



MediWound Reports Fourth Quarter and Full Year 2021 Financial Results

March 17, 2022

Full-Year 2021 Total Revenues of \$23.8 Million; Product Revenues Up 46%

Positive Top-Line Data for EscharEx Phase 2 Clinical Trial, with Full Data Set Anticipated in Second Quarter 2022

Raised Gross Proceeds of \$10 Million through Public Equity Offering

Conference Call Begins Today at 8:30 am ET

YAVNE, Israel, March 17, 2022 (GLOBE NEWSWIRE) -- MediWound Ltd. (Nasdaq: MDWD) (the "Company"), 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 year ended December 31, 2021 and provided a corporate update.

Fourth Quarter, Full-Year 2021 and Recent Weeks Financial Highlights:

- Total revenues for 2021 were \$23.8 million; compared to \$21.8 million in 2020
- Product revenues in 2021 increased by 46% over 2020 to \$11.4 million
- Total revenues for the fourth quarter of 2021 were \$5.5 million, compared to \$6.7 million in the fourth quarter of 2020
- Achieved profitability with commercial operations for NexoBrid for 2021
- The Company had \$11.0 million in cash and short-term investments as of December 31, 2021
- In March 2022, the Company raised an additional \$10 million in total gross proceeds through an equity offering

Business Highlights and Updates:

- Positive topline results from the U.S. Phase 2 clinical study of EscharEx for the debridement of venous leg ulcers (VLUs). The study met its primary endpoint, demonstrating that patients treated with EscharEx had a statistically significant higher incidence of complete debridement compared to the gel vehicle
- Gained clarity from the U.S. Food and Drug Administration (FDA) on a path forward for resubmission of the NexoBrid Biologics License Application (BLA), which is now anticipated in mid-2022
- The Biomedical Advanced Research and Development Authority (BARDA) expanded its awarded contract by providing supplemental funding of \$9 million to support the NexoBrid BLA resubmission with the FDA and the ongoing expanded access treatment protocol (NEXT)
- Positive data from the U.S. Phase 2 pharmacology study of EscharEx showing effective and rapid debridement in chronic and hard-to-heal wounds and demonstrating EscharEx reduced biofilm and bacterial load
- Following the robust results from the Phase 3 pediatric study, gained regulatory path clarity towards a pediatric label extension for NexoBrid from the European Medicines Agency (EMA) through scientific advice
- Awarded a U.S. Department of Defense research grant for the development of NexoBrid for the U.S. Army

"The Company continued to execute well across all operating areas of the business in 2021, setting up 2022 to be a transformational year for us," said Sharon Malka, Chief Executive Officer of MediWound. "Meeting the primary endpoint with superior efficacy data from our U.S. Phase 2 EscharEx trial recently announced reinforces our belief that EscharEx has the potential to become a best-in-class debridement option for the millions of patients suffering from hard-to-heal wounds. We expect the full data set for the EscharEx trial in the second quarter, which we will use to guide and develop our Phase 3 program. With NexoBrid, we are on track for resubmitting the BLA to the FDA in mid-year. We have strengthened our balance sheet, improving our liquidity and we believe we are now well-positioned as we approach several important upcoming milestones throughout the year."

Fourth Quarter 2021 Financial Results

Revenues for the fourth quarter of 2021 were \$5.5 million, a decrease of 18% compared to \$6.7 million for the fourth quarter of 2020. The decrease in revenues was primarily due to reduced BARDA emergency stockpile procurement in the fourth quarter of 2021 and decrease in revenues from

services to BARDA, resulting from the completion of DETECT and CIDS clinical studies.

Gross profit for the fourth quarter of 2021 was \$1.5 million with gross margins of 28%, compared to gross profit of \$2.3 million and gross margins of 35% for the fourth quarter of 2020.

Research and development expenses for the fourth quarter of 2021 were \$2.5 million, compared to \$2.2 million for the fourth quarter of 2020. The increase was primarily due to clinical development program of EscharEx.

Selling, general and administrative expenses for the fourth quarter of 2021 were \$2.6 million, compared to \$2.5 million in the fourth quarter of 2020.

Operating loss for the fourth quarter of 2021 was \$3.5 million, compared to an operating loss of \$2.4 million in the fourth quarter of 2020.

The Company posted a net loss of \$4.2 million, or \$0.15 per share, for the fourth quarter of 2021 compared to a net loss of \$1.7 million, or \$0.06 per share, for the fourth quarter of 2020.

Adjusted EBITDA, as defined below, for the fourth quarter of 2021 was a loss of \$2.9 million, compared to a loss of \$1.8 million for the fourth quarter of 2020.

Full-Year 2021 Financial Results

Revenues for the year ended December 31, 2021 were \$23.8 million compared to \$21.8 million for the year ended December 31, 2020, an increase of 9%. Product revenues (sales of product and license fee) in 2021 were \$11.4 million, an increase of 46% compared to \$7.8 million in 2020, primarily driven by BARDA emergency stockpile procurement and increased sales in Europe.

Gross profit for the year ended December 31, 2021 was \$8.8 million with gross margin of 37%, compared with a gross profit of \$7.5 million with gross margin of 35% in the prior year period.

Research and development expenses for the year ended December 31, 2021, were \$10.3 million, compared to \$7.7 million in the prior year. The increase was primarily due to clinical development for EscharEx.

Selling, general and administrative expenses for the year ended December 31, 2021 were \$9.7 million compared to \$8.7 million in the prior year. The increase was primarily as a result of one-time legal expenses and lease and maintenance classification costs.

Operating loss for the year ended December 31, 2021 was \$11.2 million, compared to an operating loss of \$8.8 million for the year ended December 31, 2020, primarily due to increase in research and development expenses.

The Company's net loss for the year ended December 31, 2021 was \$13.6 million or \$0.50 per share, compared to a net loss of \$9.2 million or \$0.34 per share for the year ended December 31, 2020.

Adjusted EBITDA, for the year ended December 31, 2021, was a loss of \$8.3 million, compared to a loss of \$6.4 million for the year ended December 31, 2020.

Balance Sheet Highlights

As of December 31, 2021, MediWound had \$11.0 million in cash and short-term investments, compared to \$21.6 million as of December 31, 2020. The Company utilized \$10.6 million to fund its operating activities in 2021.

On March 7, 2022, the Company completed a public offering, which provided the Company with an additional \$10 million in gross proceeds. The Company expects cash use for 2022 to be in the range of \$11 to \$13 million. Based on our current operating plan, we believe that existing cash and cash equivalents will be sufficient to fund currently anticipated operating expenses for at least the next 24 months.

Conference Call

MediWound management will host a conference call for investors today, Thursday, March 17, 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 877-602-7189 (in the U.S.) or 678-894-3057 (outside the U.S. & Israel) and entering passcode 2281543. 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 available on the Company website for 90 days at www.mediwound.com.

About MediWound Ltd.

MediWound is a biopharmaceutical company that develops, manufactures, and commercializes novel, cost effective, 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[®], 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 registration-stage in the U.S. NexoBrid is supported by the U.S. Biomedical Advanced Research and Development Authority (BARDA).

EscharEx[®], our next-generation bioactive topical therapeutic under development in the U.S. for debridement of chronic and hard to heal wounds. In two Phase 2 studies, EscharEx was 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.

MW005, our topical biological drug for the treatment of non-melanoma skin cancers, is a clinical-stage product candidate under development.

Committed to innovation, we are dedicated to improving quality of care and 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, 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 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; our ability to obtain marketing approval of our products and product candidates in the U.S. or other markets; risks related to our contracts with BARDA; 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; 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 Statements of Financial Positions
AUDITED
U.S. dollars in thousands

	December 31,	
	2021	2020
Cash, cash equivalents and short-term deposits	11,046	21,584
Trade and other receivable	2,706	3,229
Inventories	1,200	1,380
Total current assets	14,952	26,193
Other receivables	469	-
Property, plant and equipment, net	2,478	2,630
Right of-use assets, net	1,548	1,884
Intangible assets, net	297	363
Total non-current assets	4,792	4,877
Total assets	19,744	31,070
Current maturities of long-term liabilities	2,408	2,417
Trade payables and accrued expenses	4,693	2,992
Other payables	3,620	2,857
Total current liabilities	10,721	8,266
Deferred revenues	119	1,234
Liabilities in respect of IIA grants net of current maturities	7,885	7,267

Liabilities in respect of the purchase of shares	3,922	4,998
Lease liabilities net of current maturities	1,391	1,741
Severance pay liability, net	288	292
Total non-current liabilities	13,605	15,532
Shareholders' equity (deficit)	(4,582)	7,272
Total liabilities & shareholder equity	19,744	31,070

MediWound, Ltd.

Condensed consolidated Statements of Profit or Loss and Other Comprehensive Income or Loss

U.S. dollars in thousands

	Year ended December 31,		Three months ended December 31,	
	2021	2020	2021	2020
	AUDITED		UNAUDITED	
Revenues	23,763	21,763	5,487	6,673
Cost of revenues	14,992	14,218	3,948	4,345
Gross profit	8,771	7,545	1,539	2,328
Operating expenses:				
Research and development	10,256	7,698	2,461	2,225
Selling, general & administrative	9,736	8,687	2,599	2,489
Operating loss	(11,221)	(8,840)	(3,521)	(2,386)
Financial income (expenses), net	(2,303)	(436)	(635)	657
Profit (loss) from discontinued operation	-	80	-	(3)
Loss before taxes on income	(13,524)	(9,196)	(4,156)	(1,732)
Taxes on income	(27)	-	(4)	-
Loss for the period	(13,551)	(9,196)	(4,160)	(1,732)
Foreign currency translation adjustments	21	(23)	6	(12)
Total comprehensive loss	(13,530)	(9,219)	(4,154)	(1,744)
Profit (loss) per share:				
Net loss per share	(0.50)	(0.34)	(0.15)	(0.06)
Weighted average number of ordinary shares used in the computation of basic and diluted loss per share (in thousands):	27,244	27,210	27,248	27,179

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ADJUSTED EBITDA

U.S. dollars in thousand

	Year ended December 31,		Three months ended December 31,	
	2021	2020	2021	2020
Loss for the period	(13,551)	(9,196)	(4,160)	(1,732)
Adjustments:				
Financial (expenses) income, net	(2,303)	(436)	(635)	657
Profit (loss) from discontinued operation		80	-	(3)
Tax Expenses	(27)	-	(4)	-
Depreciation and amortization	(1,238)	(1,090)	(276)	(224)
Share-based compensation expenses	(1,673)	(1,322)	(390)	(399)
Total adjustments	(5,241)	(2,768)	(1,305)	31
Adjusted EBITDA	(8,310)	(6,428)	(2,855)	(1,763)

MediWound, Ltd.

Consolidated Statements of Cash Flows

U.S. dollars in thousands

Year ended **Three months ended**

	December 31,		December 31,	
	2021	2020	2021	2020
	AUDITED		UNAUDITED	
Cash Flows from Operating Activities:				
Loss for the period	(13,551)	(9,196)	(4,160)	(1,732)
Adjustments to reconcile net profit (loss) to net cash provided by (used in) continuing operating activities:				
Adjustments to profit and loss items:				
Loss (profit) from discontinued operation	-	(80)	-	3
Depreciation and amortization	1,238	1,090	276	224
Share-based compensation	1,673	1,322	390	399
Revaluation of liabilities in respect of IIA grants	919	828	111	136
Revaluation of liabilities in respect of purchase of shares	590	(433)	144	(991)
Revaluation of lease liabilities	188	305	104	178
Increase (decrease) in severance liability, net	13	33	10	(2)
Financing income, net	(11)	(297)	-	(53)
Unrealized foreign currency gain	(137)	(211)	101	(203)
	<u>4,473</u>	<u>2,557</u>	<u>1,136</u>	<u>(309)</u>
Changes in asset and liability items:				
Decrease (increase) in trade receivables	929	1,386	232	(91)
Decrease in inventories	257	141	69	372
Decrease (increase) in other receivables	(763)	(13)	315	384
Increase (decrease) in trade payables & accrued expenses	1,723	(1,096)	990	(171)
Decrease in other payables & deferred revenues	(1,984)	(479)	(817)	(1,767)
	<u>162</u>	<u>(61)</u>	<u>789</u>	<u>(1,273)</u>
Net cash used in continuing operating activities	<u>(8,916)</u>	<u>(6,700)</u>	<u>(2,235)</u>	<u>(3,314)</u>
Net cash used in discontinued operating activities	<u>-</u>	<u>(195)</u>	<u>-</u>	<u>(3)</u>
Net cash used in operating activities	<u>(8,916)</u>	<u>(6,895)</u>	<u>(2,235)</u>	<u>(3,317)</u>
Cash Flows from Investment Activities:				
Purchase of property and equipment	(489)	(923)	(116)	(443)
Interest received	35	274	-	231
Proceeds from short term bank deposits, net of investments	4,002	18,034	-	9,898
Net cash provided by (used in) continuing investing activities	<u>3,548</u>	<u>17,385</u>	<u>(116)</u>	<u>9,686</u>
Cash Flows from Financing Activities:				
Repayment of lease liabilities	(693)	(508)	(180)	25
Proceeds from exercise of options	3	-	3	-
Repayment of IIA grants, net	(360)	(121)	-	-
Net cash provided by (used in) financing activities	<u>(1,050)</u>	<u>(629)</u>	<u>(177)</u>	<u>25</u>
Exchange rate differences on cash and cash equivalent balances	<u>88</u>	<u>273</u>	<u>(109)</u>	<u>241</u>
Increase (decrease) in cash and cash equivalents from continuing activities	(6,330)	10,329	(2,637)	6,638
Decrease in cash and cash equivalents from discontinued activities	-	(195)	-	(3)
Balance of cash and cash equivalents at the beginning of the period	17,376	7,242	13,683	10,741
Balance of cash and cash equivalents at the end of the period	<u>11,046</u>	<u>17,376</u>	<u>11,046</u>	<u>17,376</u>

Source: MediWound Ltd.