
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 February 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 January 30, 2021, in connection with the FDA’s review of its 510(k) premarket notification for the single-source version of the Nanox.ARC, NANO-X IMAGING LTD (the “Company”) received additional information requests from the FDA which, among other things, require the Company to address certain deficiencies and questions, including requests that the Company provide additional support regarding the intended use of the Nanox.ARC and the comparability of the Nanox.ARC to the predicate device. The Company plans to respond to these requests promptly. In addition, the Company will continue to optimize and develop features of the Nanox.ARC, and plans to submit an additional 510(k) premarket notification to the FDA with respect to the multiple-source Nanox.ARC and the Nanox.CLOUD during 2021. If cleared by the FDA and authorized by similar regulatory agencies in other jurisdictions, the Company is targeting shipment of 1,000 Nanox Systems by the end of the first quarter of 2022, with the goal to finalize deployment of the initial 15,000 Nanox Systems by the end of 2024.

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: February 1, 2021
