
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 September 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

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)
(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): ___

Explanatory Note

The following documents are attached hereto and incorporated by reference herein:

Exhibit 99.1 Unaudited Condensed Consolidated Financial Statements as of June 30, 2022

Exhibit 99.2 Management's Discussion and Analysis of Financial Condition and Results of Operations

The content of this report on Form 6-K 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 and May 15, 2021 (Registration Nos. No. 333-195517, 333-210375, 333-223767, 333-195517, 333-210375, 333-230487, 333-236635 and 333-255784, respectively) and on Form F-3 filed with the SEC on May 25, 2022 (Registration No. 333-265203).

EXHIBIT INDEX

<u>Exhibit</u>	<u>Description</u>
99.1	Unaudited Condensed Interim Consolidated Financial Statements as of June 30, 2022
99.2	Operating and Financial Review and Prospects in connection the Unaudited Condensed Interim Consolidated Financial Statements for the six months ended June 30, 2022.

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 9, 2022

By: /s/ Boaz Gur-Lavie

Name: Boaz Gur-Lavie

Title: Chief Financial Officer

MEDIWOUND LTD. AND ITS SUBSIDIARIES

UNAUDITED CONDENSED INTERIM CONSOLIDATED FINANCIAL STATEMENTS

AS OF JUNE 30, 2022

IN U.S. DOLLARS IN THOUSANDS

UNAUDITED

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Unaudited Condensed Interim Consolidated Statements of Financial Position as of
U.S. dollars in thousands

	<u>June 30,</u> <u>2022</u>	<u>December 31,</u> <u>2021</u>
Cash and cash equivalents	7,729	11,046
Restricted deposits	168	-
Short-term bank deposits	2,509	-
Trade receivables	3,759	1,779
Inventories	1,991	1,200
Other receivables	653	927
Total current assets	16,809	14,952
Other receivables	230	469
Property, plant and equipment, net	2,439	2,478
Right of-use assets, net	1,364	1,548
Intangible assets, net	264	297
Total non-current assets	4,297	4,792
Total assets	21,106	19,744
Current maturities of non-current liabilities	2,479	2,408
Trade payables and accrued expenses	4,877	4,693
Other payables	3,060	3,620
Total current liabilities	10,416	10,721
Deferred revenues	61	119
Liabilities in respect of IIA grants	8,131	7,885
Liabilities in respect of purchase of shares	3,361	3,922
Lease liabilities	1,053	1,391
Severance pay liability, net	319	288
Total non-current liabilities	12,925	13,605
Total liabilities	23,341	24,326
Shareholders' equity:		
Ordinary shares of NIS 0.01 par value:		
Authorized: 50,000,000 shares as of June 30, 2022, December 31, 2021, and June 30, 2021; Issued and Outstanding: 33,143,414 as of June 30, 2022, 27,272,818 as of December 31, 2021 and 27,245,429 as of June 30, 2021	93	75
Share premium	154,119	143,869
Foreign currency translation adjustments	3	(19)
Accumulated deficit	(156,450)	(148,507)
Total equity (deficit)	(2,235)	(4,582)
Total liabilities and equity	21,106	19,744

The accompanying notes are an integral part of the interim financial statements.

November 7, 2022

Date of approval of the
financial statements

Nahum Shamir
Chairman of the Board

Ofer Gonen
Chief Executive Officer

Boaz Gur- Lavie
Chief Financial Officer

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)

	Six months ended June 30,		Three months ended June 30,	
	2022	2021	2022	2021
Revenues from sale of products	2,771	5,045	1,669	2,527
Revenues from development services	5,866	5,963	2,777	3,023
Revenues from license agreements	438	896	222	507
Total revenues	9,075	11,904	4,668	6,057
Cost of revenues from sale of products	1,539	2,451	1,148	1,311
Cost of revenues from development services	4,932	4,638	2,391	2,365
Cost of revenues from license agreements	31	38	16	20
Total cost of revenues	6,502	7,127	3,555	3,696
Gross profit	2,573	4,777	1,113	2,361
Research and development	4,599	4,898	2,191	2,656
Selling and marketing	1,854	1,676	935	854
General and administrative	2,769	3,019	1,352	1,746
Other expenses	309	-	309	-
Total operating expenses	9,531	9,593	4,787	5,256
Operating loss	(6,958)	(4,816)	(3,674)	(2,895)
Financial income	11	11	11	118
Financial expenses	(988)	(1,222)	(687)	(399)
Financing expenses, net	(977)	(1,211)	(676)	(281)
Loss before taxes on income	(7,935)	(6,027)	(4,350)	(3,176)
Taxes on income	(8)	(19)	(4)	(19)
Net loss	(7,943)	(6,046)	(4,354)	(3,195)
Other comprehensive income (loss):				
Foreign currency translation adjustments	22	8	17	(3)
Total comprehensive loss	(7,921)	(6,038)	(4,337)	(3,198)
Loss per share data:				
Basic and diluted net loss per share - USD	(0.26)	(0.22)	(0.13)	(0.12)
Number of shares used in calculating basic and diluted net loss per share	31,079	27,241	33,140	27,241

The accompanying notes are an integral part of the interim consolidated financial statements.

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

U.S. dollars in thousands

	<u>Share capital</u>	<u>Share premium</u>	<u>Foreign currency translation reserve</u>	<u>Accumulated deficit</u>	<u>Total equity (deficit)</u>
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	93	154,119	3	(156,450)	(2,235)
Balance as of April 1, 2021	75	142,577	(29)	(137,807)	4,816
Loss for the period	-	-	-	(3,195)	(3,195)
Other comprehensive loss	-	-	(3)	-	(3)
Total comprehensive loss	-	-	(3)	(3,195)	(3,198)
Exercise of options	(*)	-	-	-	(*)
Share-based compensation	-	500	-	-	500
Balance as of June 30, 2021	75	143,077	(32)	(141,002)	2,118

(*) Represents less than \$ 1.

The accompanying notes are an integral part of the interim consolidated financial statements.

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

U.S. dollars in thousands

	<u>Share capital</u>	<u>Share premium</u>	<u>Foreign currency translation reserve</u>	<u>Accumulated deficit</u>	<u>Total equity (deficit)</u>
Balance as of December 31, 2021	<u>75</u>	<u>143,869</u>	<u>(19)</u>	<u>(148,507)</u>	<u>(4,582)</u>
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	<u>93</u>	<u>154,119</u>	<u>3</u>	<u>(156,450)</u>	<u>(2,235)</u>
Balance as of December 31, 2020	<u>75</u>	<u>142,193</u>	<u>(40)</u>	<u>(134,956)</u>	<u>7,272</u>
Loss for the period	-	-	-	(6,046)	(6,046)
Other comprehensive income	-	-	8	-	8
Total comprehensive income (loss)	-	-	8	(6,046)	(6,038)
Exercise of options	(*)	-	-	-	(*)
Share-based compensation	-	884	-	-	884
Balance as of June 30, 2021	<u>75</u>	<u>143,077</u>	<u>(32)</u>	<u>(141,002)</u>	<u>2,118</u>

(*) Represents less than \$ 1.

The accompanying notes are an integral part of the interim consolidated financial statements.

Unaudited Condensed Interim Consolidated Statements of Cash Flows

U.S. dollars in thousands

	Six months ended June 30,		Three months ended June 30,	
	2022	2021	2022	2021
Cash flows from operating activities:				
Net loss	(7,943)	(6,046)	(4,354)	(3,195)
Adjustments to reconcile net loss to net cash used in continuing operating activities:				
Adjustments to profit and loss items:				
Depreciation and amortization	650	627	329	319
Share-based compensation	597	884	252	500
Revaluation of liabilities in respect of IIA grants	482	497	248	222
Revaluation of liabilities in respect of the purchase of shares	272	299	135	147
Revaluation of lease liabilities	(152)	35	(138)	79
Increase (decrease) in severance pay liability, net	55	(5)	35	5
Net financing income	(11)	(11)	(11)	-
Un-realized foreign currency (gain) loss	528	(226)	283	(482)
	2,421	2,100	1,133	790
Changes in asset and liability items:				
(Increase) decrease in trade receivables	(2,024)	680	(1,445)	3,087
(Increase) decrease in inventories	(747)	17	(37)	62
Decrease (increase) in other receivables	330	(432)	205	(469)
Increase (decrease) in trade payables and accrued expenses	11	1,075	(272)	803
Decrease in other payables and deferred revenues	(1,367)	(1,257)	(484)	(2,063)
	(3,797)	83	(2,033)	1,420
Net cash used in operating activities	(9,319)	(3,863)	(5,254)	(985)

The accompanying notes are an integral part of the interim consolidated financial statements.

Unaudited Condensed Interim Consolidated Statements of Cash Flows

U.S. dollars in thousands

	Six months ended June 30,		Three months ended June 30,	
	2022	2021	2022	2021
Cash Flows from Investing Activities:				
Purchase of property and equipment	(298)	(244)	(138)	(26)
Interest received	-	35	-	-
(Increase) decrease in short term bank deposits, net	(2,499)	4,002	(2,499)	(4)
Net cash provided by (used in) investing activities	(2,797)	3,793	(2,637)	(30)
Cash Flows from Financing Activities:				
Repayment of leases liabilities	(350)	(337)	(172)	(171)
Proceeds from issuance of shares, net	9,861	-	(556)	-
Repayment of IIA grant	(162)	(180)	-	-
Net cash provided by (used in) financing activities	9,349	(517)	(728)	(171)
Exchange rate differences on cash and cash equivalent balances	(550)	204	(303)	495
Decrease in cash and cash equivalents	(3,317)	(383)	(8,922)	(691)
Balance of cash and cash equivalents at the beginning of the period	11,046	17,376	16,651	17,684
Balance of cash and cash equivalents at the end of the period	7,729	16,993	7,729	16,993
Supplement disclosure of Non-cash transactions:				
ROU asset, net recognized with corresponding lease liability	43	155	43	155
Issuance of shares due to RSUs exercised	191	43	14	-

The accompanying notes are an integral part of the interim consolidated financial statements.

Notes to Unaudited Condensed Interim Consolidated Financial Statements

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, to discuss study results and Phase 3 pivotal 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 by year end 2022.

- b.** The Company's securities are listed for trading on NASDAQ since March 2014. In March, 2022, the Company completed an additional public offering. A total of 5,208,333 new ordinary shares were issued at a public offering price of \$1.92 per share. The gross proceeds before deducting underwriting discounts and commissions and offering expenses, were approximately \$10 million (see Note 3 and 5b).

Notes to Unaudited Condensed Interim Consolidated Financial Statements

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 yet 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 Drug Administration (FDA) and received an acknowledgement letter from the FDA assigning PDUFA target date to January 1, 2023.

- g. Since incorporation through June 30, 2022, the Company has incurred losses mainly attributed to its development efforts and a total accumulated deficit of \$156,450, the Company's total shareholders' equity amounted to a deficit of \$2,235. During the six-month period ended June 30, 2022, the Company incurred losses of \$7,943 and its cash used in operating activities was \$9,319. 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. Subsequent to the balance sheet date, the Company raised approximately \$30,500 to further finance its ongoing operations, see also Note 5b.

Notes to Unaudited Condensed Interim Consolidated Financial Statements

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 six and three months ended June 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.

NOTE 3: EQUITY

- a.** On March 7, 2022, the Company completed an additional 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.

Notes to Unaudited Condensed Interim Consolidated Financial Statements

U.S. dollars in thousands**NOTE 3: EQUITY (Cont.)**

- b. 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 \$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 which are required to be approved by the Company's General meeting as well. The fair value of the options and RSU's, as of the approval date, was estimated at approximately \$1,200 and \$500, respectively.

NOTE 4: OTHER EXPENSES

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

NOTE 5: SUBSEQUENT EVENTS

- a. On July 19, 2022, the Company's Shareholders General meeting approved the abovementioned grants (Note 3b, Note 4) to the directors and the CEO, the compensation terms of Mr. Ofer Gonen as the Company's new Chief Executive Officer, which terms will be effective as of July 1, 2022 and the termination terms for the previous CEO.
- 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 net proceeds from this offering in the amount of \$12,244 have been received on September 28, 2022.

Concurrently, 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.

Notes to Unaudited Condensed Interim Consolidated Financial Statements

U.S. dollars in thousands**NOTE 5: SUBSEQUENT EVENTS (Cont.)**

In an event that the Authorized Share Increase Date will not be obtained within 90 days following the abovementioned closing dates, 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 871,429 warrants to purchase up to 871,429 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.

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OPERATING AND FINANCIAL REVIEW AND PROSPECTS

A. Operating Results

The information contained in this section should be read in conjunction with our unaudited condensed interim consolidated financial statements for the year ended June 30, 2022 and related notes, and the information contained elsewhere in this Report of Foreign Private Issuer on Form 6-K, our audited consolidated financial statements and other financial information as of and for the year ended December 31, 2021 appearing in our Annual Report on Form 20-F for the year ended December 31, 2021, which we filed with the SEC on March 17, 2022 (the “Annual Report”) and Item 5—“Operating and Financial Review and Prospects” of the Annual Report. Our financial statements have been prepared in accordance with IFRS, as issued by the IASB.

Company Overview

We are a biopharmaceutical company that develops, manufactures, and commercializes novel, cost effective, bio-therapeutic, non-surgical solutions for tissue repair and regeneration. Our strategy leverages our breakthrough enzymatic technology platform into diversified portfolio of biotherapeutics across multiple indications to pioneer solutions for unmet medical needs. Our current portfolio is focused on next-generation protein-based therapies for burn care, wound care and tissue repair.

Our first innovative biopharmaceutical product, NexoBrid[®], has received marketing authorization from the European Medicines Agency (the “EMA”) and other international markets for removal of dead or damaged tissue, known as eschar, in adults with deep partial-thickness and full-thickness thermal burns, also referred to as severe burns. NexoBrid, a concentrate of proteolytic enzymes enriched in bromelain, represents a new paradigm in burn care management, and our clinical trials have demonstrated, with statistical significance, its ability to non-surgically and rapidly remove the eschar, without harming viable tissues, earlier relative to existing standard of care.

In September 2020, the U.S. Food and Drug Administration (the “FDA”) accepted for review our Biologics License Application (“BLA”) for NexoBrid for severe burns. On June 29, 2021, we received a Complete Response Letter (“CRL”) from the FDA to our Biologics License Application (“BLA”) for NexoBrid for severe burns, pursuant to which the FDA communicated that it had completed its review of the BLA, as amended, and 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 in response to the CMC information requests, which were not reviewed for this action. In addition, the CRL cited certain observations identified during good clinical practice (“GCP”) inspections related to the DETECT study, and requested that we provide our 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 any BLA resubmission, although there were no safety issues raised in the CRL. On August 3, 2022, we announced that the FDA has accepted for review our re-submitted BLA for NexoBrid for eschar removal (debridement) in adults with deep partial-thickness and/or full-thickness thermal burns, and assigned a Prescription Drug User Fee Act (“PDUFA”) target date of January 1, 2023.

We commercialize NexoBrid globally through multiple sales channels. We sell NexoBrid to burn centers in the European Union, United Kingdom and Israel, primarily through our direct sales force, focusing on key burn centers and Key Opinion Leaders (“KOL”). In the United States, we entered into exclusive license and supply agreements with Vericel Corporation (Nasdaq: VCEL) to commercialize NexoBrid in North America upon FDA approval (if received). We 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.

We have been awarded two contracts with the U.S. Biomedical Advanced Research and Development Authority (“BARDA”), for the advancement of the development and manufacturing, as well as the procurement of NexoBrid which has initiated on January 2020, as a medical countermeasure as part of BARDA preparedness for mass casualty events.

On September 20, 2022, we announced that the EMA has validated for review the Type II Variation submitted by MediWound to expand the current approved indication for NexoBrid (removal of eschar in adults with deep partial-thickness and full-thickness thermal burn wounds) into the pediatric population. MediWound expects a decision from the European Commission in the first quarter of 2023.

EscharEx[®], our next-generation enzymatic therapy under development, is a topical biological drug candidate for the debridement of chronic and other hard-to-heal wounds. Designed for the outpatient setting, EscharEx is an easy-to-use concentrate of proteolytic enzymes enriched in bromelain; having the same active pharmaceutical ingredient (“API”) as NexoBrid. In several Phase 2 trials, EscharEx was shown to be well-tolerated and demonstrated safety and efficacy in the debridement of various chronic and other hard-to-heal wounds with only few daily applications. EscharEx’s mechanism of action is mediated by the proteolytic enzymes that cleave and remove the necrotic tissue and prepare the wound bed for healing.

On May 12, 2022, we announced positive results from our U.S. Phase 2 clinical study of EscharEx for the debridement of venous leg ulcers (“VLUs”). The study met its primary endpoint with a high degree of statistical significance, demonstrating that patients treated with EscharEx had a statistically significant higher incidence of complete debridement during the 14-day measurement period within up to 8 applications, compared to gel vehicle (EscharEx: 63% (29/46) vs. gel vehicle: 30% (13/43), p-value=0.004). EscharEx efficacy superiority remained statistically significant after adjusting for pre-specified covariates ascribed to patient baseline characteristics, wound size, wound age and regions.

The study met key secondary and exploratory endpoints. Patients treated with EscharEx had a statistically significant higher incidence of complete debridement, during the same 14-day measurement period, compared to patients treated by non-surgical standard-of-care (“NSSOC”) (EscharEx: 63% (29/46) vs. NSSOC: 13% (4/30)) and the time to achieve complete debridement was significantly shorter. Estimated median time to complete debridement, was 9 days for patients treated with EscharEx and 59 days for patients treated with NSSOC (p-value=0.016). On average, complete debridement was achieved after 3.6 applications of EscharEx compared to 12.8 applications with NSSOC. Patients treated with EscharEx demonstrated significantly higher incidence of at least 75% granulation tissue at the end of the treatment period compared to gel vehicle (p-value <0.0001). Favorable trends were observed in wound area reduction and reduction of pain compared to gel vehicle.

In addition, the study showed that EscharEx was safe and well tolerated, and the overall safety was comparable between the arms as assessed by the data safety monitoring board. Importantly, there were no observed deleterious effects on wound closure and no material differences in reported adverse events. Estimated time to complete wound closure was 64 days for patients treated with EscharEx compared to 78 days for patients treated with NSSOC. Type-C meetings with the FDA to discuss the pivotal study design are targeted for the fourth quarter of 2022.

EscharEx was also evaluated in a U.S. Phase 2 pharmacology study. The study was prospective, open label, single-arm and conducted at three U.S. clinical sites. On July 7, 2022, we announced positive results from this study. 70% of patients achieved complete debridement during the course of treatment within up to 8 applications. On average, complete debridement was achieved after 3.9 applications of EscharEx. Additionally, an average reduction of 35% in wound size was achieved by the end of the 2-week follow-up period. In all patients that were positive for biofilm at baseline, the biofilm was reduced substantially to single individual microorganisms or completely removed by the end of treatment. Seven patients had positive red fluorescence (indicative of bacteria) at baseline and average red fluorescence was reduced from 1.69 cm² pre-treatment to 0.60 cm² post treatment. Biomarker analysis from wound fluid is on-going and safety data shows that EscharEx is safe and well-tolerated.

Our third innovative product candidate, MW005, is a topically applied biological drug candidate for the treatment of non-melanoma skin cancers, based on the same API of NexoBrid and EscharEx (a concentrate of proteolytic enzymes enriched in bromelain). In July 2021, we initiated a phase I/II study of MW005 for the treatment of low-risk basal cell carcinoma (“BCC”). On July 11, 2022, we announced positive initial data from this study. In the first cohort, eleven patients with either superficial or nodular BCC were treated. Patients enrolled into the study received seven topical applications of MW005, once every other day. At the end of eight weeks post treatment period, all patients undergo complete excision, and the specimen is subject to an independent histological clearance examination. Based on the data generated to date, MW005 is safe, well-tolerated and an effective treatment for BCC with a majority of patients who completed the study demonstrating a complete histological clearance of target lesions. We anticipate announcing the final data by year end of 2022.

We manufacture NexoBrid and our product candidates in our cGMP certified sterile manufacturing facility at our headquarters in Yavne, Israel.

As of June 30, 2022, we had cash and cash equivalents of \$10.4 million. Our revenues for the first half of 2022 were \$9.1 million comparing to \$11.9 million in the first half of 2021. Our net loss was \$7.9 million and \$6.0 million in the first half of 2022 and 2021, respectively. We had incurred losses mainly attributed to its development efforts at a total accumulated deficit of \$156 million as of June 30, 2022. We expect to incur significant expenses and operating losses for the foreseeable future, as research and development activities are central to our operations, which will offset by cash inflows from NexoBrid. In order to continue our future operations, we will need to obtain additional funding until becoming profitable. Subsequent to the balance sheet date, we raised approximately \$30.5 million to further finance our ongoing operations.

We expect to continue to invest in our research and development efforts, including in respect of our NexoBrid ongoing clinical trials which are funded by BARDA, as well as the clinical development and trials of EscharEx, MW005 and our other pipeline product candidates. In addition, we expect to continue to advance NexoBrid as a standard of care, and expand its commercial reach in international markets, including for potential use as a medical countermeasure during mass casualty events.

Key Components of Statements of Operations

Revenues

Sources of revenues. We derive revenues from sales of NexoBrid to burn centers and hospitals burn units in Europe and Israel as well as to local distributors in other countries in accordance with distribution agreements we have in place, which also include revenues from licenses. We generate revenues from BARDA procurement of NexoBrid for emergency stockpile pursuant to BARDA contract.

We generate revenues from development services provided to BARDA. Our ability to generate additional, more significant revenues will depend on the successful commercialization of NexoBrid, which itself will be dependent in part upon receipt of approval from the FDA.

Cost of Revenues

Our total cost of revenues includes expenses for the manufacturing of NexoBrid, including: the cost of raw materials; employee-related expenses, including salaries, equity based-compensation and other benefits and related expenses, lease payments, utility payments, depreciation, changes in inventory of finished products, royalties and other manufacturing expenses. These expenses are partially reduced by an allotment of manufacturing costs associated with research and development activities to research and development expenses.

Cost of revenues also includes costs associated with the research and development services provided to BARDA, including salaries and related expenses, clinical trials, sub-contractors and external advisors. We expect that our cost of revenues from sale of products will continue to increase as we expand the sale of NexoBrid throughout the European Union, the United States and other international markets.

Operating Expenses

Research and Development Expenses

Research and development activities are central to our business model. Product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later-stage clinical trials. We expect research and development costs to increase significantly for the foreseeable future as EscharEx progresses in its clinical program in the U.S. and our other pipeline product candidates' progress in clinical trials. However, we do not believe that it is possible at this time to accurately project total program-specific expenses to reach commercialization. There are numerous factors associated with the successful development of any of our product candidates, including future trial design and various regulatory requirements, many of which cannot be determined with accuracy at this time based on our stage of development. Additionally, future commercial and regulatory factors beyond our control will affect our clinical development programs and plans. Our actual spending could differ as our plans change and we invest in other drugs or potentially reduce our anticipated funding on research for existing products.

Research and development expenses consist primarily of compensation for employees engaged in research and development activities, including salaries, equity-based compensation, benefits and related expenses, clinical trials, contract research organization sub-contractors, development materials, external advisors and the allotted cost of our manufacturing facility for research and development purposes.

Selling and Marketing Expenses

Selling and marketing expenses consist primarily of compensation expenses for personnel engaged in sales and marketing, including salaries, equity based-compensation and benefits and related expenses, as well as promotion, marketing, market access, medical, and sales and distribution activities. These expenses also include costs related to our subsidiary in Germany, which is focused primarily on marketing NexoBrid, and cost related to maintain marketing authorization.

General and Administrative Expenses

General and administrative expenses consist principally of compensation for employees in executive and administrative functions, including salaries, equity-based compensation, benefits and other related expenses, professional consulting services, including legal and audit fees, as well as costs of office and overhead.

Financial Income/Financial Expense

Financial income includes interest income, revaluation of financial instruments and exchange rate differences. Financial expenses consist primarily of revaluation of financial instruments, financial expenses in respect of deferred revenues, revaluation of lease liabilities and exchange rate differences. The market interest due on government grants received from the IIA is also considered a financial expense and is recognized beginning on the date we receive the grant until the date on which the grant is expected to be repaid as part of the revaluation to fair value of liabilities in respect of government grants.

Taxes on Income

The standard corporate tax rate in Israel is 23%.

We do not generate taxable income in Israel, as we have historically incurred operating losses resulting in carry forward tax losses totaling approximately \$156 million as of June 30, 2022. We anticipate that we will be able to carry forward these tax losses indefinitely to future tax years. Accordingly, we do not expect to pay taxes in Israel until we have taxable income after the full utilization of our carry forward tax losses.

Under the Law for the Encouragement of Capital Investments, 5719-1959 (the “Investment Law”), we have been granted “Beneficiary Enterprise” status, which provides certain benefits, including tax exemptions and reduced corporate tax rates. Income not eligible for Beneficiary Enterprise benefits is taxed at the regular corporate tax rate. The benefit entitlement period starts from the first year that the Beneficiary Enterprise first earns taxable income, and is limited to 12 years from 2012 in which the company requested to have tax benefits apply.

Comparison of Period to Period Results of Operations

We are providing within this section a supplemental discussion that compares our historical statement of operations data in accordance with IFRS, as issued by the IASB. The below table and the below discussion provides data for each of the periods ended June 30, 2022 and 2021. The below discussion of our results of operations omits a comparison of our results for the years ended December 31, 2021 and 2020. In order to view that discussion, please see “Item 5. Operating and Financial Review and Prospects—A. Operating Results— Comparison of Period to Period Results of Operations— Year Ended December 31, 2021 Compared to Year Ended 31, 2020” in the Annual Report.

	Six Months Ended June 30,	
	2022	2021
	<i>(in thousands)</i>	
condensed statements of operations data:		
Revenues	\$ 9,075	\$ 11,904
Cost of revenues	6,502	7,127
Gross profit	2,573	4,777
Operating expenses:		
Research and development	4,599	4,898
Selling and general & administrative	4,623	4,695
Other expenses	309	-
Operating loss	(6,958)	(4,816)
Financial expenses, net	(977)	(1,211)
Loss before taxes on income	(7,935)	(6,027)
Tax expenses	(8)	(19)
Net loss	\$ (7,943)	(6,046)

Six Months Ended June 30, 2022 Compared to Six Months Ended June 30, 2021

Revenues

Total revenues for the first half of 2022 were \$9.1 million compared to \$11.9 million in the first half of 2021. Revenues from products and licenses in the first half of 2022 were \$3.2 million compared to \$5.9 million for the first half of 2021. This was primarily a result of a \$2.3 million decrease in emergency stockpile procurement by BARDA and \$0.6 million shift in revenues, due to a temporary shortage in the supply chain.

Operating loss for the first half of 2022 was \$7.0 million, compared to an operating loss of \$4.8 million in the first half of 2021.

Net loss for the first half of 2022 was \$7.9 million or \$0.26 per share compared to a net loss of \$6.0 million or \$0.22 per share for the first half of 2021.

Adjusted EBITDA, as defined below, for the first half of 2022, was a loss of \$5.4 million, compared to a loss of \$3.3 million for the first half of 2021.

B. Liquidity and Capital Resources

Our primary uses of cash are to fund working capital requirements, manufacturing costs, research and development expenses of EscharEx and other products candidates, as well as sales and marketing activities associated with the commercialization of NexoBrid in Europe.

Funding under the BARDA contracts is classified under cash use for continuing operating activities.

As of June 30, 2022, we had \$10.4 million of cash, cash equivalents and short-term deposits. Our net loss was \$ 7.9 million and \$4.8 million for the periods ended June 30, 2022 and 2021, respectively. As of June 30, 2022, we had an accumulated deficit of \$156 million. We expect to incur significant expenses and operating losses for the foreseeable future. The net losses we will incur may fluctuate from quarter to quarter.

Our capital expenditures for fiscal periods of the first half of 2022 and 2021 amounted to \$0.3 million and \$0.2 million, respectively. Capital expenditure consists primarily of investments in manufacturing equipment and leasehold improvements.

We completed an underwritten follow-on offering in September 2017, whereby we issued and sold 5,037,664 ordinary shares and received net proceeds of approximately \$22.7 million (after deducting the underwriting discount and offering expenses payable by us), pursuant to our previous shelf registration statement on Form F-3. We will continue to use the net proceeds from the sale of securities offered by us pursuant to that follow-on offering to fund our research and development activities, primarily the clinical development of EscharEx, and the remainder, if any, for working capital and other general corporate purposes. The timing and amount of our actual expenditures will be based on many factors, including cash flows from operations and the anticipated growth of our business. Under our current shelf registration statement on Form F-3 declared effective by the SEC on April 22, 2019, we may offer from time to time up to \$125 million in the aggregate of our ordinary shares, warrants and/or debt securities in one or more series or issuances. In February 2020, we entered into an Open Market Sales Agreement with Jefferies LLC to issue and sell our ordinary shares with gross sales proceeds of up to \$15 million, from time to time, through an at the market offering under which Jefferies LLC will act as our sales agent. As of the date hereof, we have not issued or sold any ordinary shares pursuant to the Open Market Sales Agreement.

In March 2022, we entered into an underwriting agreement with Oppenheimer & Co., Inc., a representative of the several underwriters (the “Underwriters”), relating to the issuance and sale of an aggregate of 5,208,333 of our ordinary shares at a price per share equal to \$1.92. Total gross proceeds of the offering was approximately \$10.0 million. The offering closed on March 7, 2022 and we received approximately \$8.7 million in net proceeds, after deducting underwriting discounts and commissions and estimated offering expenses. Certain entities affiliated with CBI purchased approximately \$2.8 million of ordinary shares in the offering at the public offering price. The Underwriters received the same underwriting discount on the shares purchased by these entities as they will on any other shares sold to the public in this offering. The securities purchased by these entities are subject to lock-up agreements with the Underwriters. We also granted the underwriters a 30-day option to purchase up to an additional 781,249 ordinary shares at the public offering price, less underwriting discounts and commissions.

On September 26, 2022, we completed a registered direct (the “RD”) offering in an aggregate amount of \$13.26 million represent a combine purchase price of \$1.75 for issuance of 7,575,513 ordinary shares 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 net proceeds from this offering in the amount of approximately \$12 million have been received on September 28, 2022.

Concurrently with the signing of the RD, On October 6, 2022, we entered into a Privet Issuance Purchase Equity agreement (the “PIPE”) with several purchasers in an aggregate amount of \$17.23 million, 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 \$16.2 million have been received on October 6, 2022.

In an event that the Authorized Share Increase Date will not be obtained within 90 days following the closing date hereof, we 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, we also issued the placement agent up to 871,429 warrants to purchase up to 871,429 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.

Our future capital requirements will depend on many factors, including our revenue growth, timing of milestone payments, the timing and extent of our spending on research and development efforts, and international expansion. We may also seek to invest in or acquire complementary businesses or technologies. To the extent that existing cash and cash from operations are insufficient to fund our future activities, we may need to raise additional funding through debt and equity financing. Additional funds may not be available on favorable terms or at all. We believe our existing cash, cash equivalents and short-term bank deposits will be sufficient to satisfy our liquidity requirements for at least the next 30 months.

Cash Flows

The following table summarizes our consolidated statement of cash flows for the periods presented. The below discussion beneath the table omits a description of our cash flows for the periods ended June 30, 2022 and 2021. In order to view that discussion, please see “Item 5. Operating and Financial Review and Prospects—B. Liquidity and Capital Resources—Cash Flows” in the Annual Report:

	Six Months Ended June 30,	
	2022	2021
Net cash provided by (used in):		
Operating activities	\$ (9,319)	\$ (3,863)
Investing activities	(2,797)	3,793
Financing activities	9,349	(517)

Net cash used in operating activities

Net cash used in all periods resulted primarily from our net loss adjusted for non-cash charges and measurements and changes in components of working capital. Adjustments for non-cash items include depreciation and amortization, equity-based compensation, revaluation of contingent liabilities and lease liability, and changes in assets and liabilities items.

Net cash used in operating activities increased to approximately \$9.3 million in the six months ended June 30, 2022 compared to net cash used by operating activities of approximately \$3.9 million in the six months ended June 30, 2021, primarily as a result of the operational net loss.

Net cash (used in) provided by investing activities

Net cash used in investing activities primarily resulted from proceeds of investments in short-term banks deposits in addition to purchases of property and equipment. Net cash used in investing activities was \$2.8 million in the six months ended June 30, 2022, compared to \$3.8 million provided during the six months ended June 30, 2021.

Net cash provided by (used in) financing activities

Net cash provided by financing activities primarily resulted from payments of lease liabilities, repayment to IIA and proceeds of issuance of shares. Net cash provided by financing activities was \$9.3 million during the six months ended June 30, 2022 compared to \$0.5 million used during the six months ended June 30, 2021.

Israeli Corporate-Level Tax Considerations and Government Programs

The following is a brief summary of the material Israeli tax laws applicable to us, and certain Israeli Government programs that benefit us and therefore impact our results of operations and financial condition. To the extent that the discussion is based on new tax legislation that has not yet been subject to judicial or administrative interpretation, we cannot assure you that the appropriate tax authorities or the courts will accept the views expressed in this discussion. The discussion below is subject to change, including due to amendments under Israeli law or changes to the applicable judicial or administrative interpretations of Israeli law, which change could affect the tax consequences described below.

General Corporate Tax Structure in Israel

Generally, Israeli companies are subject to a corporate tax on their taxable income. Effective January 1, 2018 and thereafter, the corporate tax rate is 23%. However, the effective tax rate payable by a company that derives income from an Approved Enterprise, a Beneficiary Enterprise, a Preferred Enterprise or Technology Enterprise (as discussed below) may be considerably less. Capital gains derived by an Israeli company are generally subject to the prevailing regular corporate tax rate.

Law for the Encouragement of Industry (Taxes), 5729-1969

The Law for the Encouragement of Industry (Taxes), 5729-1969 (the “Industry Encouragement Law”), provides several tax benefits for “Industrial Companies.”

The Industry Encouragement Law defines an “Industrial Company” as an Israeli resident-company which was incorporated in Israel, of which 90% or more of its income in any tax year, other than income from certain government loans, is derived from an “Industrial Enterprise” owned by it and located in Israel, or in the “Area”, in accordance with the definition under section 3A of the Israeli Income Tax Ordinance (New Version) 1961. An “Industrial Enterprise” is defined as an enterprise whose principal activity in a given tax year is industrial production.

The following tax benefits, among others, are available to Industrial Companies:

- amortization of the cost of purchased a patent, rights to use a patent, and know-how, which are used for the development or advancement of the Industrial Enterprise, over an eight-year period, commencing on the year in which such rights were first exercised;
- under limited conditions, an election to file consolidated tax returns with related Israeli Industrial Companies controlled by it; and
- expenses related to a public offering are deductible in equal amounts over a three years period commencing on the year of the offering.

Eligibility for benefits under the Industry Encouragement Law is not contingent upon approval of any governmental authority.

We believe that we currently qualify as an Industrial Company within the meaning of the Industry Encouragement Law. However, there can be no assurance that we will continue to qualify as an Industrial Company or that the benefits described above will be available in the future.

Law for the Encouragement of Capital Investments, 5719-1959

The Law for the Encouragement of Capital Investments, 5719-1959, to which we refer as the Investment Law provides certain incentives for capital investments in production facilities (or other eligible assets).

The Investment Law was significantly amended several times during recent years, with the three most significant changes effective as of April 1, 2005 (the “2005 Amendment”), as of January 1, 2011, amendment No. 68 (the “2011 Amendment”), and as of January 1, 2017, amendment No. 73 (the “2017 Amendment”). Pursuant to the 2005 Amendment, tax benefits granted in accordance with the provisions of the Investment Law prior to its revision by the 2005 Amendment remain in force but any benefits granted subsequently are subject to the provisions of the amended Investment Law. Similarly, the 2011 Amendment introduced new benefits to replace those granted in accordance with the provisions of the Investment Law in effect prior to the 2011 Amendment. However, companies entitled to benefits under the Investment Law as in effect prior to January 1, 2011 were entitled to choose to continue to enjoy such benefits, provided that certain conditions are met, or elect instead, irrevocably, to forego such benefits and have the benefits of the 2011 Amendment apply. The 2017 Amendment introduces new benefits for Technological Enterprises, alongside the existing tax benefits. Prior to 2011, we did not utilize any of the benefits for which we were eligible under the Investment Law.

Tax Benefits Subsequent to the 2005 Amendment

The 2005 Amendment applies to new investment programs and investment programs commencing after 2004, but does not apply to investment programs approved prior to April 1, 2005 (“Approved Enterprise”). The 2005 Amendment provides that terms and benefits included in any certificate of approval that was granted before the 2005 Amendment became effective (April 1, 2005) will remain subject to the provisions of the Investment Law as in effect on the date of such approval. Pursuant to the 2005 Amendment, the Israeli Authority for Investments and Development of the Israeli Ministry of Economy (the “Investment Center”) will continue to grant Approved Enterprise status to qualifying investments. The 2005 Amendment, however, limits the scope of enterprises that may be approved by the Investment Center by setting criteria for the approval of a facility as an Approved Enterprise.

The 2005 Amendment provides that Approved Enterprise status will only be necessary for receiving cash grants. As a result, it is no longer necessary for a company to obtain the advance approval of the Investment Center in order to receive the tax benefits previously available under the alternative benefits track. Rather, a company may claim the tax benefits offered by the Investment Law directly in its tax returns, provided that its facilities meet the criteria for tax benefits set forth in the 2005 Amendment. Companies or programs under the new provisions receiving these tax benefits are referred to as Beneficiary Enterprises. Companies that have a Beneficiary Enterprise, are entitled to approach the Israel Tax Authority for a pre-ruling regarding their eligibility for tax benefits under the Investment Law, as amended.

Tax benefits are available under the 2005 Amendment to production facilities (or other eligible facilities), which are generally required to derive more than 25% of their business income from export to specific markets with a population of at least 14 million in 2012 (such export criteria will further increase in the future by 1.4% per annum). In order to receive the tax benefits, the 2005 Amendment states that a company must make an investment which meets certain conditions, including exceeding a minimum investment amount specified in the Investment Law. Such investment allows a company to receive "Beneficiary Enterprise" status, and may be made over a period of no more than three years offending in the year in which the company chose to have the tax benefits apply to its Beneficiary Enterprise. The benefits period under the Beneficiary Enterprise status is limited to 12 years from the year the company chose to have its tax benefits apply. Where the company requests to apply the tax benefits to an expansion of existing facilities, only the expansion will be considered to be a Beneficiary Enterprise and the company's effective tax rate will be the weighted average of the applicable rates. In this case, the minimum investment required in order to qualify as a Beneficiary Enterprise is required to exceed a certain percentage of the value of the company's production assets before the expansion.

The extent of the tax benefits available under the 2005 Amendment to qualifying income of a Beneficiary Enterprise depends on, among other things, the geographic location in Israel of the Beneficiary Enterprise. The location will also determine the period for which tax benefits are available. Such tax benefits include an exemption from corporate tax on undistributed income for a period of between two to ten years, depending on the geographic location of the Beneficiary Enterprise in Israel, and a reduced corporate tax rate of between 10% to 25% for the remainder of the benefits period, depending on the level of foreign investment in the company in each year. A company qualifying for tax benefits under the 2005 Amendment which pays a dividend out of income attributed to its Beneficiary Enterprise during the tax exemption period will be subject to corporate tax in respect of the amount of the dividend distributed (grossed-up to reflect the pre-tax income that it would have had to earn in order to distribute the dividend) at the corporate tax rate that would have otherwise been applicable. Dividends paid to Israeli shareholders out of income attributed to a Beneficiary Enterprise (or out of dividends received from a company whose income is attributed to a Beneficiary Enterprise) are generally subject to withholding tax at source at the rate of 15% (in the case of non-Israeli shareholders - subject to the receipt in advance of a valid certificate from the ITA allowing for a reduced tax rate, 15%), or such lower rate as may be provided in an applicable tax treaty, applicable to dividends and distributions out of income attributed to a Beneficiary Enterprise. The reduced rate of 15% is limited to dividends and distributions out of income attributed to a Beneficiary Enterprise during the benefits period and actually paid at any time up to 12 years thereafter, except with respect to a qualified Foreign Investment Company (as such term is defined in the Investment Law), in which case the 12-year limit does not apply.

The benefits available to a Beneficiary Enterprise are subject to the fulfillment of conditions stipulated in the Investment Law and its regulations. If a company does not meet these conditions, it would be required to refund the amount of tax benefits, as adjusted by the Israeli consumer price index, and interest, or other monetary penalties.

We currently have Beneficiary Enterprise programs under the Investment Law, which we believe will entitle us to certain tax benefits. The majority of any taxable income from our Beneficiary Enterprise programs (once generated) would be tax exempt for a period of ten years commencing in the year in which we will first earn taxable income relating to such enterprises, subject to the 12-year limitation from the year the company chose to have its tax benefits apply.

Tax Benefits Under the 2011 Amendment

The 2011 Amendment canceled the availability of the tax benefits granted under the Investment Law prior to 2011 and, instead, introduced new tax benefits for income generated by a “Preferred Company” through its “Preferred Enterprise” (as such terms are defined in the Investment Law) as of January 1, 2011. The definition of a Preferred Company includes a company incorporated in Israel that is not fully owned by a governmental entity, and that has, among other things, Preferred Enterprise status and is controlled and managed from Israel.

The tax benefits under the 2011 Amendment for a Preferred Company meeting the criteria of the law include, among others, a reduced corporate tax rate of 15% for preferred income attributed to a Preferred Enterprise in 2011 and 2012, unless the Preferred Enterprise was located in a specified development zone, in which case the rate was 10%. Under the 2011 Amendment, such corporate tax rate was reduced in 2013 from 15% and 10%, respectively, to 12.5% and 7%, respectively, and then increased to 16% and 9%, respectively, in 2014 and thereafter until 2016. Pursuant to the 2017 Amendment, in 2017 and thereafter, the corporate tax rate for Preferred Enterprise which is located in a specified development zone was decreased to 7.5%, while the reduced corporate tax rate for other development zones remains 16%. Income attributed to a Preferred Company from a “Special Preferred Enterprise” (as such term is defined in the Investment Law) would be entitled, during a benefits period of 10 years, to reduced tax rates of 8%, or 5% if the Special Preferred Enterprise is located in a certain development zone. As of January 1, 2017, the definition of “Special Preferred Enterprise” includes less stringent conditions.

Dividends paid to Israeli shareholders out of preferred income attributed to a Preferred Enterprise or to a Special Preferred Enterprise are generally subject to withholding tax at source at the rate of 20% (in the case of non-Israeli shareholders - subject to the receipt in advance of a valid certificate from the ITA allowing for a reduced tax rate, 20%, or such lower rate as may be provided in an applicable tax treaty). However, if such dividends are paid to an Israeli company, no tax is required to be withheld (although, if such dividends are subsequently distributed to individuals or a non-Israeli company, the aforesaid will apply).

The 2011 Amendment also provided transitional provisions to address companies already enjoying existing tax benefits under the Investment Law. These transitional provisions provide, among other things, that: unless an irrevocable request is made to apply the provisions of the Investment Law as amended in 2011 with respect to income to be derived as of January 1, 2011, a Beneficiary Enterprise can elect to continue to benefit from the benefits provided to it before the 2011 Amendment came into effect, provided that certain conditions are met.

We have examined the possible effect, if any, of these provisions of the 2011 Amendment on our financial statements and have decided, at this time, not to opt to apply the new benefits under the 2011 Amendment. There can be no assurance that we will comply with the conditions required to remain eligible for benefits under the Investment Law in the future or that we will be entitled to any additional benefits thereunder.

New Tax benefits under the 2017 Amendment that became effective on January 1, 2017.

The 2017 Amendment was enacted as part of the Economic Efficiency Law that was published on December 29, 2016, and is effective as of January 1, 2017. The 2017 Amendment provides new tax benefits for two types of “Technology Enterprises,” as described below, and is in addition to the other existing tax beneficial programs under the Investment Law.

The 2017 Amendment provides that a technology company satisfying certain conditions will qualify as a “Preferred Technology Enterprise” and will thereby enjoy a reduced corporate tax rate of 12% on income that qualifies as “Preferred Technology Income,” as defined in the Investment Law. The tax rate is further reduced to 7.5% for a Preferred Technology Enterprise located in development zone A. In addition, a Preferred Technology Company will enjoy a reduced corporate tax rate of 12% on capital gain derived from the sale of certain “Benefitted Intangible Assets” (as defined in the Investment Law) to a related foreign company if the Benefitted Intangible Assets were acquired from a foreign company after January 1, 2017 for at least NIS 200 million, and the sale receives prior approval from the Israeli Innovation Authority.

The 2017 Amendment further provides that a technology company satisfying certain conditions will qualify as a “Special Preferred Technology Enterprise” and will thereby enjoy a reduced corporate tax rate of 6% on “Preferred Technology Income” regardless of the company’s geographic location within Israel. In addition, a Special Preferred Technology Enterprise will enjoy a reduced corporate tax rate of 6% on capital gain derived from the sale of certain “Benefitted Intangible Assets” to a related foreign company if the Benefitted Intangible Assets were either developed by Special Preferred Technology Enterprise or acquired from a foreign company after January 1, 2017, and the sale received prior approval from IIA. A Special Preferred Technology Enterprise that acquires Benefitted Intangible Assets from a foreign company for more than NIS 500 million will be eligible for these benefits for at least ten years, subject to certain approvals as specified in the Investment Law.

Dividends distributed by a Preferred Technology Enterprise or a Special Preferred Technology Enterprise to Israeli shareholders, paid out of Preferred Technology Income, are generally subject to withholding tax at source at the rate of 20% (in the case of non-Israeli shareholders - subject to the receipt in advance of a valid certificate from the ITA allowing for a reduced tax rate, 20%, or such lower rate as may be provided in an applicable tax treaty). However, if such dividends are paid to an Israeli company, no tax is required to be withheld (although, if such dividends are subsequently distributed to individuals or a non-Israeli company, the aforesaid will apply). If such dividends are distributed to a foreign company that holds solely or together with other foreign companies 90% or more in the Israeli company and other conditions are met, the withholding tax rate will be 4% (or a lower under the tax treaty, if applicable, subject to the receipt in advance of a valid certificate from the Israeli Tax Authority allowing for a reduced tax rate).

C. Research and Development, Patents and Licenses, etc.

Our research and development strategy is centered on developing our patented proteolytic enzyme technology, which underlies NexoBrid and EscharEx, into additional products for high-value indications. Our research and development team is located at our facilities in Yavne, Israel, and consists of 25 employees as of June 30, 2022 and is supported by highly experienced consultants in various research and development disciplines.

We have received government grants (subject to our obligation to pay royalties) as part of the NexoBrid and EscharEx research and development programs approved by the IIA. The total gross amount of grants actually received by us from the IIA, including accrued LIBOR interest and net of royalties actually paid, totaled approximately \$13.8 million as of June 30, 2022 and the amortized cost (using the interest method) of the liability totaled approximately \$8.5 million and \$7.8 million as of June 30, 2022 and 2021, respectively. Because the repayment of IIA grants is in the form of future royalties, the balance of the commitments to the IIA is presented as an amortized liability on our balance sheet. As of June 30, 2022, we had accrued and paid royalties to the IIA totaling \$1.3 million.

We received funds from BARDA in accordance with the terms of our BARDA contracts. As of June 30, 2022 we had accrued \$74 million of BARDA’s participation in NexoBrid’s research and development programs.

D. Trend Information

The COVID-19 pandemic has impacted companies in Israel and around the world, and as its trajectory remains highly uncertain, we cannot predict the duration and severity of the outbreak, its containment measures or the nature, timing and strength of recovery from it. Further, we cannot predict impacts, trends and uncertainties involving the pandemic’s effects on economic activity, the size of our labor force, our third-party partners, our investments in marketable securities, and the extent to which our revenue, income, profitability, liquidity, or capital resources may be materially and adversely affected prospectively. See also “ITEM 3.D. – Risk Factors – “The coronavirus (COVID-19) outbreak could adversely impact our business, financial condition and results of operations.” and – “We depend on a sole supplier to obtain our intermediate drug substance, bromelain SP, which is necessary for the production of our products.”

Other than the foregoing and as disclosed in the Annual Report, we are not aware of any trends, uncertainties, demands, commitments or events for the period from January 1, 2022 to the present time that are reasonably likely to have a material adverse effect on our net revenues, income, profitability, liquidity or capital resources, or that would cause the disclosed financial information to be not necessarily indicative of future operating results or financial condition.

E. Critical Accounting Estimates

Our consolidated financial statements are prepared in conformity with IFRS, as issued by the IASB. The preparation of these historical financial statements in conformity with IFRS requires management to make estimates, assumptions and judgments in certain circumstances that affect the reported amounts of assets, liabilities and contingencies as of the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. We evaluate our assumptions and estimates on an ongoing basis. We base our estimates on historical experience and on various other assumptions

that we believe to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions. Our critical accounting estimates are described in Notes 2 and 3 to our consolidated financial statements included in the Annual Report.
