
UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934

For the month of August 2021

Commission File Number: 001-39461

NANO-X IMAGING LTD

Communications Center
Neve Ilan, Israel 9085000
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of 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):

Note: Regulation S-T Rule 101(b)(1) only permits the submission in paper of a Form 6-K if submitted solely to provide an attached annual report to security holders.

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):

Note: Regulation S-T Rule 101(b)(7) only permits the submission in paper of a Form 6-K if submitted to furnish a report or other document that the registrant foreign private issuer must furnish and make public under the laws of the jurisdiction in which the registrant is incorporated, domiciled or legally organized (the registrant's "home country"), or under the rules of the home country exchange on which the registrant's securities are traded, as long as the report or other document is not a press release, is not required to be and has not been distributed to the registrant's security holders, and, if discussing a material event, has already been the subject of a Form 6-K submission or other Commission filing on EDGAR.

On August 12, 2021, NANO-X IMAGING LTD (the “Company”) received a request for additional information from the U.S. Food and Drug Administration (the “FDA”) concerning the Company’s last 510(k) submission of its multi-source device, Nanox.ARC. The submission file is placed on hold pending a complete response to the FDA’s list of deficiencies. The Company’s response is due within 180 days from the date of the request for additional information.

The Company plans to respond by the due date which is 180 days from the date of the request for additional information. The Company expects to continue to optimize and develop further features of Nanox.ARC and is considering submitting an additional 510(k) application for the next version of multi-source Nanox.ARC during the fourth quarter of 2021, which will benefit from the FDA’s feedback on the first version of the multi-source Nanox.ARC.

The information contained in this report is hereby incorporated by reference into the Registration Statement on Form S-8, File No. 333-248322.

Forward-Looking Statements

This report may contain forward-looking statements that are subject to risks and uncertainties. All statements that are not historical facts contained in this report are forward-looking statements. Such statements include, but are not limited to, any statements relating to the initiation, timing, progress and results of the Company’s research and development, manufacturing and commercialization activities with respect to its X-ray source technology and the Nanox.Arc. In some cases, you can identify forward-looking statements by terminology such as “can,” “might,” “believe,” “may,” “estimate,” “continue,” “anticipate,” “intend,” “should,” “plan,” “should,” “could,” “expect,” “predict,” “potential,” or the negative of these terms or other similar expressions. Forward-looking statements are based on information the Company has when those statements are made or management’s good faith belief as of that time with respect to future events, and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. Factors that could cause actual results to differ materially from those currently anticipated include: risks related to business interruptions resulting from the COVID-19 pandemic or similar public health crises could cause a disruption of the development, deployment or regulatory clearance of the Nanox System and adversely impact our business; the Company’s ability to successfully demonstrate the feasibility of its technology for commercial applications; the Company’s expectations regarding the necessity of, timing of filing for, and receipt and maintenance of, regulatory clearances or approvals regarding its X-ray source technology and the Nanox.Arc from regulatory agencies worldwide and its ongoing compliance with applicable quality standards and regulatory requirements; the Company’s ability to enter into and maintain commercially reasonable arrangements with third-party manufacturers and suppliers to manufacture the Nanox.Arc; the market acceptance of the Nanox.Arc and the proposed pay-per-scan business model; the Company’s expectations regarding collaborations with third-parties and their potential benefits; and the Company’s ability to conduct business globally, among others. Except as required by law, Nanox undertakes no obligation to update publicly any forward-looking statements after the date of this report to conform these statements to actual results or to changes in the Company’s expectations.

SIGNATURES

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.

NANO-X IMAGING LTD

By: /s/ Tal Shank

Name: Tal Shank

Title: Vice President of Corporate Development

Date: August 19, 2021
