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UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF NEW YORK

SECURITIES AND EXCHANGE COMMISSION,

Plaintiff,

Civil Action No. 1:23-cv-8611

ECF CASE

-against-

NANO-X IMAGING LTD. and RAN POLIAKINE,

Defendants.

COMPLAINT

Plaintiff Securities and Exchange Commission ("SEC" or the "Commission") files this Complaint against Defendants Nano-X Imaging Ltd. ("Nanox" or the "Company") and Ran Poliakine ("Poliakine") (collectively, "Defendants"), and alleges as follows:

SUMMARY

1. From August 2020 through May 2021, Nanox, an Israel-based medical imaging company, and Poliakine, its founder and then CEO, negligently made a series of false and misleading statements to investors about the estimated cost to manufacture at least 15,000 units of its flagship product, the Nanox.ARC—a device the Company is developing that it claimed would make diagnostic imaging substantially more affordable than currently available medical imaging systems and accessible to patients around the globe.

^{*} Not admitted in SDNY, pro hac vice application filed herewith.

2. In its final prospectus filed in August 2020, Nanox stated that its estimated aggregate cost of purchasing and assembling the components of the Nanox.ARC will be approximately \$8,000 to \$12,000 per unit, assuming at least 15,000 units were manufactured. In reality, as early as October 2019, multiple Nanox executives had internally expressed serious doubts concerning the Company's ability to manufacture the device within this range. After the Company's initial public disclosure of this cost estimate in August 2020 through May 2021, Nanox and Poliakine continued to cite the \$8,000 to \$12,000 cost estimate in SEC filings, earnings calls, and interviews, failing to inform investors regarding the *actual* estimated cost to manufacture its flagship product assuming at least 15,000 units will be manufactured.

JURISDICTION AND VENUE

- 3. The Court has jurisdiction over this action under Sections 20(b), 20(d) and 22 of the Securities Act of 1933 ("Securities Act") [15 U.S.C. §§ 77t(b), 77t(d) and 77v] and Sections 21(d), 21(e) and 27 of the Securities Exchange Act of 1934 ("Exchange Act") [15 U.S.C. §§ 78u(d), 78u(e) and 78aa]. Defendants directly or indirectly made use of means or instrumentalities of interstate commerce, or of the mails, or the facilities of a national securities exchange, in connection with the transactions, acts, practices, and courses of business alleged herein.
- 4. Venue in this district is proper under Section 22 of the Securities Act [15 U.S.C. § 77v] and Section 27 of the Exchange Act [15 U.S.C. § 78aa] because certain acts, practices, transactions, and courses of business constituting the violations alleged herein occurred within this district.

DEFENDANTS

5. **Nanox**, a medical imaging company, is incorporated under the laws of the State of Israel and is headquartered in Neve Ilan, Israel. Since August 2020, Nanox has had a class of

shares registered pursuant to Section 12(b) of the Exchange Act and has filed periodic reports with the Commission. Nanox's shares are listed and traded on the NASDAQ Global Market under the symbol NNOX.

6. **Poliakine** is a citizen of Israel. Poliakine is the founder of Nanox and served as its CEO from September 2019 to December 31, 2021. Poliakine also served as Executive Chairman of the Nanox Board of Directors from August 20, 2020 to September 30, 2022. He is currently the Non-Executive Chairman of the Nanox Board of Directors.

FACTUAL ALLEGATIONS

Background

- diagnostic imaging company, which claimed its mission is to democratize healthcare by making diagnostic imaging more accessible and affordable. Nanox's flagship device, the Nanox.ARC, is a diagnostic imaging device designed to produce three-dimensional, high-resolution X-ray images, ideal for early detection of diseases. The Nanox.ARC uses Nanox's proprietary X-ray tube, based on cold cathode technology, to significantly reduce the amount of heat generated by its X-ray tube as compared to traditional X-ray tubes. Nanox claims this technology will allow it to manufacture cheaper X-ray tubes and a smaller, less expensive imaging device in comparison to currently available medical imaging systems, such as computed tomography. The actual cost to mass-manufacture the Nanox.ARC is central to the Company's business model. And the more the Nanox.ARC's cost were to exceed the estimated \$8,000 to \$12,000 range, the higher the likelihood that the Company would not achieve its goal of widespread deployment and acceptance of the device (assuming all other inputs remain static).
- 8. As founder and CEO, Poliakine functioned as the Company's main ambassador, speaking on behalf of Nanox and promoting its products to investors and the public in

interviews, articles, and industry events. From August 2020 through May 2021, Poliakine promoted the Nanox.ARC as a low-cost alternative to legacy three-dimensional X-ray devices with the ability to make diagnostic-quality images.

<u>Defendants Negligently Misrepresented the Estimated Cost of the Nanox.ARC at Mass</u> <u>Production during the Company's IPO</u>

- 9. In early 2019, Nanox developed its initial Nanox.ARC prototype ("ARC 1.0"). In January 2020, the Nanox employee who designed the ARC 1.0 estimated its manufacturing cost, for producing 15,000 units, to be \$8,000 to \$12,000 per unit. In the months following, certain Company insiders questioned the feasibility of manufacturing the ARC 1.0 for this amount.
- 10. In March 2020, Nanox hired a new engineer tasked with developing the second iteration of the Nanox.ARC prototype ("ARC 2.0"), with the intent of mass producing this iteration of the device. This employee estimated that it would cost approximately \$52,000 per unit to manufacture the employee's ARC 2.0 design. In April 2020, this employee presented his \$52,000 cost estimate to Poliakine and other Nanox executives during a management meeting. Although Poliakine agreed during the meeting to begin the process of developing the ARC 2.0 generally in accordance with this engineer's plan, he disagreed with this engineer's cost estimate. Based on his previous experience achieving cost reductions and analysis provided by other Company employees, Poliakine believed that the initial, and internally disputed, ARC 1.0 estimate of \$8,000 to \$12,000 per unit in mass production was applicable to the ARC 2.0.
- 11. As Nanox sought to go public in the summer of 2020, the Company continued to promote the Nanox.ARC as a breakthrough, low-cost alternative to expensive and cumbersome legacy three-dimensional X-ray imaging devices. And despite ongoing internal concerns and skepticism regarding the Company's ability to manufacture the ARC 2.0 for the ARC 1.0's lower cost estimate, Nanox's August 20, 2020 initial public offering ("IPO") prospectus stated, "We

currently estimate the aggregate cost of purchasing and assembling the components of the Nanox.ARC will be approximately \$8,000 to \$12,000 per unit, assuming at least 15,000 Nanox.ARC units will be manufactured. We believe this will enable us to offer the Nanox System at a substantially lower cost than the cost of existing medical imaging systems based on analog X-ray sources. For example, a new high-end CT scanner sells for \$1,350,000 to \$2,100,000, with an additional \$35,000 to \$100,000 for cardiac software, \$15,500 to \$35,000 for lung software and approximately 10% to 14% of the capital expenditure cost for annual support and maintenance services, reaching a total cost of ownership in the millions of dollars." Nanox raised approximately \$165 million in its IPO; and Poliakine received \$240,000 in incentive-based compensation for taking the Company public. Defendants obtained these sums, at least in part, due to the misleading cost estimate contained in Nanox's IPO prospectus.

Defendants Continued to Negligently Mislead Investors Post-IPO

- estimate to manufacture the Nanox.ARC at mass production, despite continued internal skepticism by certain employees. During a September 22, 2020 interview with The Motley Fool, Poliakine stated, "[Nanox] can actually build a full body scanner for as little as \$10,000 in mass production." Although the Company's engineering team modified the ARC 2.0 prototype in an effort to lower its estimated manufacturing cost, the ARC 2.0's lead engineer continued to estimate a significantly higher cost than the approximately \$8,000 to \$12,000 range disclosed by Defendants. By the end of September 2020, the ARC 2.0 engineer estimated that the modified ARC 2.0 would cost \$42,000 per unit to manufacture at mass production.
- 13. In November 2020, Nanox retained an X-ray engineering expert to, in part, assess the feasibility of building an X-ray tube manufacturing facility in Israel. The engineering expert concluded that, if the Company built and ran an X-ray tube manufacturing facility in Israel, each

tube would cost roughly \$2,100—approximately \$10,500 in costs related to just the tubes in a five-tube device. Poliakine received a copy of this expert's report.

- 14. In early 2021, Nanox created a cost reduction task force, led by the Company's Chief Operating Officer ("COO"), to attempt to reduce the ARC 2.0's estimated manufacturing cost to \$10,000 per unit at mass production. In July 2021, the COO told Poliakine and other Nanox executives that the Company would not reach the \$10,000 per unit goal without a total redesign of the ARC 2.0. Between July 2021 and November 2021, the ARC 2.0's initial engineer again expressed his concerns to Poliakine about the feasibility of the cost estimate—even with the proposed redesign. Nanox continued to redesign the ARC 2.0, but did not begin mass production or achieve its target \$10,000 per unit cost with the ARC 2.0.
- Nanox and Poliakine continued to tell investors that the low-cost estimate for the device was on track. During Nanox's March 2, 2021 earnings call, Poliakine, in response to an analyst's question regarding the cost of the first devices, stated that the Company "always envisioned that the first 100 units will be a bit more expensive than the target cost of between \$10,000 to \$15,000" per unit and that the Company was "getting very close to the targeted price. That's [the Company's] estimation." The Company's April 6, 2021 Form 20-F, which was signed by, among others, Poliakine, repeated the IPO prospectus's disclosure that the Nanox.ARC's cost would be "approximately \$8,000 to \$12,000 per unit, assuming at least 15,000 Nanox.ARC units will be manufactured." During Nanox's May 11, 2021 earnings call, Poliakine, in response to an analyst's question regarding whether the Company's decision to use glass tubes impacted the cost estimate, again reiterated a \$10,000 per unit cost goal: "the other component[s], like the power supply detector, mechanics are much more impactful in terms of meeting the \$10,000 goals over time than the tubes themselves."

16. To date, Nanox has not yet achieved mass production or developed a device within the \$8,000 to \$12,000 cost estimate range at mass production. In fact, in the fall of 2022, the Company internally projected that a future version of the Nanox.ARC, called the ARC 2.4, would cost roughly \$25,000 per unit to manufacture, assuming more than 5,000 units were manufactured, which is more than twice the cost at the high end of the continually touted price range.

FIRST CLAIM FOR RELIEF

Defendants Violated Section 17(a)(2) of the Securities Act [15 U.S.C. § 77q(a)]

- 17. The SEC realleges and incorporates by reference each and every allegation contained in the paragraphs above.
- 18. By engaging in the conduct described above, Defendants, directly or indirectly, in the offer or sale of a security, by use of the means or instruments of transportation or communication in interstate commerce or by use of the mails, obtained money or property by means of an untrue statement of a material fact or omitted to state a material fact necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.
 - 19. Defendants were negligent in their conduct alleged herein.
- 20. By reason of the foregoing, Defendants violated and, unless enjoined, will continue to violate, Section 17(a)(2) of the Securities Act [15 U.S.C. § 77q(a)(2)].

SECOND CLAIM FOR RELIEF

Nanox Violated Section 13(a) of the Exchange Act [15 U.S.C. § 78m(a)] and Rules 12b-20 and 13a-1 thereunder [17 C.F.R. §§ 240.12b-20 and 240.13a-1]

21. The SEC realleges and incorporates by reference each and every allegation contained in the paragraphs above.

- 22. Nanox is an issuer of securities registered under Section 12 of the Exchange Act that filed required reports with the Commission under Section 13(a) of the Exchange Act and related rules and regulations.
- 23. By engaging in the conduct described above, Nanox failed to file an annual report with the Commission that was true and correct and failed to include material information in its required statements and reports as was necessary to make the statements made, in light of the circumstances under which they were made, not misleading.
- 24. By reason of the foregoing, Nanox violated and, unless enjoined, will continue to violate, Section 13(a) of the Exchange Act [15 U.S.C. § 78m(a)] and Rules 12b-20 and 13a-1 thereunder [17 C.F.R. §§ 240.12b-20 and 240.13a-1].

THIRD CLAIM FOR RELIEF

Poliakine Aided and Abetted Violations of Section 13(a) of the Exchange Act [15 U.S.C. § 78m(a)] and Rules 12b-20 and 13a-1 thereunder [17 C.F.R. §§ 240.12b-20 and 240.13a-1]

- 25. The SEC realleges and incorporates by reference each and every allegation contained in the paragraphs above.
- 26. As set forth above, by its conduct alleged herein, Nanox violated Section 13(a) of the Exchange Act [15 U.S.C. § 78m(a)] and Rules 12b-20 and 13a-1 thereunder [17 C.F.R. §§ 240.12b-20 and 240.13a-1].
- 27. Poliakine, acting with the requisite state of mind, provided substantial assistance to Nanox in committing its violations of Section 13(a) of the Exchange Act [15 U.S.C. § 78m(a)] and Rules 12b-20 and 13a-1 thereunder [17 C.F.R. §§ 240.12b-20 and 240.13a-1].
- 28. By reason of the foregoing, Poliakine aided and abetted Nanox's violations of Section 13(a) [15 U.S.C. § 78m(a)] and Rules 12b-20 and 13a-1 thereunder [17 C.F.R. §§ 240.12b-20 and 240.13a-1] and, unless enjoined, will continue to aid and abet such violations.

PRAYER FOR RELIEF

THEREFORE, the Commission respectfully requests that the Court enter a Final Judgment that:

- A. Permanently enjoins Defendants Nanox and Poliakine from violating, directly or indirectly, Section 17(a)(2) of the Securities Act [15 U.S.C. § 77q(a)(2)];
- B. Permanently enjoins Defendant Nanox from violating, directly or indirectly, Section 13(a) of the Exchange Act [15 U.S.C. § 78m(a)] and Rules 12b-20 and 13a-1 thereunder [17 C.F.R. §§ 240.12b-20 and 240.13a-1];
- C. Permanently enjoins Defendant Poliakine from aiding or abetting any violation of Section 13(a) of the Exchange Act [15 U.S.C. § 78m(a)] and Rules 12b-20 and 13a-1 thereunder [17 C.F.R. §§ 240.12b-20 and 240.13a-1];
- D. Orders Defendant Poliakine to disgorge all ill-gotten gains received as a result of the violations alleged herein, plus prejudgment interest on those amounts, pursuant to the Court's equitable powers and Sections 21(d)(3), 21(d)(5), and 21(d)(7) of the Exchange Act [15 U.S.C. §§ 78u(d)(3), 78u(d)(5), and 78u(d)(7)];
- E. Orders Defendants to pay civil penalties under Section 20(d) of the Securities Act [15 U.S.C. § 77t(d)] and Section 21(d)(3) of the Exchange Act [15 U.S.C. § 78u(d)(3)]; and
 - F. Grant such further relief as the Court deems just and proper.

Date: September 29, 2023 Respectfully submitted,

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