## SECURITIES AND EXCHANGE COMMISSION

Washington,	D.C.	20549

## FORM 6-K

## REPORT OF FOREIGN PRIVATE ISSUER

Pursuant to Rule 13a-16 or 15d-16 of the Securities Exchange Act of 1934

For the month of November 2022

Commission File Number: 001-36349

# MediWound Ltd.\_

(Translation of registrant's name into English)

## 42 Hayarkon Street Yavne, 8122745 Israel

(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.

	Form 20-F ⊠ Form 40-F □
(1):	Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)
(7):	Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)

## **EXPLANATORY NOTE**

On November 15, 2022, MediWound Ltd. (the "Company") issued a press release entitled "MediWound Reports Third Quarter 2022 Financial Results and Provides Company Update". A copy of this press release is attached to this Form 6-K as Exhibit 99.1.

In addition, pursuant to the Information Rights Agreement between the Company and Clal Biotechnology Industries Ltd. ("CBI"), dated March 3, 2014 (which was attached to the Company's registration statement as exhibit 4.3), the Company is required to provide CBI with certain information necessary for CBI to meet its obligations under Israeli Securities Law. This Form 6-K includes an Un-Audited Condensed Consolidated Interim Financial Statements as of September 30, 2022, attached as Exhibit 99.2, which was provided by the Company to CBI on November 14, 2022 pursuant to such contractual obligation.

The content of this report on Form 6-K (including the information contained in Exhibit 99.1, but excluding quotes of senior management of the Company) is hereby incorporated by reference into the Company's Registration Statements on Form S-8 filed with the SEC on April 28, 2014, March 24, 2016, March 19, 2018, March 25, 2019, February 25, 2020 May 15, 2021 and August 9, 2022 (Registration Nos. No. 333-195517, 333-210375, 333-223767, 333-195517, 333-210375, 333-230487, 333-236635, 333-255784, and 333-266697 respectively) and on Form F-3 filed with the SEC on May 25, 2022 (Registration No. 333-265203).

## **SIGNATURE**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

MEDIWOUND LTD.

Date: November 15, 2022 By: /s/ Boaz Gur-Lavie

Name: Boaz Gur-Lavie
Title: Chief Financial Officer

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## **EXHIBIT INDEX**

The following exhibit is filed as part of this Form 6-K:

<u>Exhibit</u>	<u>Description</u>
<u>99.1</u>	Press release dated November 15, 2022 titled "MediWound Reports Third Quarter 2022 Financial Results and Provides Company Update".
<u>99.2</u>	Un-Audited Condensed Consolidated Interim Financial Statements as of September 30, 2022.



## MediWound Reports Third Quarter 2022 Financial Results and Provides Company Update

\$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, November 15, 2022** -- 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 \$2.6 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: <a href="https://ir.mediwound.com/events-and-presentations">https://ir.mediwound.com/events-and-presentations</a>

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, biotherapeutic 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 <a href="https://www.mediwound.com">www.mediwound.com</a>.

### **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.

#### **Contacts:**

Boaz Gur-Lavie Chief Financial Officer MediWound Ltd. <u>ir@mediwound.com</u> **Monique Kosse** 

Managing Director LifeSci Advisors 212-915-3820 monique@lifesciadvisors.com

# MediWound, Ltd.

# CONDENSED CONSOLIDATED BALANCE SHEETS

	Septembe	September 30,	
	2022	2021	2021
	Un-audi	Un-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
Trade and 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)

	Nine months ended September 30,		Three months ended 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	27,245

## MediWound, Ltd.

## ADJUSTED EBITDA

U.S. dollars in thousands

		Nine months ended September 30,		ns ended er 30,
	2022	2021	2022	2021
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)

	Nine months ended September 30,		Three months ended September 30,	
•	2022	2021	2022	2021
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)

	Nine months ended September 30,		Three months ended September 30,	
•	2022	2021	2022	2021
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 September 30,		Three months ended September 30,	
	2022	2021	2022	2021
Cash Flows from Investment Activities:		<u> </u>		
Purchase of property and equipment	(381)	(373)	(83)	(129)
Interest received	3	35	3	-
Decrease (Increase) in short term bank deposits, net	(2,499)	4,002	-	-
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

## MEDIWOUND LTD. AND ITS SUBSIDIARIES

## CONDENSED INTERIM CONSOLIDATED FINANCIAL STATEMENTS

## AS OF SEPTEMBER 30, 2022

## IN U.S. DOLLARS IN THOUSANDS

# UNAUDITED

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# **Unaudited Condensed Interim Consolidated Statements of Financial Position**

## U.S. dollars in thousands

	September 30,		December 31,	
	2022	2021	2021	
Cash and cash equivalents	14,905	13,683	11,046	
Restricted deposits	166	183	-	
Short-term bank deposits	2,521	-	-	
Trade receivables	4,146	2,026	1,779	
Inventories	1,880	1,252	1,200	
Other receivables	830	1,527	927	
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 non-current assets	4,137	4,495	4,792	
Total assets	28,585	23,166	19,744	
Current maturities of non-current 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	
Total Cultent Habilities	9,012	9,901	10,721	
Deferred revenues	31	352	119	
Warrants	5,092	-	-	
Liabilities in respect of IIA grants	8,451	7,715	7,885	
Liabilities in respect of purchase of shares	3,076	4,195	3,922	
Lease liabilities	952	1,483	1,391	
Severance pay liability, net	315	281	288	
Total non-current liabilities	17,917	14,026	13,605	
Total liabilities	26,929	23,987	24,326	
Should Haday 2				
Shareholders' equity:				
Ordinary shares of NIS 0.01 par value: Authorized: 50,000,000 shares as of September 30, 2022, December 31, 2021, and September 30,				
2021; Issued and Outstanding: 40,735,197 as of September 30, 2022, 27,272,818 as of	115	7.5	7.5	
December 31, 2021 and 27,247,096 as of September 30, 2021	115	75	75	
Share premium  Foreign autropalation adjustments	162,175	143,476	143,869	
Foreign currency translation adjustments Accumulated deficit	15 (160,649)	(25) (144,347)	(148 507)	
			(148,507)	
Total equity (deficit)	1,656	(821)	(4,582)	
Total liabilities and equity	28,585	23,166	19,744	

## **Unaudited Condensed Interim Consolidated Statements of Profit or Loss and Other Comprehensive Income or Loss**

## U.S. dollars in thousands (except loss per share data)

	Nine months ended September 30,		Three months ended September 30,		Year ended December 31,
•	2022	2021	2022	2021	2021
Revenues from sale of products	4,178	7,689	1,407	2,644	9,613
Revenues from development services	10,180	9,260	4,314	3,297	12,372
Revenues from license agreements	520	1,327	82	431	1,778
Total revenues	14,878	18,276	5,803	6,372	23,763
Cost of revenues from sale of products	2,326	3,672	787	1,221	4,983
Cost of revenues from development services	7,511	7,321	2,579	2,683	9,907
Cost of revenues from license agreements	34	51	3	13	102
Total cost of revenues	9,871	11,044	3,369	3,917	14,992
Gross profit	5,007	7,232	2,434	2,455	8,771
Research and development	7,482	7,795	2,883	2,897	10,256
Selling and marketing	3,033	2,548	1,179	872	3,388
General and administrative	4,651	4,589	1,882	1,570	6,348
Other expenses	309	-	-	-	-
Total operating expenses	15,475	14,932	5,944	5,339	19,992
Operating loss	(10,468)	(7,700)	(3,510)	(2,884)	(11,221)
Financial income	23	11	97	-	11
Financial expenses	(1,684)	(1,679)	(781)	(457)	(2,314)
Financing expenses, net	(1,661)	(1,668)	(684)	(457)	(2,303)
Loss before taxes on income	(12,129)	(9,368)	(4,194)	(3,341)	(13,524)
Taxes on income	(13)	(23)	(5)	(4)	(27)
Net loss	(12,142)	(9,391)	(4,199)	(3,345)	(13,551)
Other comprehensive income:					
Foreign currency translation adjustments	34	15	12	7	21
Total comprehensive loss	(12,108)	(9,376)	(4,187)	(3,338)	(13,530)
Loss per share data:					
Basic and diluted net loss per share - USD	(0.38)	(0.34)	(0.13)	(0.12)	(0.50)
Number of shares used in calculating basic and diluted net loss per share	31,818	27,243	33,482	27,245	27,244
•					

# **Unaudited Condensed Interim Consolidated Statements of Changes in Shareholders' Equity (Deficit)**

## U.S. dollars in thousands

	Share capital	Share premium	Foreign currency translation reserve	Accumulated deficit	Total equity )deficit)
Balance as of July 1, 2022	93	154,119	3	(156,450)	(2,235)
Loss for the period	-	-	-	(4,199)	(4,199)
Other comprehensive income	-	-	12	-	12
Total comprehensive income (loss)		-	12	(4,199)	(4,187)
Issuance of ordinary shares and warrants, net of issuance expenses (see note 3)	22	7,349	_		7,371
Exercise of options	(*)	-	-	-	(*)
-					
Share-based compensation		707			707
Balance as of September 30, 2022	115	162,175	15	(160,649)	1,656
Balance as of July 1, 2021	75	143,077	(32)	(141,002)	2,118
Loss for the period	_	-	_	(3,345)	(3,345)
Other comprehensive income	_	_	7	-	7
Total comprehensive Income (loss)			7	(3,345)	(3,338)
Exercise of options	(*)	-	-	-	(*)
Share-based compensation		399			399
Balance as of September 30, 2021	75	143,476	(25)	(144,347)	(821)

# (\*) Represents less than \$ 1.

# **Unaudited Condensed Interim Consolidated Statements of Changes in Shareholders' Equity (Deficit)**

## U.S. dollars in thousands

	Share capital	Share premium	Foreign currency translation reserve	Accumulated deficit	Total equity (deficit)
Balance as of December 31, 2021 (audited)	75	143,869	(19)	(148,507)	(4,582)
Loss for the period				(12,142)	(12,142)
Other comprehensive income	-	-	34	-	34
Total comprehensive income (loss)	-	_	34	(12,142)	(12,108)
Issuance of ordinary shares and warrants, net of issuance					
expenses (see note 3)	40	17,002	-	-	17,042
Exercise of options	(*)	-	-	-	(*)
Share-based compensation		1,304			1,304
Balance as of September 30, 2022	115	162,175	15	(160,649)	1,656
Balance as of December 31, 2020 (audited)	75	142,193	(40)	(134,956)	7,272
Loss for the period	-	-	-	(9,391)	(9,391)
Other comprehensive income	-	-	15	-	15
Total comprehensive income (loss)		_	15	(9,391)	(9,376)
Exercise of options	(*)	-	-	-	(*)
Share-based compensation		1,283			1,283
Balance as of September 30, 2021	75	143,476	(25)	(144,347)	(821)
Balance as of December 31, 2020 (audited)	75	142,193	(40)	(134,956)	7,272
Loss for the period	_	_	_	(13,551)	(13,551)
Other comprehensive income	-	-	21	-	21
Total comprehensive income (loss)	_	_	21	(13,551)	(13,530)
Exercise of options	(*)	3	-	(,)	3
Share-based compensation	-	1,673	-	-	1,673
Balance as of December 31, 2021 (audited)	75	143,869	(19)	(148,507)	(4,582)

# (\*) Represents less than \$ 1.

## **Unaudited Condensed Interim Consolidated Statements of Cash Flows**

## U.S. dollars in thousands

Nine months ended September 30,		Three months ended September 30,		Year ended December 31,
2022	2021	2022	2021	2021
(12,142)	(9,391)	(4,199)	(3,345)	(13,551)
988	962	338	335	1,238
		707		1,673
		330		919
404	446	132	147	590
(146)	84	6	49	188
64	3	9	8	13
334	(11)	345	-	(11)
465	(238)	(63)	(12)	(137)
4,225	3,337	1,804	1,237	4,473
(2,445)	697	(421)	17	929
(608)	188	139	171	257
143	(1,078)	(187)	(646)	(763)
(1,232)	733	(1,243)	(342)	1,723
				(1,984)
(5,968)	(627)	(2,171)	(710)	162
(13.885)	(6.681)	(4 566)	(2.818)	(8,916)
	988 1,304 812 404 (146) 64 334 465 4,225 (2,445) (608)	September 30,       2022     2021       (12,142)     (9,391)       988     962       1,304     1,283       812     808       404     446       (146)     84       64     3       334     (11)       465     (238)       4,225     3,337       (2,445)     697       (608)     188       143     (1,078)       (1,232)     733       (1,826)     (1,167)       (5,968)     (627)	September 30,         September 2022           (12,142)         (9,391)         (4,199)           988         962         338           1,304         1,283         707           812         808         330           404         446         132           (146)         84         6           64         3         9           334         (11)         345           465         (238)         (63)           4,225         3,337         1,804           (2,445)         697         (421)           (608)         188         139           143         (1,078)         (187)           (1,232)         733         (1,243)           (1,826)         (1,167)         (459)           (5,968)         (627)         (2,171)	September 30,         September 30,           2022         2021           (12,142)         (9,391)         (4,199)         (3,345)           988         962         338         335           1,304         1,283         707         399           812         808         330         311           404         446         132         147           (146)         84         6         49           64         3         9         8           334         (11)         345         -           465         (238)         (63)         (12)           4,225         3,337         1,804         1,237           (2,445)         697         (421)         17           (608)         188         139         171           143         (1,078)         (187)         (646)           (1,232)         733         (1,243)         (342)           (1,826)         (1,167)         (459)         90           (5,968)         (627)         (2,171)         (710)

## **Unaudited Condensed Interim Consolidated Statements of Cash Flows**

## U.S. dollars in thousands

	Nine months ended September 30,		Three months ended September 30,		Year ended December 31,
	2022	2021	2022	2021	2021
Cash Flows from Investing Activities:					
Purchase of property and equipment	(381)	(373)	(83)	(129)	(489)
Interest received	3	35	3	-	35
Decrease (Increase) in short term bank deposits, net	(2,499)	4,002			4,002
Net cash (used in) provided by investing activities	(2,877)	3,664	(80)	(129)	3,548
Cash Flows from Financing Activities:					
Repayment of leases liabilities	(531)	(513)	(181)	(176)	(693)
Proceeds from issuance of shares and warrants, net	21,915	-	12,054	-	3
Repayment of IIA grant	(258)	(360)	(96)	(180)	(360)
Net cash provided by (used in) financing activities	21,126	(873)	11,777	(356)	(1,050)
Exchange rate differences on cash and cash equivalent balances	(505)	197	45	(7)	88
Increase (decrease) in cash and cash equivalents	3,859	(3,693)	7,176	(3,310)	(6,330)
Balance of cash and cash equivalents at the beginning of the period	11,046	17,376	7,729	16,993	17,376
Balance of cash and cash equivalents at the end of the period	14,905	13,683	14,905	13,683	11,046
Supplement disclosure of Non-cash transactions:					
ROU asset, net recognized with corresponding lease liability	117	155	74	-	155
Issuance of shares due to RSUs exercised	326	53	135	10	147

#### U.S. dollars in thousands

#### NOTE 1: GENERAL

#### a. Description of the Company and its operations:

MediWound Ltd. was incorporated in Israel. The Company which is located in Yavne, Israel (The "Company" or "MediWound"), is biopharmaceutical company that develops, manufactures and commercializes novel, cost effective, bio-therapeutic solutions for tissue repair and regeneration. The Company's strategy leverages its breakthrough enzymatic technology platform into diversified portfolio of biotherapeutics across multiple indications to pioneer solutions for unmet medical needs. The Company's current portfolio is focused on next-generation bio-active therapies for burn and wound care and tissue repair.

The Company's first innovative biopharmaceutical product, NexoBrid, has received marketing authorization from the European Medicines Agency ("EMA") as well as the

Israeli, Argentinean, South-Korean, Russian, Taiwanese, Ukrainian, United Arab Emirates, Chilean, Peruvian and Switzerland Ministries of Health, for removal of dead or damaged tissue, known as eschar, in adults with deep partial and full thickness thermal burns.

The Company sells NexoBrid in the European Union, United Kingdom, Norway, Switzerland and Israel through its commercial organizations while establishing additional local distribution channels to extend its outreach in the European Union. In other international markets the Company sells NexoBrid through local distributors which are also responsible for obtaining the local marketing authorization within the relevant territory. In the United States, the Company entered into exclusive license and supply agreements with Vericel Corporation ("Vericel") to commercialize NexoBrid in North America upon FDA's approval.

The Company's second investigational innovative product, EscharEx, is a topical biological drug being developed for debridement of chronic and other hard-to-heal wounds. In May 2022, the company announced positive results from its U.S. phase 2 study. The study met its primary endpoint, its key secondary endpoints with high degree of statistical significance, as well as its wound closure safety measurements. The Company anticipates meeting with the U.S. Food and Drug Administration (the "FDA") in the fourth quarter of 2022, for a type C meeting to discuss the Phase 3 design for EscharEx.

The third clinical-stage innovative product candidate, MW005, is a topical biological drug candidate for the treatment of non-melanoma skin cancers. A U.S. phase 1/2 study of MW005 for the treatment of low-risk basal cell carcinoma (BCC) was initiated in July 2021, and in July 2022, a positive initial data was announced. The Company anticipates announcing the final data in the fourth quarter of 2022.

**b.** The Company's securities are listed for trading on NASDAQ since March 2014. During the three quarters of 2022, the Company completed several public offerings (see also Note 3a, 3b).

#### U.S. dollars in thousands

#### NOTE 1: GENERAL (Cont.)

- c. The Company has three wholly owned subsidiaries: MediWound Germany GmbH, acting as Europe ("EU") marketing authorization holder and EU sales and marketing arm, and MediWound UK Limited and MediWound US, Inc. which are currently inactive companies.
- d. The Company was awarded two contracts with the U.S. Biomedical Advanced Research and Development Authority ("BARDA") valued at up to \$168,000 for the advancement of the development, manufacturing and emergency readiness for NexoBrid deployment as well as the procurement of NexoBrid as a medical countermeasure as part of BARDA preparedness for mass casualty events. In February 2022 BARDA has expanded its awarded contract providing supplemental funding of approximately \$9,000 to support the NexoBrid BLA resubmission to the FDA and the continuous expanded access program.
- e. On February 17, 2022 the Company engaged with the U.S. Department of Defense ("DoD"), through the Medical Technology Enterprise Consortium (MTEC), for a \$1,800 contract for the development of NexoBrid as a non-surgical solution for field-care burn treatment for the U.S. Army.
- f. On June 29, 2021, the Company received a Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) regarding its Biologics License Application (BLA) seeking approval of NexoBrid for eschar removal (debridement) in adults with deep partial-thickness and/or full-thickness thermal burns.
  - The FDA communicated that it had completed its review of the BLA, as amended, and has determined that the application cannot be approved in its present form. The FDA identified issues related to the Chemistry, Manufacturing and Controls ("CMC") section of the BLA and requested additional CMC information. The FDA acknowledged receipt of several CMC amendments, submitted by the Company in response to the CMC information requests, which were not reviewed at that time by the FDA.
  - FDA inspection of NexoBrid's manufacturing facilities in Israel and Taiwan, is anticipated in the fourth quarter of 2022. The inspection is required before the FDA can approve the BLA. In addition, the CRL cited certain observations identified during good clinical practice (GCP) inspections related to the U.S. Phase 3 study (DETECT), and requested the Company to provide its perspective on the potential impact, if any, of these observations on the efficacy findings in the study. The FDA also requested to provide a safety update as part of its BLA resubmission, although there were no safety issues raised in the CRL.
  - On July 1, 2022, the Company has re-submitted the Biologics License Application (BLA) to the U.S. Food and Drugs Administration (FDA) and received an acknowledgement letter from the FDA assigning PDUFA target date to January 1, 2023.
- g. Since incorporation through September 30, 2022, the Company has incurred losses mainly attributed to its development efforts at total accumulated deficit of \$---160,293. The Company expects to continue to incur significant research and development and other costs related to its ongoing operations, and in order to continue its future operations, the Company will need to obtain additional funding until becoming profitable. See also Note 5b.

#### U.S. dollars in thousands

#### NOTE 1: GENERAL (Cont.)

**h.** The Company addresses the challenges associated with the ongoing COVID-19 pandemic, while prioritizing the health and safety of its workforce and maintaining operational efficiency and flexibility.

#### NOTE 2: SIGNIFICANT ACCOUNTING POLICIES

The following accounting policies have been applied consistently in the financial statements for all periods presented unless otherwise stated.

a. Basis of presentation of financial statements:

These financial statements have been prepared in accordance with International Financial Reporting Standards ("IFRS") as issued by the International Accounting Standards Board ("IASB").

**b.** Basis of preparation of the interim consolidated financial statements:

The interim condensed consolidated financial statements for the nine and three months ended September 30, 2022 have been prepared in accordance with IAS 34 "Interim Financial Reporting".

The interim condensed consolidated financial statements do not include all the information and disclosures required in the annual financial statements, and should be read in conjunction with the Company's annual financial statements as of December 31, 2021 that were included in the Annual Report on Form 20-F filed on March 17, 2022.

The accounting policies adopted in the preparation of the interim condensed consolidated financial statements are consistent with those followed in the preparation of the Company's annual consolidated financial statements for the year ended December 31, 2021 that were included in the Annual Report on Form 20-F filed on March 17, 2022. Regarding the warrants, the accounting policy adopted following the Registered Direct Offering is detailed in Note 3b.

## NOTE 3: EQUITY

a. On March 7, 2022, the Company completed a public offering. A total of 5,208,333 new ordinary shares were issued in consideration to offering price of \$1.92 per share. The net proceeds were \$8,641, after deducting commissions and other offering expenses. In addition, on March 22, 2022 the underwriters exercised their options to purchase an additional 623,082 ordinary shares at the public offering price, less underwriting discounts and commissions at an additional net proceeds of \$1,030.

As part of the above, mentioned public offering, certain entities affiliated with CBI purchased 1,458,333 of ordinary shares at the public offering price.

#### U.S. dollars in thousands

## NOTE 3: EQUITY (Cont.)

b. On September 26, 2022, the Company completed a registered direct (the "RD") offering in an aggregate amount of \$13,257 represent a combine purchase price of \$1.75 for issuance of 7,575,513 ordinary shares issuable thereunder and 7,575,513 warrants that will become exercisable upon the Company's receipt of shareholders' approval to increase the number of its authorized ordinary shares (hereinafter: "the Authorized Share Increase Date"), at an exercise price of \$1.925 per ordinary share which will expire in four years from the Authorized Share Increase Date.

The warrants issued have been classified as a non-current financial liability due to a net settlement provision.

This liability was initially recognized at its fair value on the date the contract was entered into and is subsequently accounted for fair value at each balance sheet date.

The fair value of the warrants is computed using the Black-Scholes option pricing model.

The fair value of the warrants upon issuance was computed based on the then current price of the shares. A risk-free interest rate of 4.37% and an average standard deviation of 68%.

In addition, the Company also issued the placement agent up to 378,776 warrants to purchase up to 378,776 ordinary shares. The warrants have substantially the same terms as the RD Warrants, except that the placement agent's warrants have an exercise price equal to \$2.1875 per share (which represents 125% of the offering price per ordinary Share in the offerings) and will expire four years after the Authorized Share Increase Date, but no more than five years following the commencement of the sales pursuant to the RD Offering.

In an event that the Authorized Share Increase Date will not be obtained within 90 days following the closing date hereof, the Company would be liable for partial liquidated damages under the terms of the above warrants and shall pay in cash a damages fee equal to 1.5% from the proceeds.

The net proceeds from this offering in the amount of \$12,244 have been received on September 28, 2022.

**c.** Over the second quarter of 2022, the Company's Board of Directors approved the grant of 2,052,922 options to purchase the Company's ordinary shares, for an exercise price of \$ 2.06 per share as well as 275,000 restricted share units ("RSU's") to its CEO, officers and employees. The fair value of the options and RSU's as of the grant date, was estimated at approximately \$2,400 and \$500 respectively.

The above-mentioned grant includes the grant of 1,062,500 options to purchase the Company's ordinary shares and 275,000 restricted share units ("RSU's") to the directors and the CEO of the Company. The fair value of the options and RSU's, as of the approval date, was estimated at approximately \$1,200 and \$500, respectively.

**d.** On July 19, 2022, the Company's Shareholders General meeting approved the abovementioned grants to the directors and the CEO, the compensation terms of Mr. Ofer Gonen as the Company's new Chief Executive Officer, which are effective since July 1, 2022 and the termination terms for the previous CEO (see Note 4).

#### U.S. dollars in thousands

### NOTE 4: OTHER EXPENSES

The other one-time expenses amounted \$309 are attributed to the termination expenses of the previous CEO which were approved by the Shareholders General meeting.

### NOTE 5: SUBSEQUENT EVENTS

On October 6, 2022, the Company entered into a privet Issuance Purchase Equity agreement (the "PIPE") with several purchasers in an aggregate amount of \$17,233, in connection with the offering of 9,853,058 unregistered Pre-Funded warrants to purchase up to 9,853,058 ordinary shares and 9,853,058 warrants to purchase up to 9,853,058 ordinary shares. The Pre-Funded warrants will be exercisable upon the Authorized Share Increase Date at an exercise price of \$0.001 per ordinary share and the warrants will be also exercisable upon the Authorized Share Increase Date at an exercise price of \$1.925 per ordinary share and will expire four years from the Authorized Share Increase Date.

The net proceeds from this offering in the amount of approximately \$16,200 have been received on the same day.

In an event that the Authorized Share Increase Date will not be obtained within 90 days following the closing date hereof, the Company would be liable for partial liquidated damages under the terms of the above warrants and shall pay in cash a damages fee equal to 1.5% from the proceeds.

Upon closing of the Offerings, the Company also issued the placement agent up to 492,653 warrants to purchase up to 492,653 ordinary Shares. The warrants have substantially the same terms as the PIPE Warrants, except that the placement agent's warrants have an exercise price equal to \$2.1875 per share (which represents 125% of the offering price per ordinary Share in the offerings) and will expire four years after the Authorized Share Increase Date, but no more than five years following the commencement of the sales pursuant to the PIPE Offering. See also Note 3b for the additional warrant issued to the placement agent.