



MediWound Reports Fourth Quarter and Full Year 2022 Financial Results and Company Update

March 16, 2023

2022 total revenues of \$26.5 million

FDA approval of NexoBrid® in December 2022; U.S. commercial availability expected in the second quarter of 2023

EscharEx® Phase III protocol design is under review by the FDA; study to be initiated in the second half of 2023

Cash position of \$66 million, including cash received for the NexoBrid approval milestone and recent equity financing

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

YAVNE, Israel, March 16, 2023 (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 fourth quarter and the year ended December 31, 2022 and provided a corporate update.

"The year 2022 was truly transformative for MediWound on multiple fronts. We are proud to have received U.S. FDA approval for NexoBrid, we made significant clinical development advancements with EscharEx, and we bolstered our balance sheet by approximately \$70 million in cash, while attracting new institutional investors," said Ofer Gonen, Chief Executive Officer of MediWound. "As we move into 2023 and continue to execute, we are confident that our current strategy will further propel MediWound's evolution into a world-class biopharmaceutical company. With NexoBrid set to launch commercially in the U.S. in the second quarter of 2023 through our partner Vericel, and the expansion of our global footprint into key markets such as Japan and India, we have already begun the process of scaling up our manufacturing capabilities to meet the growing demand. Building on the successful completion of two Phase II studies, EscharEx is primed to move into Phase III and help drive needed innovation in our field. We are excited about the future of MediWound and remain fully committed to making a positive impact on patient lives around the world."

2022 Highlights and Recent Developments:

- Raised \$30.5 million in September and October 2022 in registered direct and PIPE offerings.
- Raised \$27.5 million in February 2023 in a registered direct offering of ordinary shares with participation from new and current institutional shareholders, including Point 72, Israel Biotech Fund, Deep Insight, and aMoon.
- Received approval from the U.S. Food and Drug Administration (FDA) for NexoBrid for the removal of eschar in adults with deep partial-thickness and/or full-thickness thermal burns, triggering a \$7.5 million milestone payment from Vericel.
- Concluded two Phase II studies with EscharEx, which showed EscharEx to be significantly more effective and faster than the current standard-of-care in the debridement of Venous Leg Ulcers (VLUs) and Diabetic Foot Ulcers (DFUs) and was found to be safe and well tolerated. EscharEx Phase III protocol design is under review by the FDA; the study is expected to be initiated in the second half of 2023.
- Announced marketing approvals for NexoBrid in Japan and India. Kaken Pharmaceutical, a top ranked Japanese pharmaceutical company, has the exclusive rights to market and distribute NexoBrid in Japan. Bharat Serums and Vaccines Limited (BSV), a leading biopharmaceutical company in India, has the exclusive rights to market and distribute NexoBrid in India. Launch in both countries is expected in mid-2023.
- Announced that the European Medicines Agency (EMA) accepted for review MediWound's application for the extended indication for NexoBrid to treat pediatric patients with severe thermal burns. A decision from the European Commission is expected in mid-year 2023.
- Announced positive data from a Phase I/II study to evaluate the safety and efficacy of MW005 in the treatment of low-risk basal cell carcinoma (BCC). The data showed MW005 to be safe and well-tolerated, with patients achieving complete clinical and histological clearance of their target lesions.
- Initiated facility manufacturing scale-up to meet the growing global demand for NexoBrid.
- Announced Ms. Hani Luxenburg as new Chief Financial Officer, effective May 14, 2023. Ms. Luxenburg will replace Mr. Boaz Gur-Lavie, who will remain with the Company through July 31, 2023, to ensure an orderly transition. Additionally, as part of the Company's focus on expanding its Global leadership team, Mr. Barry Wolfenson was appointed as Executive Vice President of Strategy and Corporate Development, and Ms. Alicia Torrenova was appointed as Vice President of European Operations. All bring extensive leadership experience to help drive the Company's future growth.

Fourth Quarter Financial Highlights

Total revenues for the fourth quarter of 2022 were \$11.6 million, compared to \$5.5 million for the fourth quarter of 2021. License revenues were \$8.2 million compared to \$1.8 million for the fourth quarter of 2021, driven by the \$7.5 million BLA approval milestone from Vericel. Revenues from products were \$1.2 million compared to \$1.9 million in the fourth quarter of 2021. This was primarily due to a \$1.0 million decrease in the emergency stockpile procurement by BARDA, partially offset by Europe and international markets sales increase.

Gross profit for the fourth quarter of 2022 was \$8.2 million, or 70% of net revenues, compared to a gross profit of \$1.5 million, or 28% of net revenues, for the fourth quarter of 2021. The increase was primarily driven by the \$7.5 million milestone payment from Vericel upon the BLA approval.

Research and development expenses for the fourth quarter of 2022 were \$2.7 million, compared to \$2.5 million in the fourth quarter of 2021.

Selling, general and administrative expenses for the fourth quarter of 2022 were \$3.0 million, compared to \$2.6 million in the fourth quarter of 2021. The increase was primarily a result of one-time expenses related to the BLA approval.

Other expenses for the fourth quarter of 2022 were \$0.4 million, compared to zero in the fourth quarter of 2021 due to a one-time expense related to the BLA approval.

Operating profit for the fourth quarter of 2022 was \$2.1 million compared to a loss of \$3.5 million in the fourth quarter of 2021. The improvement was primarily driven by the \$7.5 million milestone payment from Vericel upon the BLA approval.

The Company posted a net loss for the fourth quarter of 2022 of \$7.5 million, or \$1.18 per share, compared to a net loss of \$4.2 million, or \$1.07 per share, for the fourth quarter of 2021. The increase in loss was due to non-cash financial expenses, primarily due to the warrant's revaluation from the September and October 2022 financing.

Adjusted EBITDA, as defined below, for the fourth quarter of 2022 was a profit of \$3.4 million, compared to a loss of \$2.9 million for the fourth quarter of 2021.

Full-Year 2022 Financial Highlights

Total revenues for the year ended December 31, 2022, were \$26.5 million, compared to \$23.8 million for the year ended December 31, 2021. Revenues from products in 2022 were \$5.3 million, a 44% decrease compared to \$9.6 million in 2021. This was primarily the result of BARDA's \$4.3 million decrease in emergency stockpile procurement. Revenues from licenses were \$8.2 million compared to \$1.8 million in 2021, driven by the BLA approval milestone payment from Vericel.

Gross profit for the year ended December 31, 2022 was \$13.2 million with a gross margin of 50%, compared to a gross profit of \$8.8 million and a gross margin of 37% in the prior year period. The increase was primarily driven by the \$7.5 million milestone payment from Vericel upon the BLA approval.

Research and development expenses for the year ended December 31, 2022, were \$10.2 million, compared to \$10.3 million in the prior year.

Selling, general and administrative expenses for the year ended December 31, 2022 were \$10.6 million compared to \$9.7 million in the prior year. The increase was primarily a result of one-time expenses related to the BLA approval and management changes in mid-2022.

Operating loss for the year ended December 31, 2022 was \$8.3 million, compared to an operating loss of \$11.2 million for the year ended December 31, 2021.

Net loss for the year ended December 31, 2022 was \$19.6 million, or \$3.93 per share compared to a net loss of \$13.6 million or \$3.48 per share for the year ended December 31, 2021. The increase of loss is due to non-cash financial expenses, due to warrant's revaluation from the September and October 2022 financing.

Adjusted EBITDA, as defined below, for the year ended December 31, 2022, was a loss of \$4.4 million, compared to a loss of \$8.3 million for the year ended December 31, 2021.

Balance Sheet Highlights

As of December 31, 2022, the Company had \$34.1 million in cash and short-term investments, compared with \$11 million as of December 31, 2021. The Company utilized \$11.9 million to fund its operating activities and \$3.1 for contingent liabilities and capital expenditure (CAPEX) in 2022.

In February 2023, the Company received a \$7.5 million milestone payment from its partner, Vericel, for U.S. FDA approval of NexoBrid in December 2022. On February 7, 2023, the Company completed a registered direct offering, which provided the Company with an additional \$27.5 million in gross proceeds. The Company expects its cash use for 2023 to be in the range of \$16 to \$18 million. The existing cash and cash equivalents will provide sufficient funds for the Company's current operating plan through 2026.

Conference Call

MediWound management will host a conference call for investors today, Thursday, March 16, 2023, 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 1-833-630-1956 (in the U.S.), 1-80-921-2373 (Israel), or 1-412-317-1837 (outside the U.S. & Israel) and entering passcode 4784335. The call will be available via webcast by [clicking HERE](#) or on the [Events & Presentations](#) page of Company's website.

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, non-surgical, bio-therapeutic solutions for tissue repair and regeneration. Our strategy leverages our enzymatic technology platform, focused on next generation, bioactive therapies for burn care, wound care and tissue repair.

NexoBrid[®] is our commercial orphan biological product for early non-surgical eschar removal of deep-partial and full-thickness thermal burns. It 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, Japan, India, and other international markets, and recently received FDA approval for marketing in the U.S. NexoBrid is supported by the US Biomedical Advanced Research and Development Authority (BARDA), Administration for Strategic Preparedness and Response (ASPR), within the U.S. Department of Health and Human Services (HHS).

EscharEx[®] is based on the same active pharmaceutical ingredient as NexoBrid. It is under development for the debridement of chronic and hard-to-heal wounds. Results from Phase II studies show that EscharEx is significantly more effective and faster than SOC or placebo control in debridement of Venous Leg Ulcers (VLUs) and Diabetic Foot Ulcers (DFUs), with a good safety and tolerability profile. MediWound has discussions with the FDA regarding the EscharEx pivotal Phase III study design which is expected to be initiated in the second half of 2023.

MW005 is a topical biological drug under development for the treatment of low-risk Basal Cell Carcinoma (BCC). In a Phase I/II open-label, multicenter, randomized clinical trial conducted in the U.S., MW005 was shown to be safe, well-tolerated, and an effective treatment for BCC with patients demonstrating complete clinical and histological clearance of target lesions. Study results are expected in Q3 2023.

Committed to innovation, we are dedicated to improving the standard of care and enhancing patient lives. For more information, please visit www.mediwound.com and follow the Company on [LinkedIn](#).

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 including EscharEx[®] and NexoBrid[®]. Among the factors that may cause results to be materially different from those stated herein are the inherent uncertainties associated with the 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 FDA, the European Medicines Agency 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; the clinical utility, potential advantages and timing or likelihood of regulatory filings and approvals of our products and products; our expectations regarding future growth, including 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 current global macroeconomic climate on 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 prospectus supplement, the annual report on Form 20-F for the year ended December 31, 2022, filed with the Securities and Exchange Commission ("SEC") on March 16, 2023, 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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Condensed Consolidated Statements of Financial Position
AUDITED
U.S. dollars in thousands

	December 31,	
	2022	2021
Cash, cash equivalents and short-term deposits	33,895	11,046
Trade and other receivable	9,982	2,706
Inventories	1,963	1,200
Total current assets	45,840	14,952
Other receivables	364	469
Property, plant and equipment, net	2,366	2,478
Right of-use assets, net	1,215	1,548
Intangible assets, net	231	297
Total non-current assets	4,176	4,792
Total assets	50,016	19,744
Current maturities of long-term liabilities	2,242	2,408
Trade payables and accrued expenses	5,656	4,693
Other payables	4,159	3,620
Total current liabilities	12,057	10,721
Deferred revenues	-	119
Warrants, net	15,606	-
Liabilities in respect of IIA grants, net of current maturity	7,445	7,885
Liabilities in respect of TEVA, net of current maturity	2,788	3,922
Lease liabilities net of current maturity	846	1,391
Severance pay liability, net	360	288
Total non-current liabilities	27,045	13,605

Shareholders' equity (deficit)	10,914	(4,582)
Total liabilities & shareholder equity	50,016	19,744

MediWound, Ltd.

Condensed Consolidated Statements of Profit or Loss and Other Comprehensive Income or Loss
U.S. dollars in thousands

	Year ended		Three months ended	
	December 31,		December 31,	
	2022	2021	2022	2021
	AUDITED		UNAUDITED	
Revenues	26,496	23,763	11,618	5,487
Cost of revenues	13,331	14,992	3,460	3,948
Gross profit	13,165	8,771	8,158	1,539
Operating expenses:				
Research and development	10,181	10,256	2,699	2,461
Selling, general & administrative	10,645	9,736	2,961	2,599
Other expenses	684	-	375	-
Operating profit (loss)	(8,345)	(11,221)	2,123	(3,521)
Financial expenses, net	(11,176)	(2,303)	(9,515)	(635)
Loss before taxes on income	(19,521)	(13,524)	(7,392)	(4,156)
Taxes on income	(78)	(27)	(65)	(4)
Loss for the period	(19,599)	(13,551)	(7,457)	(4,160)
Foreign currency translation adjustments	14	21	(20)	6
Total comprehensive loss	(19,585)	(13,530)	(7,477)	(4,154)
Profit (loss) per share:				
Total basic and diluted net loss per share	(3.93)	(3.48)	(1.18)	(1.07)

Weighted average number of ordinary shares used in the computation of basic and diluted loss per share (in thousands)*:

4,987	3,892	6,333	3,893
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*Restated to reflect 1:7 reverse ratio of shares

MediWound, Ltd.

ADJUSTED EBITDA

U.S. dollars in thousand

	Year ended		Three months ended	
	December 31,		December 31,	
	2022	2021	2022	2021
Loss for the period	(19,599)	(13,551)	(7,457)	(4,160)
Adjustments:				
Financial expenses, net	(11,176)	(2,303)	(9,515)	(635)
Other expenses	(684)	-	(375)	-
Tax expenses	(78)	(27)	(65)	(4)
Depreciation and amortization	(1,272)	(1,238)	(284)	(276)
Share-based compensation expenses	(1,946)	(1,673)	(642)	(390)
Total adjustments	(15,156)	(5,241)	(10,881)	(1,305)
Adjusted EBITDA	(4,443)	(8,310)	3,424	(2,855)

MediWound, Ltd.

Consolidated Statements of Cash Flows

U.S. dollars in thousands

	Year ended		Three months ended	
	December 31,		December 31,	
	2022	2021	2022	2021
	AUDITED		UNAUDITED	

Cash Flows from Operating Activities:

Loss for the period	(19,599)	(13,551)	(7,457)	(4,160)
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Adjustments to reconcile net loss to net cash (used in) provided by operating activities:

Adjustments to profit and loss items:

Depreciation and amortization	1,272	1,238	284	276
Share-based compensation	1,946	1,673	642	390
Revaluation of warrants accounted at fair value	8,997		8,997	-
Issuance expenses of warrants through profit and loss	1,911		1,523	-
Revaluation of liabilities in respect of IIA grants	(132)	918	(944)	110
Revaluation of liabilities in respect of TEVA	533	591	129	145
Revaluation of lease liabilities	(109)	187	37	103
Increase in severance liability, net	109	14	45	11
Financing income, net	(74)	(11)	(408)	-
Unrealized foreign currency gain	525	(137)	60	101
	14,958	4,473	10,345	1,136

Changes in asset and liability items:

Decrease (increase) in trade receivables	(7,582)	929	(5,137)	232
Decrease(increase) in inventories	(721)	257	(113)	69
Decrease (increase) in other receivables	364	(763)	221	315
Increase in trade payables & accrued expenses	414	1,723	784	990
Increase (decrease) in other payables & deferred revenues	281	(1,984)	2,107	(817)
	(7,244)	162	(2,138)	789
Net cash (used in) provided by operating activities	(11,885)	(8,916)	750	(2,235)

Cash Flows from Investment Activities:

Purchase of property and equipment	(555)	(489)	(174)	(116)
Interest received	74	35	71	-

Proceeds from short term bank deposits, net of investments	-	4,002	2,499	-
Net cash (used in) provided by investing activities	(482)	3,548	2,396	(116)
<u>Cash Flows from Financing Activities:</u>				
Repayment of lease liabilities	(701)	(693)	(170)	(180)
Proceeds from issuance of shares and warrants	38,390	3	16,475	3
Repayment of liabilities in respect of TEVA	(1,667)	-	(417)	-
Repayment of IIA grants, net	(258)	(360)	-	-
Net cash provided by (used in) financing activities	35,764	(1,050)	15,588	(177)
Exchange rate differences on cash and cash equivalent balances	(549)	88	(44)	(109)
Increase (decrease) in cash and cash equivalents from activities	22,849	(6,330)	18,990	(2,637)
Balance of cash and cash equivalents at the beginning of the period	11,046	17,376	14,905	13,683
Balance of cash and cash equivalents at the end of the period	33,895	11,046	33,895	11,046