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 ☒ Form 40-F ☐

NexoBrid U.S. Launch Update

Our Partner, Vericel Corporation Inc. ("**Vericel**") has received the first lot of NexoBrid® finished product from MediWound Ltd. ("**we**" or 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 we are 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, we are currently preparing for a production campaign scheduled to begin in September 2023. Vericel expects to begin commercial sales of future NexoBrid lots during the first quarter of 2024.

The FDA's evaluation of the deviation will not affect the $3 million committed by the Biomedical Advanced Research and Development Authority (BARDA) for the replacement of NexoBrid previously procured for emergency response preparedness, which has since expired.

The Company anticipates that a potential delay in the U.S. launch, if occur, will not have an impact on its revenues for the years 2023-2024.

Cautionary Note Regarding Forward-Looking Statements

The Company 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 availability of NexoBrid in the U.S. market, the FDA feedback, our forecasted revenues and BARDA's commitment to purchase NexoBrid for stockpiling. Among the factors that may cause results to be materially different from those stated herein are the inherent uncertainties associated with the uncertain nature of the product development process; 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 in the U.S. or other markets; risks associated with BARDA contract, the clinical utility, potential advantages and timing or likelihood of regulatory filings and approvals of our products; our expectations regarding future growth; market acceptance of our products; 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 the Company'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 the Company's current views as of the date hereof and the Company 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.

Incorporation by Reference

The contents of this Report of Foreign Private Issuer on Form 6-K 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.

Date: August 2, 2023

By: /s/ Hani Luxenburg
Name: Hani Luxenburg
Title: Chief Financial Officer