexoBrid BLA is progressing; inspections of manufacturing facilities in Taiwan and Israel are underway.
- The European Medicines Agency (EMA) validated for review the Company's Type II Variation to expand NexoBrid's currently approved indication for the pediatric population. The company anticipates a decision from the EMA during the first quarter of calendar year 2023.
- NexoBrid was highlighted in 45 posters and presentations at the 19th European Burns Association Congress in Turin, Italy. Leading European burn specialists and thought leaders from around the world shared their positive experiences and patient outcomes using NexoBrid in a wide range of settings.
- Positive initial data from the Company's U.S. Phase I/II study of MW005 for the treatment of low-risk basal cell carcinoma (BCC) was announced. The initial data showed MW005 to be safe and well-tolerated, and target lesions clearance data provided clinical efficacy proof-of-concept. Additional study data expected later this year.
- Strategic Advisory Board (SAB) of esteemed industry leaders was established to add significant expertise and insight to MediWound's strategic and operational activities.
- Total revenues for the third quarter of 2022 were \$5.8 million compared to \$6.4 million in the third quarter of 2021, and \$4.7 million in the second quarter of 2022.
- Cash and short-term investments of \$17.6 million as of September 30, 2022. An additional \$17.2 million in gross proceeds (\$16.6 million net proceeds) was received from the Private Placement Offering closed on October 6, 2022. The Company has sufficient cash to fund its expected operations through 2025.

Third Quarter Financial Highlights

Total revenues for the third quarter of 2022 were \$5.8 million, compared to \$6.4 million for the third quarter of 2021. Revenues from products in the third quarter of 2022 were \$1.4 million compared to \$6.2 million in the third quarter of 2021. This was primarily due to decrease in emergency stockpile procurement by BARDA.

Gross profit for the third quarter of 2022 was \$2.4 million, or 42% of net revenues, compared to a gross profit of \$2.5 million, or 39% of net revenues, for the third quarter of 2021.

Research and development expenses for the third quarter of 2022 were \$2.9 million same as in the third quarter of 2021.

Selling, general and administrative expenses for the third quarter of 2022 were \$3.1 million, compared to \$2.4 million in the third quarter of 2021. The increase was primarily a result of approximately \$0.2 million of share-based compensation costs and \$0.3 million of one-time marketing expenses.

Operating loss for the third quarter of 2022 was \$3.5 million compared to \$2.9 million in the third quarter of 2021.

The Company posted a net loss for the third quarter of 2022 of \$4.2 million, or \$0.13 per share, compared to a net loss of \$3.3 million, or \$0.12 per share, for the third quarter of 2021.

Adjusted EBITDA, as defined below, for the third quarter of 2022 was a loss of \$2.4 million, compared to a loss of \$2.2 million for the third quarter of 2021.

Year-to-Date 2022 Financial Results

Total revenues for the first nine months of 2022 were \$14.9 million, compared to \$18.3 million in the first nine months of 2021. Revenues from products in the first nine months of 2022 were \$4.2 million compared to \$7.7 million for the first nine months of 2021. This was primarily the result of a decrease in emergency stockpile procurement by BARDA.

Operating loss for the first nine months of 2022 was \$10.5 million, compared to an operating loss of \$7.7 million in the first nine months of 2021.

Net loss for the first nine months of 2022 was \$12.1 million, or \$0.38 per share compared to a net loss of \$9.4 million or \$0.34 per share for the first nine months of 2021.

Adjusted EBITDA, as defined below, for the first nine months of 2022, was a loss of \$7.8 million, compared to a loss of \$5.5 million for the first nine months of 2021.

Balance Sheet Highlights

As of September 30, 2022, MediWound had \$17.6 million in cash and short-term investments, compared with \$11.0 million as of December 31, 2021, and no debt. MediWound utilized \$4.6 million in the third quarter of 2022 for its operational activities. The Company reiterates its cash use for 2022 to be in the range of \$13 to \$15 million. In addition, \$17.2 million in gross proceeds (\$16.6 million in net proceeds were received in October from the \$30.5 equity offering), to support the Company's expected operations through 2025.

Conference Call

MediWound management will host a conference call for investors today, Tuesday, November 15, 2022, 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 833-630-1956 (in the U.S.), 80-921-2373 (Israel), or 412-317-1837 (outside the U.S. & Israel) and entering passcode 4399134. The call will be webcast live on the Events & Presentations page of Company's website at: <https://ir.mediwound.com/events-and-presentations>

A replay of the call will be available on the Company's website 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

MediWound is a biopharmaceutical company that develops, manufactures, and commercializes novel, cost effective, bio-therapeutic solutions for tissue repair and regeneration. Our strategy is to leverage our enzymatic technology platform, focusing on next-generation bioactive therapies for burn care, wound care, and tissue repair.

NexoBrid, our commercial orphan biological product for non-surgical eschar removal of deep-partial and full-thickness thermal burns, is a bromelain-based biological product containing a sterile mixture of proteolytic enzymes that selectively removes burn eschar within four hours without harming surrounding viable tissue. NexoBrid is currently marketed in the European Union and other international markets and is at the registration-stage with the United States Food and Drug Administration (FDA) with a PDUFA date set as of January 1, 2023. NexoBrid is supported by the U.S. Biomedical Advanced Research and Development Authority (BARDA).

EscharEx is our next-generation bioactive topical therapeutic under development in the U.S. for debridement of chronic and hard to heal wounds. EscharEx is well-tolerated and has demonstrated safety and efficacy in the debridement of various chronic and other hard-to-heal wounds within a few daily applications in several Phase 2 trials. A meeting with the FDA to discuss the Phase 3 pivotal study design is targeted for the fourth quarter of calendar year 2022.

MW005, our topical biological drug for the treatment of non-melanoma skin cancers, is a clinical-stage product candidate under development. The initial data from a Phase I/II study showed MW005 to be safe and well-tolerated, with a majority of the patients who completed the study with MW005 achieving complete histological clearance of their target lesions. The Company anticipates announcing the final data in the fourth quarter of calendar year 2022.

Committed to innovation, we are dedicated to improving standard of care and enhancing patient lives. For more information, please visit www.mediwound.com.

Cautionary Note Regarding Forward-Looking Statements

MediWound cautions 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, study design, expected data timing, objectives anticipated timelines, expectations and commercial potential of our products and product candidates. Among the factors that may cause results to be materially different from those stated herein are the inherent uncertainties associated with the market potential of our products and product candidates, our expectations regarding future growth and revenues, uncertain, lengthy and expensive nature of the product development process; the timing and conduct of our studies of our products and product candidates, including the timing, progress and results of current and future clinical studies, and our research and development programs; the approval of regulatory submission by the European Medicines Agency, FDA or by any other regulatory authority, our ability to obtain marketing approval of our products and product candidates in the U.S. or other markets. For Example the clinical utility, potential advantages and timing or likelihood of regulatory filings and approvals of our products and products; our ability to develop new products; risks related to our contracts with BARDA; market acceptance of our products and product candidates; our ability to maintain adequate protection of our intellectual property; competition risks; the need for additional financing; the impact of government laws and regulations and 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 ability to recruit patients, the ability to conduct the studies in medical sites and 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 our products and product candidates 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, 2021, filed with the Securities and Exchange Commission (“SEC”) on March 17, 2022, 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

	September 30,		December 31,
	2022	2021	2021
	Un-audited		Audited
Cash, cash equivalents and short-term deposits	17,592	13,866	11,046
Accounts and other receivable	4,976	3,553	2,706
Inventories	1,880	1,252	1,200
Total current assets	24,448	18,671	14,952
Other receivables	230	-	469
Property, plant and equipment, net	2,354	2,531	2,478
Right of use assets, net	1,305	1,650	1,548

Intangible assets, net	248	314	297
Total long-term assets	4,137	4,495	4,792
Total assets	28,585	23,166	19,744
Current maturities of long-term liabilities	2,461	1,867	2,408
Trade payables and accrued expenses	3,565	3,710	4,693
Other payables	2,986	4,384	3,620
Total current liabilities	9,012	9,961	10,721
Deferred revenues	31	352	119
Liability in respect of Israeli Innovation Authority grants net of current maturity	8,451	7,715	7,885
Contingent consideration for the purchase of shares net of current maturity	3,076	4,195	3,922
Lease liability, net of current maturity	952	1,483	1,391
Warrants	5,092	-	-
Severance pay liability, net	315	281	288
Total long-term liabilities	17,917	14,026	13,605
Shareholders' equity (deficit)	1,656	(821)	(4,582)
Total liabilities & shareholder equity	28,585	23,166	19,744

MediWound, Ltd.

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

U.S. dollars in thousands

	Nine months ended		Three months ended	
	September 30,		September 30,	
	2022	2021	2022	2021
Revenues	14,878	18,276	5,803	6,372
Cost of revenues	9,871	11,044	3,369	3,917
Gross profit	5,007	7,232	2,434	2,455
Operating expenses:				
Research and development, net	7,482	7,795	2,883	2,897
Selling, general & administrative	7,684	7,137	3,061	2,442
Other expenses	309	-	-	-
Operating loss	(10,468)	(7,700)	(3,510)	(2,884)
Financial expenses, net	(1,661)	(1,668)	(684)	(457)
Loss before Taxes on Income	(12,129)	(9,368)	(4,194)	(3,341)
Taxes on Income	(13)	(23)	(5)	(4)
Net Loss	(12,142)	(9,391)	(4,199)	(3,345)
Foreign currency translation adjustments	34	15	12	7
Total comprehensive loss	(12,108)	(9,376)	(4,187)	(3,338)
Net loss per share	(0.38)	(0.34)	(0.13)	(0.12)
Weighted average number of ordinary shares used in the computation of basic and diluted loss per share:	31,818	27,243	33,482	27,141

MediWound, Ltd.

ADJUSTED EBITDA

U.S. dollars in thousands

	Nine months ended	Three months ended
	September 30,	September 30,

	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Loss for the period	(12,142)	(9,391)	(4,199)	(3,345)
Adjustments:				
Financial expenses, net	(1,661)	(1,668)	(684)	(457)
Other expenses	(309)	-	-	-
Tax Expenses	(13)	(23)	(5)	(4)
Depreciation and amortization	(988)	(962)	(338)	(335)
Share-based compensation expenses	(1,304)	(1,283)	(707)	(399)
Total adjustments	(4,275)	(3,936)	(1,734)	(1,195)
Adjusted EBITDA	(7,867)	(5,455)	(2,465)	(2,150)

ADJUSTED EBITDA – PROFIT (LOSS) (UNAUDITED)

U.S. dollars in thousands

	<u>Nine months ended</u> <u>September 30,</u>		<u>Three months ended</u> <u>September 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Revenues	14,878	18,276	5,803	6,372
Cost of Revenues	9,213	10,474	3,129	3,721
Gross Profit	5,665	7,802	2,674	2,651
Research and development	6,934	7,262	2,676	2,723
Selling, general & administrative	6,598	5,995	2,463	2,078
Operating Loss	(7,867)	(5,455)	(2,465)	(2,150)

MediWound, Ltd.

CONDENSED CONSOLIDATED STATEMENT OF CASH FLOW (UNAUDITED)

U.S. dollars in thousands

	<u>Nine months ended</u> <u>September 30,</u>		<u>Three months ended</u> <u>September 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Cash Flows from Operating Activities:				
Net loss	(12,142)	(9,391)	(4,199)	(3,345)
Adjustments to reconcile net loss to net cash used in operating activities:				
Adjustments to profit and loss items:				
Depreciation and amortization	988	962	338	335
Share-based compensation	1,304	1,283	707	399
Revaluation of liabilities in respect of IIA grants	812	808	330	311
Revaluation of liabilities in respect of purchase of shares	404	446	132	147
Revaluation of lease liabilities	(146)	84	6	49
Increase in severance liability, net	64	3	9	8
Net financing expenses (income)	334	(11)	345	-
Unrealized foreign currency (gain) loss	465	(238)	(63)	(12)
	4,225	3,337	1,804	1,237
Changes in asset and liability items:				
Decrease (increase) in trade receivables	(2,445)	697	(421)	17
Decrease (increase) in inventories	(608)	188	139	171
Decrease (Increase) in other receivables	143	(1,078)	(187)	(646)
Increase (decrease) in trade payables and prepaid expenses	(1,232)	733	(1,243)	(342)
Increase (decrease) in other payables & deferred revenues	(1,826)	(1,167)	(459)	90
	(5,968)	(627)	(2,171)	(710)
Net cash used in operating activities	(13,885)	(6,681)	(4,566)	(2,818)

	Nine months ended		Three months ended	
	September 30,		September 30,	
	2022	2021	2022	2021
Cash Flows from Investment Activities:				
Purchase of property and equipment	(381)	(373)	(83)	(129)
Interest received	3	35	3	-
Decrease (Increase) in short term bank deposits, net	(2,499)	4,200	-	-
Net cash (used in) provided by (used in) investing activities	(2,877)	3,664	(80)	(129)
Cash Flows from Financing Activities:				
Repayment of lease liabilities	(531)	(513)	(181)	(176)
Proceeds from issuance of shares and warrants, net	21,915	-	12,054	-
Proceeds from IIA grants, net of repayments	(258)	(360)	(96)	(180)
Net cash provided by (used in) financing activities	21,126	(873)	11,777	(356)
Exchange rate differences on cash and cash equivalent balances	(505)	197	45	(7)
Increase (decrease) in cash and cash equivalents from continuing activities	3,859	(3,693)	7,176	(3,310)
Balance of cash and cash equivalents at the beginning of the period	11,046	17,376	7,729	16,993
Balance of cash and cash equivalents at the end of the period	14,905	13,683	14,905	13,683



Source: MediWound, Ltd.