# 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 August 2023

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  $\boxtimes$  Form 40-F  $\square$ 

#### **EXPLANATORY NOTE**

On August 15, 2023, MediWound Ltd. (the "Company") issued a press release entitled "MediWound Reports Second Quarter 2023 Financial Results and Provides Company Updates". 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 June 30, 2023, attached as Exhibit 99.2, which was provided by the Company to CBI on August 15, 2023 pursuant to such contractual obligation.

The contents of this Report of Foreign Private Issuer on Form 6-K (including the information contained in Exhibits 99.1 and 99.2, but excluding quotes of senior management of the Company) are 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, 333-230487, 333-236635, 333-255784, and 333-266697, respectively) and on Form F-3, filed with the SEC on May 25, 2022 and March 31, 2023 (Registration Nos. 333-265203 and 333-268297, respectively).

# 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.

By: /s/ Hani Luxenburg

Date: August 15, 2023

Name: Hani Luxenburg
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 August 15, 2023 titled "MediWound Reports Second Quarter 2023 Financial Results and Provides Company Updates".
99.2	<u>Un-Audited Condensed Consolidated Interim Financial Statements as of June 30, 2023.</u>



# MediWound Reports Second Quarter 2023 Financial Results and Provides Company Update

EscharEx® Phase III study protocol: FDA/EMA-aligned; patient enrollment commencing early 2024; two key research collaborations with wound industry leaders

NexoBrid® U.S. commercial launch timing not anticipated to impact revenues in 2023-2024 Cash of \$51.3 million; operating cash runway through profitability

Conference call on Wednesday, August 16 at 8:30 a.m. Eastern Time

**YAVNE, Israel, August 15, 2023** -- MediWound Ltd. (Nasdaq: MDWD), the global leader in next-generation enzymatic therapeutics for tissue repair, today announced financial results for the second quarter ended June 30, 2023, and provided a corporate update.

"We have achieved significant progress this quarter on many levels," stated Ofer Gonen, CEO of MediWound. "Our EscharEx Phase III study protocol is aligned with feedback from both FDA and EMA, and patient enrollment is planned for early 2024. Executing multiple collaborations on our EscharEx program with leading wound care companies, underscores the growing interest in this potential game-changing treatment and our commitment to maximize the likelihood of a successful study outcome." Mr. Gonen added, "We dispatched initial batches of NexoBrid to both Japan and the U.S., with commercial availability already underway in Japan. Furthermore, our new manufacturing facility, set to be active by mid-2024, will increase our production capabilities to meet the rising global demand."

#### **Second Quarter 2023 Highlights and Recent Developments:**

- Shipped NexoBrid finished product to Vericel for the U.S. commercial launch in June 2023. However, Vericel is unable to commercially release the product at this time due to a deviation associated with a third-party testing lab used during the manufacturing process. MediWound and Vericel are actively engaged with the U.S. Food and Drug Administration (FDA) to address this matter. Future production lots will not be impacted by this process deviation issue. Vericel expects to begin commercial sales of NexoBrid from a scheduled September 2023 production run, during the first quarter of 2024. MediWound believes that a possible delay in the U.S. launch, will not have an impact on NexoBrid revenues for the years 2023-2024.
- Received positive scientific advice from the Committee for Medicinal Products for Human Use (CHMP) within the European Medicine Agency (EMA) for the development of EscharEx. This advice aligns with feedback from the FDA, providing a clear path forward for the Company's global Phase III study in patients with venous leg ulcers (VLUs). The Company is in the process of qualifying study sites, selecting vendors (including CRO, data management, and central labs), and producing final batches of EscharEx for the clinical study. These activities are to be completed by the fourth quarter of 2023, with patient enrollment in the Phase III study expected to begin in early 2024.
- Secured research and development collaborations with leading wound care companies, MIMEDX and Mölnlycke, to advance the EscharEx Phase III clinical study. MediWound is actively engaged with additional prominent companies to explore further collaboration opportunities.

- Awarded an additional \$10 million in funding from BARDA to support NexoBrid's \$3 million replenishment, the pediatric indication sBLA submission, and the enrollment of an additional 50 patients in the expanded access treatment protocol (NEXT).
- Signed a turnkey scale-up agreement to bolster the Company's manufacturing infrastructure supporting its long-term growth trajectory. The Company will establish, commission, and validate a cutting-edge, sterile, and GMP-compliant manufacturing facility to significantly increase the Company's current production capacity. An estimated \$12 million will be invested in this new state-of-the-art facility, which is projected to be completed by mid-2024, with full-scale manufacturing expected to commence in 2025.
- Announced commercial launch of NexoBrid in Japan for the treatment of deep partial thickness and full thickness burns in adults and pediatric
  patients with the Company's strategic partner, Kaken Pharmaceutical Co. Ltd., a top ranked Japanese pharmaceutical company.
- Reported positive data from its Phase I/II study of MW005 in low-risk basal cell carcinoma (BCC). Results showed MW005 to be safe and well-tolerated, with eleven of the fifteen patients enrolled achieving complete clearance of their BCCs, with a majority of the patients also having histologically confirmed complete clearance.
- Appointed Mr. Shmuel (Milky) Rubinstein as an independent director to the Company's Board of Directors. With a distinguished record of
  pharmaceutical and biotechnology leadership, Mr. Rubinstein previously held the position of CEO at Taro Pharmaceuticals (Nasdaq: TARO),
  which subsequently was acquired by Sun Pharmaceuticals. He currently holds the title of Chairperson of the Board at Trima Pharma and is a board
  member at Strata Skin Sciences (Nasdaq: SSKN), Medison Biotech, and Keystone Dental. Mr. Rubinstein will become a MediWound Board
  member, following the tenure of Mr. Assaf Segal, who stepped down from the MediWound Board of Directors.
- Cash and short-term deposits of \$51.3 million as of June 30, 2023.

#### Second Quarter 2023 Financial Highlights

- Revenues: Revenues for the second quarter 2023 were \$4.8 million, compared to \$4.7 million in the second quarter of 2022.
- **Gross Profit**: Gross profit in the second quarter 2023 was \$1.1 million, representing 24% of total revenue, unchanged from the second quarter 2022

## Expenditures:

- o Research and development expenses in the second quarter 2023 were \$2.0 million compared to \$2.2 million in the second quarter of 2022.
- o Selling, general, and administrative expenses in the second quarter 2023 were \$3.1 million, compared to \$2.3 million in the second quarter of 2022. This increase is primarily attributed to the addition of several full-time employees to bolster future growth, along with greater share-based compensation expenses.
- Operating Results: Operating loss in the second quarter of 2023 was \$4.0 million, compared to a \$3.7 million loss in the second quarter of 2022.
- **Net Profit/Loss**: Net profit in the second quarter of 2023 was \$0.9 million or \$0.10 per share, compared to the net loss of \$4.4 million, or \$0.92 per share in the second quarter of 2022. This change is primarily attributed to a favorable adjustment from the revaluation of warrants.
- Adjusted EBITDA: Adjusted EBITDA in the second quarter of 2023 was a loss of \$3.0 million, compared to a loss of \$2.8 million in the second quarter of 2022.

#### Year-to-Date 2023 Financial Highlights

- **Revenues**: Total revenues in the first half of 2023 were \$8.6 million, compared to \$9.1 million in the first half of 2022. The decline in revenues is primarily a result of the sales to BARDA's emergency stockpile procurement in 2022.
- **Operating Results**: Operating loss in the first half of 2023 was \$8.4 million, up from the \$7.0 million loss in the first half of 2022. This increase is primarily attributed to the addition of several full-time employees to bolster future growth, along with greater share-based compensation expenses.
- **Net Loss**: Net loss in the first half of 2023 was \$2.8 million, or \$0.32 per share, compared to a net loss of \$7.9 million or \$1.79 per share in the first half of 2022. This decrease is primarily attributed to a favorable adjustment from the revaluation of warrants.
- **Adjusted EBITDA**: Adjusted EBITDA in the first half of 2023, as further detailed below, was a loss of \$6.4 million, compared to a \$5.4 million loss in the first half of 2022.

#### **Balance Sheet Overview**

As of June 30, 2023, the Company's cash and short-term deposits were \$51.3 million, compared to \$34.1 million reported on December 31, 2022. In the first quarter of 2023 the Company raised a gross amount of \$27.5 million through a registered direct offering. During the second quarter of 2023, the Company used \$6.0 million to fund its operating activities. Existing cash and cash equivalents are expected to provide sufficient funds for the Company's current operating plan through profitability.

#### **Conference Call**

MediWound management will host a conference call for investors on Wednesday, August 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). The call will be available via webcast by <u>clicking HERE</u> or on the <u>Events & Presentations</u> page of Company's website.

A replay of the call will be available on the Company's website at <a href="www.mediwound.com">www.mediwound.com</a>.

#### **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 Ltd. (Nasdaq: MDWD) is the global leader in next-generation enzymatic therapeutics focused on non-surgical tissue repair. Specializing in the development, production and commercialization of solutions that seek to replace existing standards of care. The Company is committed to providing rapid and effective biologics that improve patient experiences and outcomes, while reducing costs and unnecessary surgeries.

MediWound's first drug, NexoBrid®, is an FDA-approved orphan biologic for eschar removal in severe burns that can replace surgical interventions and minimize associated costs and complications. Utilizing the same core biotherapeutic enzymatic platform technology, MediWound has developed a strong R&D pipeline including the Company's lead drug under development, EscharEx®. EscharEx is a Phase III biologic for debridement of chronic wounds with significant advantages over the \$300 million monopoly legacy drug and an opportunity to expand the market. MediWound's pipeline also includes MW005, a topical therapeutic for the treatment of basal cell carcinoma that has demonstrated positive results in a recently completed Phase I/II study.

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 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 and 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: Hani Luxenburg

Chief Financial Officer MediWound Ltd. ir@mediwound.com **Monique Kosse** 

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

# MediWound, Ltd.

# CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITIONS (UNAUDITED)

U.S. dollars in thousands

June 30,	Dec 31,	
2023 2022	2022	
Unaudited	Audited	
equivalents and short-term bank deposits 51,122 10,406	33,895	
receivable 3,818 4,412	9,982	
3,113 1,991	1,963	
ssets 58,053 16,809	45,840	
277	264	
es 277 230	364	
and equipment, net 4,705 2,439	2,366	
sets 1,133 1,364 s, net 198 264	1,215 231	
ent assets 6,313 4,297	4,176	
<u>64,366</u> <u>21,106</u>	50,016	
ies of long-term liabilities 1,961 2,479	2,242	
and accrued expenses 3,531 4,877	5,656	
2,817 3,060	4,159	
iabilities 8,309 10,416	12,057	
ies - 61		
9,683 -	15,606	
spect of IIA grants 7,806 8,131	7,445	
pect of TEVA 2,529 3,361	2,788	
677 1,053	846	
liability, net 433 319	360	
rent liabilities 21,128 12,925	27,045	
eficit) 34,929 (2,235)	10,914	
and equity 64 266 21 106	50,016	
eficit) 34,929	21,106	

# MediWound, Ltd.

# CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHET COMPREHENSIVE INCOME OR LOSS (UNAUDITED)

U.S. dollars in thousands

	Six months ended		Three mont	hs ended
	June	30,	June 3	30,
	2023	2022	2023	2022
Total revenues	8,572	0.075	4 772	4 CC0
Total cost of revenues	6,609	9,075	4,773	4,668
111 1111 1111		6,502	3,636	3,555
Gross profit	1,963	2,573	1,137	1,113
Research and development	4,126	4,599	2,024	2,191
Selling, general & administrative	6,208	4,623	3,120	2,287
Other expenses	-	309	-	309
Total operating expenses	10,334	9,531	5,144	4,787
Operating loss	(8,371)	(6,958)	(4,007)	(3,674)
Financial income (expenses), net	5,611	(977)	4,935	(676)
Profit (loss) before taxes on income	(2,760)	(7,935)	928	(4,350)
Taxes on income	(17)	(8)	(12)	(4)
Net profit (loss)	(2,777)	(7,943)	916	(4,354)
Foreign currency translation adjustments	(9)	22		17
Total comprehensive profit (loss)	(2,786)	(7,921)	916	(4,337)
Basic and diluted net profit (loss) per share:				
	(0.32)	(1.79)	0.10	(0.92)
Weighted average number of ordinary shares used in calculation basic and				
diluted net profit (loss) per share	8,803	<u>4,440</u>	9,209	4,734

# MediWound, Ltd.

# ADJUSTED EBITDA

 $U.S.\ dollars\ in\ thousands$ 

	Six months ended June 30,		Three month June 3	
	2023	2022	2023	2022
Net profit (loss) for the period	(2,777)	(7,943)	916	(4,354)
Adjustments:				
Financial income (expenses), net	5,611	(977)	4,935	(676)
Other expenses	-	(309)	-	(309)
Tax expenses	(17)	(8)	(12)	(4)
Depreciation and amortization	(618)	(650)	(315)	(329)
Share-based compensation expenses	(1,331)	(597)	(712)	(252)
Total adjustments	3,645	(2,541)	3,896	(1,570)
Adjusted EBITDA	(6,422)	(5,402)	(2,980)	(2,784)

# MediWound, Ltd.

# CONDENSED CONSOLIDATED STATEMENT OF CASH FLOW (UNAUDITED)

U.S. dollars in thousands

Six months ended June 30,			
2023	2022	2023	2022
_			
(2,777)	(7,943)	916	(4,354)
618	650	315	329
1,331	597	712	252
(5,923)	-	(4,990)	-
492	482	233	248
241	272	119	135
(22)	(152)	(9)	(138)
67	55	(10)	35
(1,005)	(11)	(759)	(11)
466	528	120	283
(3,735)	2,421	(4,269)	1,133
(-,,	,	( , ,	,
6,115	(2,024)	(707)	(1,445)
			(37)
122		435	205
(1.636)		312	(272)
* ' '			(484)
1,913	(3,797)	(1,898)	(2,033)
(4,599)	(9,319)	(5,251)	(5,254)
(2.570)	(298)	(1.065)	(138)
	(230)		(130)
	(2.499)		(2,499)
(33,521)	(2,797)	(26,078)	(2,637)
(22.4)	(250)	(157)	(170)
			(172)
		(248)	(556)
	(162)	-	
		- (10=)	(=20)
23,848	9,349	(405)	(728)
(457)	(550)	(120)	(303)
(14,729)	(3,317)	(31,854)	(8,922)
33,895	11,046	51,020	16,651
19,166	7,729	19,166	7,729
	(2,777)  618 1,331 (5,923) 492 241 (22) 67 (1,005) 466 (3,735)  6,115 (1,162) 122 (1,636) (1,526) 1,913  (4,599)  (2,570) 879 (31,830) (33,521)  (334) 24,909 (310) (417) 23,848  (457) (14,729) 33,895	1023   2022   (2,777)   (7,943)   (7,943)   (7,943)   (7,943)   (7,943)   (7,943)   (7,943)   (7,943)   (7,943)   (7,943)   (7,97)   (7,943)   (7,97)   (7,943)   (7,97)   (7,943)   (7,97)   (7,943)   (7,97)   (7,943)   (7,97)   (7,943)   (7,97)   (7,943)   (7,97)   (7,92	June 30,   2022   2023

# MEDIWOUND LTD. AND ITS SUBSIDIARIES

# CONDENSED INTERIM CONSOLIDATED FINANCIAL STATEMENTS

# **AS OF JUNE 30, 2023**

# IN U.S. DOLLARS IN THOUSANDS

# UNAUDITED

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# MEDIWOUND LTD. AND ITS SUBSIDIARIES

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

## U.S. dollars in thousands

	June 3	0,	December 31,
	2023	2022	2022
Cash and cash equivalents	19,166	7,729	33,895
Restricted deposits	-	168	-
Short-term bank deposits	31,956	2,509	-
Trade receivables	3,228	3,759	9,332
Inventories	3,113	1,991	1,963
Other receivables	590	653	650
Total current assets	58,053	16,809	45,840
Other receivables	277	230	364
Property, plant and equipment, net	4,705	2,439	2,366
Right of-use assets, net	1,133	1,364	1,215
Intangible assets, net	198	264	231
Total non-current assets	6,313	4,297	4,176
		· · ·	
Total assets	64,366	21,106	50,016
Current maturities of non-current liabilities	1,961	2,479	2,242
Trade payables and accrued expenses	3,531	4,877	5,656
Other payables	2,817	3,060	4,159
Total current liabilities	8,309	10,416	12,057
Deferred revenues	-	61	-
Warrants	9,683	-	15,606
Liabilities in respect of IIA grants	7,806	8,131	7,445
Liabilities in respect of TEVA	2,529	3,361	2,788
Lease liabilities	677	1,053	846
Severance pay liability, net	433	319	360
Total non-current liabilities	21,128	12,925	27,045
Total liabilities	29,437	23,341	39,102
Shareholders' equity:			
Ordinary shares of NIS 0.01 par value:			
Authorized: 20,000,000 shares as of June 30, 2023, 12,857,143 as of December 31, 2022; and 7,142,858 as of June 30, 2022; Issued and Outstanding: 7,252,234 as of June 30, 2023;			
7,240,020 as of December 31, 2022 and 4,734,774 as of June 30, 2022	184	93	143
Share premium	205,642	154,119	178,882
Foreign currency translation adjustments	(14)	3	(5)
Accumulated deficit	(170,883)	(156,450)	(168,106)
Total equity (deficit)	34,929	(2,235)	10,914
Total liabilities and equity	64,366	21,106	50,016
Total naomics and equity	U4,3UU	21,100	50,016

	Six months June 3				Year ended December 31,
	2023	2022	2023	2022	2022
Revenues from sale of products	2,358	2,771	1,206	1,669	5,347
Revenues from development services	6,149	5,866	3,534	2,777	12,943
Revenues from license agreements	65	438	33	222	8,206
Total revenues	8,572	9,075	4,773	4,668	26,496
Cost of revenues from sale of products	1,436	1,539	628	1,148	3,184
Cost of revenues from development services	5,170	4,932	3,005	2,391	9,829
Cost of revenues from license agreements	3	31	3	16	318
Total cost of revenues	6,609	6,502	3,636	3,555	13,331
Gross profit	1,963	2,573	1,137	1,113	13,165
Research and development	4,126	4,599	2,024	2,191	10,181
Selling and marketing	2,438	1,854	1,332	935	3,725
General and administrative	3,770	2,769	1,788	1,352	6,920
Other expenses		309		309	684
Total operating expenses	10,334	9,531	5,144	4,787	21,510
Operating loss	(8,371)	(6,958)	(4,007)	(3,674)	(8,345)
Financial income	7,480	11	5,828	11	461
Financial expenses	(1,869)	(988)	(893)	(687)	(11,637)
Financing income (expenses), net	5,611	(977)	4,935	(676)	(11,176)
Profit (loss) before taxes on income	(2,760)	(7,935)	928	(4,350)	(19,521)
Thurs on income	(17)	(0)	(12)	(4)	(70)
Taxes on income	(17)	(8)	(12) 916	(4)	(78)
Net profit (loss)	(2,777)	(7,943)	916	(4,354)	(19,599)
Other comprehensive income:					
Foreign currency translation adjustments	(9)	22	-	17	14
Total consultation of the Consultation	(2.706)	(7.021)	016	(4.227)	(10.505)
Total comprehensive profit (loss)	(2,786)	(7,921)	916	(4,337)	(19,585)
Loss per share data:					
Basic and diluted net profit (loss) per share - USD	(0.32)	*(1.79)	0.10	*(0.92)	(3.93)
Number of shares used in calculating basic and diluted net loss per share	8,803	*4,440	9,209	*4,734	4,987
1055 per snate	0,003	4,440	9,209	4,/34	4,30/

<sup>\*</sup>Restated to reflect 1:7 reverse ratio of shares

	Share capital	Share premium	Foreign currency translation reserve	Accumulated deficit	Total equity (deficit)
Balance as of April 1, 2023	183	204,930	(14)	(171,799)	33,300
Profit for the period	-	-	-	916	916
Other comprehensive income	-	-	-	-	-
Total comprehensive income	-		-	916	916
Issuance expenses, see Note 3	-	-	-	-	-
Exercise of options	1	-	-	-	1
Share-based compensation	<u> </u>	712			712
Balance as of June 30, 2023 (unaudited)	184	205,642	(14)	(170,883)	34,929
Balance as of April 1, 2022	93	153,962	(14)	(152,096)	1,945
Loss for the period	_	_	-	(4,354)	(4,354)
Other comprehensive income	-	-	17	-	17
Total comprehensive Income (loss)	-		17	(4,354)	(4,337)
Issuance expenses, see Note 3	-	(95)	-	-	(95)
Exercise of options	(*)	-	-	-	(*)
Share-based compensation		252			252
Balance as of June 30, 2022 (unaudited)	93	154,119	3	(156,450)	(2,235)

# (\*) 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, 2022 (audited)	143	178,882	(5)	(168,106)	10,914
Loss for the period	_		_	(2,777)	(2,777)
Other comprehensive (loss)	-	-	(9)	-	(9)
Total comprehensive (loss)			(9)	(2,777)	(2,786)
Issuance of ordinary shares, net of issuance expenses (see					
Note 3)	40	25,429	-	-	25,469
Exercise of options	1	-	-	-	1
Share-based compensation		1,331			1,331
Balance as of June 30, 2023 (unaudited)	184	205,642	(14)	(170,883)	34,929
Balance as of December 31, 2021 (audited)	75	143,869	(19)	(148,507)	(4,582)
Loss for the period	-	-	-	(7,943)	(7,943)
Other comprehensive income	-	-	22	-	22
Total comprehensive income (loss)	-	-	22	(7,943)	(7,921)
Issuance of ordinary shares, net of issuance expenses (see					
Note 3)	18	9,653	-	-	9,671
Exercise of options	(*)	-	-	-	(*)
Share-based compensation	-	597	-	-	597
Balance as of June 30, 2022 (unaudited)	93	154,119	3	(156,450)	(2,235)
Balance as of December 31, 2021 (audited)	75	143,869	(19)	(148,507)	(4,582)
Loss for the period	-	-	-	(19,599)	(19,599)
Other comprehensive income	-	-	14	-	14
Total comprehensive loss	-		14	(19,599)	(19,585)
Exercise of options	(*)	(*)	-	-	(*)
Issuance of ordinary shares, net of issuance expenses	40	17,389	-	-	17,429
Exercise of pre-funded warrants	28	15,678	-	-	15,706
Share-based compensation	-	1,946	-	-	1,946
Balance as of December 31, 2022 (audited)	143	178,882	(5)	(168,106)	10,914

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

						Three months ended June 30,	
<del>-</del>	2023	2022	2023	2022	2022		
Cash flows from operating activities:							
Net income (loss)	(2,777)	(7,943)	916	(4,354)	(19,599)		
		<u> </u>					
Adjustments to reconcile net income (loss) to net cash used							
in operating activities:							
Adjustments to profit and loss items:							
Depreciation and amortization	618	650	315	329	1,272		
Share-based compensation	1,331	597	712	252	1,946		
Revaluation of warrants accounted at fair value	(5,923)	-	(4,990)	-	8,977		
Issuance expenses of warrants through profit and loss	-	-	-	-	1,911		
Revaluation of liabilities in respect of IIA grants	492	482	233	248	(132)		
Revaluation of liabilities in respect of TEVA	241	272	119	135	533		
Revaluation of lease liabilities	(22)	(152)	(9)	(138)	(109)		
Increase (decrease) in severance pay liability, net	67	55	(10)	35	109		
Net financing income	(1,005)	(11)	(759)	(11)	(74)		
Un-realized foreign currency loss	466	528	120	283	525		
	(3,735)	2,421	(4,269)	1,133	14,958		
Changes in asset and liability items:							
Decrease (increase) in trade receivables	6,115	(2,024)	(707)	(1,445)	(7,582)		
Increase in inventories	(1,162)	(747)	(579)	(37)	(721)		
Decrease in other receivables	122	330	435	205	364		
Increase (decrease) in trade payables and accrued							
expenses	(1,636)	11	312	(272)	414		
Increase (decrease) in other payables and deferred							
revenues	(1,526)	(1,367)	(1,359)	(484)	281		
	1,913	(3,797)	(1,898)	(2,033)	(7,244)		
Net cash (used in) operating activities	(4,599)	(9,319)	(5,251)	(5,254)	(11,885)		

	Six months ended Three months end June 30, June 30,		Three months ended June 30,								Year ended December 31,
- -	2023	2022	2023	2022	2022						
Cash Flows from Investing Activities:											
Purchase of property and equipment	(2,570)	(298)	(1,065)	(138)	(555)						
Interest received	879	-	577	-	74						
Investment in short term bank deposits, net	(31,830)	(2,499)	(25,590)	(2,499)							
Net cash used in investing activities	(33,521)	(2,797)	(26,078)	(2,637)	(481)						
Cash Flows from Financing Activities:											
Repayment of leases liabilities	(334)	(350)	(157)	(172)	(701)						
Proceeds from exercise of options	(*)	(*)	(*)	(*)	(*)						
Proceeds from exercise of pre-funded warrants	-	-	-	-	10						
Proceeds from (Repayment of) issuance of shares and											
warrants, net	24,909	9,861	(248)	(556)	38,380						
Repayment of IIA grants, net	(310)	(162)	-	-	(258)						
Repayment of liabilities in respect of TEVA	(417)	<u> </u>	<u> </u>	<u>-</u>	(1,667)						
Net cash provided by (used in) financing activities	23,848	9,349	(405)	(728)	35,764						
Exchange rate differences on cash and cash equivalent balances	(457)	(550)	(120)	(303)	(549)						
	(4.4.700)	(0.045)	(04.05.4)	(0.000)	22.040						
Increase (decrease) in cash and cash equivalents	(14,729)	(3,317)	(31,854)	(8,922)	22,849						
Balance of cash and cash equivalents at the beginning of the period	33,895	11,046	51,020	16,651	11,046						
Balance of cash and cash equivalents at the end of the period	19,166	7,729	19,166	7,729	33,895						
Considerate displacement New resilent											
Supplement disclosure of Non-cash transactions:	154	40	102	40	117						
ROU asset, net recognized with corresponding lease liability	154	43	102	43	117						

#### 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, non-surgical 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 protein-based therapies for burn care, wound care and tissue repair.

The Company's first innovative biopharmaceutical product, NexoBrid, has received in December 2022, an approval from the U.S. Food and Drug Administration ("FDA") and marketing approval in each of India, Switzerland and Japan. In addition it has a marketing authorization from the European Medicines Agency ("EMA") and regulatory agencies in other international markets for removal of dead or damaged tissue, known as eschar, in adults with deep partial and full thickness thermal burns.

The Company commercialize NexoBrid globally through multiple sales channels.

- The Company sell NexoBrid to burn centers in the European Union, United Kingdom and Israel, primarily through its commercial organizations.
- The Company have established local distribution channels in multiple international markets, focusing on Asia Pacific, EMEA, CEE and LATAM, which local distributors are also responsible for obtaining local marketing authorization within the relevant territories.
- 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 approval.

The Company's second investigational next-generation enzymatic therapy product, EscharEx, a topical biological drug being developed for debridement of chronic and other hard-to-heal wounds, is currently under discussions with the FDA regarding the pivotal Phase 3 study design.

The third clinical-stage innovative product candidate, MW005, is a topical applied 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 an investigator-initiated phase II trial of MW005 in non-melanoma skin cancer is being conducted in parallel in Israel. In December 2022, the Company announced final positive results from the study. Based on the positive results, The Company plan to continue enrolling patients in its Phase 1/2 study.

#### Notes to Unaudited Condensed Interim Consolidated Financial Statements

#### U.S. dollars in thousands

#### Note 1: General (Cont.)

- **b.** The Company's securities are listed for trading on NASDAQ since March 2014.
- 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 awarded two contracts with the U.S. Biomedical Advanced Research and Development Authority ("BARDA") valued at up to \$209,000 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.
  - On May 9, 2023 BARDA has awarded an additional \$10,000 to the Company. The supplemental funding will support \$7,000 R&D activities and \$3,000 replenishment of expired product previously procured for emergency preparedness, the pediatric indication sBLA submission to the U.S. Food and Drug Administration (FDA), and enrollment of an additional 50 patients in the ongoing expanded access treatment protocol (NEXT).
- e. Our Partner, Vericel Corporation Inc. ("Vericel") has received the first lot of NexoBrid® finished product from the company for the U.S. commercial market in June 2023, which currently is warehoused at Vericel's third-party logistics distributor. Although this NexoBrid finished product batch has met all required release criteria for distribution in the U.S., Vericel is unable to release this product into the commercial channel at this time due to a deviation associated with a third-party testing lab used during the manufacturing process. A detailed risk assessment prepared by the Company and Vericel has concluded that the deviation presents no incremental risk to the finished product's quality and safety, and the company actively engaged with Vericel and the U.S. Food and Drug Administration (FDA) to address this matter. Future manufacturing of NexoBrid drug product for the U.S. market will not be impacted because the at-issue test will be conducted directly by the Company. As the FDA has not yet authorized the commercial release of the finished product affected by the deviation, the company is currently preparing for a production campaign scheduled to begin in September 2023.
- f. In 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. This contract was amended in April 2023 to extend the total value, up to a total amount of \$2,700.

#### Notes to Unaudited Condensed Interim Consolidated Financial Statements

#### U.S. dollars in thousands

#### **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 six and three months ended June 30, 2023 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, 2022 that were included in the Annual Report on Form 20-F filed on March 16, 2023.

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, 2022 that were included in the Annual Report on Form 20-F filed on March 16, 2023.

## **Note 3:** Equity

- **1.** On February 7, 2023, the Company completed a public offering of 1,964,286 new ordinary shares which were issued in consideration to offering price of \$14.0 per share. The gross proceeds were \$27,500, before deducting commissions and other offering expenses in the amount of \$2,031.
- **2.** On February 15, 2023, the Company granted to its employees and officers 130,600 share options for an exercise price of \$13.32 per share and 9,100 RSUs. The share options vest over a period of 4 years. The total value was estimated at \$1,129.
- **3.** On April 3, 2023, the Company granted to its board members and officers 160,400 share options for an exercise price of \$11.89 and \$11.91 per share. The grants to the directors and CEO were subject to the approval of the shareholders' meeting held on May, 2023. The share options vest over a period of 1-4 years and the total value was estimated at \$884.
- **4.** On May 31, 2023 the Shareholders of the Company approved an amendment to Article 6 of the Company's Amended and Restated Articles of Association, which increased the Company's authorized share capital from 900,000 NIS consisting of 12,857,143 ordinary shares par value NIS 0.07 to NIS 1,400,000, consisting of 20,000,000 ordinary shares, par value NIS 0.07 per share.

## **Note 3:** Equity (Cont.)

- **5.** On May 31, 2023 the Shareholders of the Company approved the increase by 1,000,000 in the number of ordinary shares available for issuance under the Company's 2014 Equity Incentive Plan.
- **6.** On May 31, 2023 the Shareholders of the Company approved the extension to the exercise period of options which were granted to the company's directors on April 23, 2020 for an additional five years, until April 23, 2030. According to this extension, an expense of \$146 was recognized.

#### **Note 4: Subsequent events**

1. On July 17, 2023 the company signed a turnkey scale-up agreement with Biopharmax Group Ltd. This strategic agreement is designed to bolster the company's manufacturing infrastructure to support our long-term growth trajectory. The objective of this agreement is to establish, commission, and validate a cutting-edge, sterile, and GMP-compliant manufacturing facility. The venture aims to increase our production capacity significantly, projected to expand to six times the current capacity, aligning with our strategic plan to meet the escalating global demand for NexoBrid.

The new facility, equipped with fully operational clean rooms, will be exclusively designed for NexoBrid production. It will comply with stringent regulations from the GMP, FDA, EMA, Israeli Ministry of Health, and relevant Israeli regulatory bodies. An estimated \$12,000 will be invested in the project, set for completion by mid-2024, with full-scale manufacturing expected to commence in 2025.

The Scale-up Agreement encompasses various standard provisions, including those related to reporting, compliance, guarantees, representations, liability, insurance, confidentiality, and ownership.

2. Alongside entering the Scale-up Agreement, the company has also secured a new lease agreement with the current property owner. This agreement allows the company to continue the utilization of our existing facilities and the planned manufacturing site. This property, located in Yavne, Israel, serves as the base for the company's administrative headquarters, research and development laboratories, and manufacturing plant. The duration of the lease extends until 2035, with an option for a further three-year extension until 2038. In parallel the existing sub lease agreement with Clal Life Science L.P. and the company was terminated.

The property, measuring approximately 32,500 square feet, will encompass the new manufacturing facility. As per the Lease Agreement, the annual rent is set at approximately \$625. This rent is indexed to the Israeli Consumer Price Index and will see a staged increase of 6% every three years.