

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

FORM 20-F

(Mark One)

REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2020

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

OR

SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Date of event requiring this shell company report

For the transition period from to

Commission file number 001-38024

NANO-X IMAGING LTD

(Exact name of Registrant as specified in its charter)

N/A

(Translation of Registrant's name into English)

State of Israel

(Jurisdiction of incorporation or organization)

Communication Center,
Neve Ilan, Israel 9085000

(Address of principal executive offices)

Ran Poliakine, Chairman of the Board and Chief Executive Officer

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Communication Center,
Neve Ilan, Israel 9085000

(Name, Telephone, E-mail and/or Facsimile number and Address of Company Contact Person)

Securities registered or to be registered pursuant to Section 12(b) of the Act.

Title of each class	Trading Symbol	Name of each exchange on which registered
Ordinary Shares, par value NIS 0.01 per share	NNOX	The NASDAQ Stock Market LLC

Securities registered or to be registered pursuant to Section 12(g) of the Act: None

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act: None

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report: 46,100,173 Ordinary Shares as of December 31, 2020

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. Yes No

Note—Checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 from their obligations under those sections.

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes No

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or an emerging growth company. See definition of "large accelerated filer," "accelerated filer," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Emerging growth company	<input checked="" type="checkbox"/>

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 13(a) of the Exchange Act.

† The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report.

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this annual report:

U.S. GAAP International Financial Reporting Standards as issued by the International Accounting Standards Board Other

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow. Item 17 Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

(APPLICABLE ONLY TO ISSUERS INVOLVED IN BANKRUPTCY PROCEEDINGS DURING THE PAST FIVE YEARS)

Indicate by checkmark whether the registrant has filed all documents and reports required to be filed by Sections 12, 13 or 15(d) of the Securities Exchange Act of 1934 subsequent to the distribution of securities under a plan confirmed by a court. Yes No

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INTRODUCTION

NANO-X IMAGING LTD was incorporated under the laws of the State of Israel on December 20, 2018 and commenced operations on September 3, 2019. Unless the context otherwise requires, all references to “Nanox,” “we,” “us,” “our,” the “Company” and similar designations refer to NANO-X IMAGING LTD, an Israeli company, its wholly-owned Japanese subsidiary and its wholly-owned Korean subsidiary, or, where applicable, its predecessor company, Nanox Imaging PLC, a Gibraltar public limited company, and its wholly-owned Japanese subsidiary. Unless derived from our financial statements or otherwise noted, the terms “shekels” and “NIS” refer to New Israeli Shekels, the lawful currency of the State of Israel, the terms “dollar” or “\$” refer to U.S. dollars, the lawful currency of the United States, “Yen” refers to Japanese Yen, the lawful currency of Japan, and “KRW” refers to Korean Won, the lawful currency of South Korea.

FORWARD-LOOKING STATEMENTS

This annual report on Form 20-F contains forward-looking statements that are based on our management’s belief and assumptions and on information currently available to our management. Although we believe that the expectations reflected in these forward-looking statements are reasonable, these statements relate to future events or our future financial performance, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, levels of activity, performance or achievements to be materially different from any future results, levels of activity, performance or achievements stated in or implied by these forward-looking statements.

All statements that are not historical facts contained in this annual report on Form 20-F are forward-looking statements. These forward-looking statements include information about possible or assumed future results of our business, financial condition, results of operations, prospects, liquidity, plans and objectives. 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 we have when those statements are made or our 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. Forward-looking statements include, but are not limited to, statements concerning:

- The initiation, timing, progress and results of our research and development, manufacturing and commercialization activities with respect to our X-ray source technology, the Nanox.ARC, the Nanox.CLOUD and the Nanox System;
- our ability to successfully demonstrate the feasibility of our technology for commercial applications;
- our expectations regarding the necessity of, timing of filing for, and receipt of, regulatory clearances or approvals regarding our technology, the Nanox.ARC and the Nanox.CLOUD;
- our ability to secure and maintain required U.S. Food and Drug Administration (the “FDA”) clearance and similar approvals from regulatory agencies worldwide and comply with applicable quality standards and regulatory requirements;
- our ability to manufacture the Nanox.ARC, if cleared, at substantially lower costs compared to medical imaging systems that use a legacy analog X-ray source;
- our expectations regarding the planned deployment schedule to meet our target minimum installed base of 1,000 Nanox Systems and final deployment of 15,000 Nanox Systems;
- the pricing structure of our products and services, if such products and services receive regulatory clearance or approval;
- the implementation of our business models;
- our expectations regarding collaborations with third-parties and their potential benefits;

- our ability to enter into and maintain our arrangements with third-party manufacturers and suppliers;
- our ability to conduct business globally;
- our expectations regarding when certain patents may be issued and the protection and enforcement of our intellectual property rights;
- our ability to operate our business without infringing the intellectual property rights and proprietary technology of third parties;
- regulatory developments in the United States and other jurisdictions;
- estimates of our expenses, future revenues, capital requirements and our needs for additional financing;
- the rate and degree of market acceptance of our technology and our products;
- development relating to our competitors and the medical imaging industry;
- our estimates of the adoption of the MSaaS-based model by market participants;
- our estimates regarding the market opportunities for our technology and our products;
- our ability to attract, motivate and retain key executive managers;
- our ability to comply with data protection laws, regulations and similar rules and to establish and maintain adequate cyber-security and data protection;
- our ability to obtain third-party payor coverage or reimbursement of our Nanox System;
- our expectation regarding the maintenance of our foreign private issuer and emerging growth company status;
- the effect of the COVID-19 pandemic, including mitigation efforts and economic effects, on any of the foregoing or other aspects of our business operations, including but not limited to the development, deployment and regulatory clearance of the Nanox Systems;
- the costs incurred with respect to and the outcome of the securities class-action litigation we are currently subject to and any similar or other claims and litigation we may be subject to in the future; and
- our success at managing other risks and uncertainties, including those listed under “Item 3. Key Information—D. Risk Factors.”

Many important factors, in addition to the factors described above and in other sections of this annual report on Form 20-F, could adversely impact our business and financial performance. The forward-looking statements contained in this annual report on Form 20-F speak only as of the date of this annual report on Form 20-F and are subject to a number of known and unknown risks, uncertainties and assumptions, including those described under the sections in this annual report on Form 20-F entitled “Item 3. Key Information—D. Risk Factors” and “Item 5. Operating and Financial Review and Prospects” and elsewhere in this annual report on Form 20-F. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond our control, you should not rely on these forward-looking statements as predictions of future events. Moreover, we operate in an evolving environment. New risks and uncertainties emerge from time to time, and it is not possible for our management to predict all risks and uncertainties, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from estimates or forward-looking statements. We qualify all of our forward-looking statements by these cautionary statements. Except as required by law, we undertake no obligation to update publicly any forward-looking statements after the date of this annual report on Form 20-F to conform these statements to actual results or to changes in our expectations.

PART I

Item 1. Identity of Directors, Senior Management and Advisors

Not applicable.

Item 2. Offer Statistics and Expected Timetable

Not applicable.

Item 3. Key Information

A. Selected Financial Data

The following tables set forth our selected consolidated historical financial data which is derived from our audited financial statements, which have been prepared in accordance with generally accepted accounting principles in the United States (“U.S. GAAP”). The selected statement of operations for each of the years in the three-year period ended December 31, 2020 and the consolidated balance sheet data as of December 31, 2020 and 2019 have been derived from our audited consolidated financial statements included elsewhere in this annual report on Form 20-F. You should read this data together with our audited consolidated financial statements and related notes included elsewhere in this annual report on Form 20-F and the information under the caption “Item 5. Operating and Financial Review and Prospects.” Our historical results are not necessarily indicative of our future results.

	Year ended December 31,		
	2020	2019	2018
	(\$ in thousands)		
OPERATING EXPENSES:			
Research and development	9,210	2,717	672
Marketing	12,445	1,556	209
General and administrative	22,268	18,298	1,023
TOTAL OPERATING EXPENSES	43,923	22,571	1,904
OPERATING LOSS	(43,923)	(22,571)	(1,904)
FINANCIAL (INCOME) EXPENSES, net	(108)	(8)	5
NET LOSS	(43,815)	(22,563)	(1,909)
BASIC AND DILUTED LOSS PER SHARE	(1.23)	(0.90)	(0.09)
THE WEIGHTED AVERAGE OF THE NUMBER OF ORDINARY SHARES (in thousands)	35,654	25,181	20,793

	December 31,	
	2020	2019
	(\$ in thousands)	
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	213,468	8,072
Prepaid expenses and other current assets	6,325	1,564
TOTAL CURRENT ASSETS	219,793	9,636
NON-CURRENT ASSETS:		
Restricted cash	316	145
Property and equipment, net	14,020	228
Deferred offering costs	-	1,197
Operating lease right-of-use asset	1,359	526
Other non-current assets	661	139
TOTAL NON- CURRENT ASSETS	16,356	2,235
TOTAL ASSETS	236,149	11,871
Liabilities and Shareholders' Equity (Capital Deficiency)		
CURRENT LIABILITIES:		
Accounts payable	435	475
Accrued expenses and other liabilities	3,526	1,828
Related party liability	-	17,748
Related party accrued liability	-	72
Current maturities of operating leases	519	140
TOTAL CURRENT LIABILITIES	4,480	20,263
NON-CURRENT LIABILITIES:		
Non-current operating leases	923	386
TOTAL NON-CURRENT LIABILITIES	923	386
TOTAL LIABILITIES	5,403	20,649
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY (CAPITAL DEFICIENCY):		
Ordinary Shares, par value NIS 0.01 per share, 100,000,000 and 40,000,000 shares authorized at December 31, 2020 and 2019, respectively; 46,100,173 and 27,150,080 issued and outstanding at December 31, 2020 and 2019, respectively.	131	75
Additional paid-in capital	315,031	31,748
Accumulated deficit	(84,416)	(40,601)
TOTAL SHAREHOLDERS' EQUITY (CAPITAL DEFICIENCY)	230,746	(8,778)
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY (CAPITAL DEFICIENCY)	236,149	11,871

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. Risk Factors

Risk Factors Summary

Risks Related to Our Business

- We are a development-stage company with limited operating history. We may never be able to effectuate our business plan or achieve any revenue or reach profitability. Therefore, at this stage of our business, potential investors have a high probability of losing their entire investment.
- Our efforts may never demonstrate the feasibility of our digital X-ray source technology, including both the MEMs X-ray chips and tubes, for commercial applications.
- Two of our business models depend on the successful commercial application of the Nanox.CLOUD, which is subject to numerous risks and uncertainties.
- We are highly dependent on the successful development, marketing and sale of our X-ray source technology and the related products and services.
- Products utilizing our technology may need to be approved or cleared by the FDA and similar regulatory agencies worldwide. We may not receive, or may be delayed in receiving, the necessary approval or clearance for our future products, which would adversely affect business, financial condition, results of operations and prospects.
- We may need to obtain additional financing to fund our future operations. If we are unable to obtain such financing, we may be unable to complete the development and commercialization of our technology and our products and services.
- The success of our primary business model, the Subscription Model, is subject to numerous risks and uncertainties.
- We may not be successful in tailoring our X-ray source to the specific systems of other medical imaging companies under our Licensing Model, and/or entering into licensing agreements on terms favorable to us.
- To the extent that we license our X-ray source technology to other medical imaging companies, the products integrating our technology may need to be approved or cleared by the FDA or similar regulatory agencies.
- A pandemic, epidemic or outbreak of an infectious disease, such as COVID-19, may materially and adversely affect our business and our financial results and could cause a disruption to the development or deployment of the Nanox System.
- Our industry is highly competitive and is subject to technological change, which may result in new products or solutions that are superior to our technology or other future products we may bring to market from time to time. If we are unable to anticipate or keep pace with changes in the marketplace and the direction of technological innovation and customer demands, our technology may become less useful or obsolete and our operating results will suffer.
- We expect to depend on third parties to manufacture the Nanox.ARC and to supply certain component parts. Our reliance on third-party manufacturers and suppliers involve certain risks that may result in, among others, increased costs, quality or compliance issues, or failure to timely manufacture the Nanox.ARC, any of which could materially harm our business.
- We may experience development or manufacturing problems and higher costs, or delays that could limit our revenue, if any, or increase our losses.
- We may not be able to successfully execute our business models.
- We have a limited operating history. If we successfully commercially launch the Nanox.ARC or the Nanox.CLOUD, and they do not achieve widespread market acceptance, we will not be able to generate the revenue necessary to support our business.
- We plan to do business globally, including in certain countries where we might have limited resources and would be subject to additional regulatory burdens and other risks and uncertainties.

- Because the Nanox System is still in the development stage, it is not yet approved for third-party payor coverage or reimbursement. If in the future we are approved for and are otherwise able to commercialize it, but are unable to obtain adequate reimbursement or insurance coverage from third-party payors, we may not be able to generate significant revenue, in which case we may need to obtain additional financing.
- Recent changes in the United States related to payment policies for imaging procedures could have a negative impact on the utilization of our imaging services.
- Billing complexities associated with obtaining payment or reimbursement may negatively affect our revenue, cash flow and profitability.
- Any collaborative and MSaaS arrangements that we have established or may establish in the future may not be successful or we may otherwise not realize the anticipated benefits from these collaborations. We do not control third parties with whom we have or may have collaborative or MSaaS arrangements, and we will rely on them to achieve results which may be significant to us. In addition, any current or future collaborative and MSaaS arrangements may place the development and commercialization of our technology outside our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us.
- We could become subject to product liability claims, product recalls, and warranty claims that could be expensive, divert management's attention and harm our business reputation and financial results.
- We are highly dependent on key members of our executive management team. Our inability to retain these individuals could impede our business plan and growth strategies, which could have a negative impact on our business and the value of your investment.
- The mishandling or the perceived mishandling of sensitive information, or the occurrence of data security breaches, could harm our business.
- Our business and operations would suffer in the event of computer system failures, cyber-attacks or deficiencies in our cyber-security.
- Exchange rate fluctuations between the U.S. dollar, Japanese Yen, the New Israeli Shekel and the South Korean Won and inflation may negatively affect our results of operations, and we may not be able to hedge our currency exchange risks successfully.
- If significant tariffs or other restrictions related to "trade wars" are placed on Chinese imports or any related counter-measures are taken by China, our revenue and results of operations may be materially harmed.
- Our business may be impacted by changes in general economic conditions.
- We are currently subject to securities class-action litigation and may be subject to similar or other claims and litigation in the future, all of which will require significant management attention, could result in significant legal expenses and may result in unfavorable outcomes, all or any of which could have a material adverse impact on our financial condition and results of operations, harm our reputation or otherwise negatively impact our business.
- We do not expect to carry any business interruption insurance or any other insurance (except for director and officer, property and product liability insurance). As a result, we may incur uninsured losses, increasing the possibility that you would lose your entire investment in our company.
- Certain of our directors and/or officers may have interests that compete with ours.
- Our management team has limited experience managing a public company.

Risks Related to Our Intellectual Property

- It is difficult and costly to protect our intellectual property and our proprietary technologies, and we may not be able to ensure their protection.
- Patent terms may be inadequate to protect our competitive position on our future products for an adequate amount of time.
- Claims that our technology or our future products or the sale or use of our future products infringe the patents or other intellectual property rights of third parties could result in costly litigation or could require substantial time and money to resolve, even if litigation is avoided.

- Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated if we or our future licensors do not comply with these requirements.
- We may be subject to claims that our employees, consultants or advisers have wrongfully used or disclosed alleged trade secrets of their former employers or claims asserting ownership of what we regard as our own intellectual property.
- If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.
- Our rights to develop and commercialize our products may be subject to the terms and conditions of licenses and sublicenses granted to us by third parties.
- We may be required to pay certain milestones and royalties and fulfill other obligations under our license agreements with third-party licensors.
- If we choose to license our technology to third parties, this could result in disputes or otherwise limit our future operations.

Risks Related to Government Regulation

- Our product candidates and operations are subject to extensive government regulation and oversight both in the United States and abroad, and our failure to comply with applicable requirements could harm our business.
- We may not receive, or may be delayed in receiving, the necessary clearances or approvals for our future products, and failure to timely obtain necessary clearances or approvals for our future products would adversely affect our ability to grow our business.
- Failure to comply with post-marketing regulatory requirements could subject us to enforcement actions, including substantial penalties, and might require us to recall or withdraw a product from the market.
- Our products must be manufactured in accordance with federal, state and foreign regulations, and we could be forced to recall our devices or terminate production if we fail to comply with these regulations.
- The misuse or off-label use of our products may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.
- Our products may cause or contribute to adverse medical events or be subject to failures or malfunctions that we are required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us.
- Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.
- Changes in laws or regulations relating to data protection, or any actual or perceived failure by us to comply with such laws and regulations or our privacy policies, could materially and adversely affect our business or could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.
- If we do not obtain and maintain international regulatory registrations, clearances or approvals for our products, we will be unable to market and sell our products outside of the United States.
- Legislative or regulatory reforms in the United States or the EU may make it more difficult and costly for us to obtain regulatory clearances or approvals for our products or to manufacture, market or distribute our products after clearance or approval is obtained.
- Healthcare reform laws could adversely affect our products and financial condition.
- Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, cleared or approved or commercialized in a timely manner or at all, which could negatively impact our business.

Risks Related to Employee Matters

- Under applicable employment laws, we may not be able to enforce covenants not to compete and therefore may be unable to prevent our competitors from benefiting from the expertise of some of our former employees.
- We may not be able to attract and retain the highly skilled employees we need to support our planned growth.

Risks Related to Owning Our Ordinary Shares

- Our share price may be volatile, and you may lose all or part of your investment.
- We are an “emerging growth company” under the JOBS Act and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our ordinary shares less attractive to investors.
- Our status as an “emerging growth company” under the JOBS Act may make it more difficult to raise capital as and when we need it.
- As a foreign private issuer, we are exempt from certain requirements that apply to domestic issuers and we are permitted to follow certain home country corporate governance practices instead of applicable SEC and Nasdaq requirements, which may result in less protection than is accorded to shareholders under rules applicable to domestic issuers.
- We may lose our foreign private issuer status which would then require us to comply with the Exchange Act’s domestic reporting regime and cause us to incur significant legal, accounting and other expenses.
- We have not paid dividends in the past and have no immediate plans to pay dividends.
- We incur significant increased costs as a result of operating as a public company that reports to the SEC and our management may be required to devote substantial time to meet compliance obligations.
- Shares eligible for future sale may adversely affect the market for our ordinary shares and the issuance of additional ordinary shares as a result of the exercise of our outstanding warrants and options will dilute the percentage ownership of our other shareholders.
- The purchase price of the ordinary shares may not reflect our actual value.
- We have identified material weaknesses in our internal control over financial reporting that could, if not remediated, result in material misstatements in our financial statements. If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our ordinary shares.
- It is likely that we will be classified as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes for our taxable year ended December 31, 2020, for the current taxable year and possibly for future taxable years, which could result in adverse U.S. federal income tax consequences to U.S. Holders of our ordinary shares.

Risks Related to Our Operations in Israel

- Conditions in Israel could materially and adversely affect our business.
- The termination or reduction of tax and other incentives that the Israeli government provides to Israeli companies may increase our costs and taxes.
- It may be difficult to enforce a U.S. judgment against us, our officers and directors named in this annual report on Form 20-F in Israel or the United States, or to assert U.S. securities laws claims in Israel or serve process on our officers and directors.
- Your rights and responsibilities as our shareholder will be governed by Israeli law, which may differ in some respects from the rights and responsibilities of shareholders of U.S. corporations.

- Our amended and restated articles of association contains exclusive forum provisions for certain claims, which could limit our shareholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.
- Provisions of our amended and restated articles of association and Israeli law and tax considerations may delay, prevent or make difficult an acquisition of us, which could prevent a change of control and negatively affect the price of our ordinary shares.

Risks Related to Our Business

We are a development-stage company with limited operating history. We may never be able to effectuate our business plan or achieve any revenue or reach profitability. Therefore, at this stage of our business, potential investors have a high probability of losing their entire investment.

We are a development-stage company, and are subject to all of the risks inherent in the establishment of a new business enterprise. We have a limited operating history and only a preliminary and unproven business plan upon which investors may evaluate our prospects. We have not yet demonstrated the feasibility of our digital X-ray source technology for commercial applications. Although we have produced a working prototype of the Nanox.ARC and developed a prototype of the Nanox.CLOUD, we have not produced any of the approximately 15,000 Nanox.ARC units planned for the initial global deployment under the contract manufacturing agreement with FoxSemicon Integrated Technology, Inc., a subsidiary of Foxconn ("FITI"). Due, in part, to travel restrictions as a result of the COVID-19 pandemic, we engaged Dagesh P.K. Ltd. ("Dagesh") to manufacture a small number of Nanox.ARC units in Israel on a purchase order basis that we expect will be used for the acceptance tests under our MSaaS agreements, demonstrations, regulatory approvals and for the initial global deployment, among other purposes. Even if we are able to manufacture the Nanox.ARC, we may not be able to do so at the low costs needed to support our business models, including the Subscription Model, which is our primary business model. We may not receive, or may be delayed in receiving, the necessary approval or clearance for the Nanox.ARC or our future products. We also have not entered into any commercial arrangement for the licensing of our X-ray source under the Licensing Model.

Furthermore, even if our technology becomes commercially viable, our business models may not generate sufficient revenue necessary to support our business. We estimate that effectively stimulating market interest in our Nanox System will require deploying at least 5,000 to 10,000 Nanox.ARC units. In addition, we estimate that a minimum installed base of at least 1,000 Nanox.ARC units will be needed to support our business during the initial deployment, assuming we enter into at least one licensing agreement on commercially reasonable terms. We may never achieve any of these thresholds for units deployed in the near-to-mid-term at any level or at all, which may cause our business to fail. The Subscription Model is based on selling the Nanox System at low cost or no cost using a pay-per-scan pricing structure, which is pioneering for medical imaging companies and is subject to numerous risks. The medical imaging industry is also highly competitive and our technology, products, services or business models may not achieve widespread market acceptance. If we are unable to address any issues mentioned above, or encounter other problems, expenses, difficulties, complications, and delays in connection with the starting and expansion of our business, our entire business may fail, in which case you may lose your entire investment.

We have a history of net losses and negative cash flow from operations since inception and we expect such losses and negative cash flows from operations to continue in the foreseeable future. As of December 31, 2020 and 2019, we had working capital (deficiency) of approximately \$215.3 million and \$(10.6) million, respectively, and shareholders' equity (deficit) of approximately \$230.7 million and \$(8.8) million, respectively. For the years ended December 31, 2020, 2019 and 2018, we incurred net losses of approximately \$43.8 million, \$22.6 million and \$1.9 million, respectively. As of December 31, 2020 and 2019, we had an accumulated deficit of approximately \$84.4 million and \$40.6 million, respectively, and negative cash flow from operations of \$21.5 million, \$5.5 million and \$3.7 million for the years ended December 31, 2020, 2019 and 2018, respectively. We anticipate our losses will continue to increase from current levels because we expect to incur additional costs related to developing our business, including research and development costs, manufacturing costs, employee-related costs, costs of complying with government regulations, intellectual property development and prosecution costs, marketing and promotion costs, capital expenditures, general and administrative expenses, and costs associated with operating as a public company.

Our ability to generate revenue from our operations and, ultimately, achieve profitability will depend on, among others, whether we can complete the development and commercialization of our technology, our future products and our services, including our X-ray source technology, the Nanox.ARC and the Nanox.CLOUD, whether we can manufacture the Nanox.ARC on a commercial scale in such amounts and at such costs as we anticipate, and whether we can achieve market acceptance of our products, services and business models. We may never generate any revenue or operate on a profitable basis. Even if we achieve profitability, we may not be able to sustain it.

Our efforts may never demonstrate the feasibility of our digital X-ray source technology, including both the MEMs X-ray chips and tubes, for commercial applications.

We have developed our X-ray source technology, including both the MEMs X-ray chips and tubes, and a working prototype of the Nanox.ARC. Even though we believe our X-ray source has achieved commercial applicability, our technology has not been tested over extended periods of time and therefore no meaningful data exists regarding the durability, safety and effectiveness of our X-ray source over extended periods. Although we have produced a working prototype of the Nanox.ARC, we may not be able to successfully integrate our X-ray source into the Nanox.ARC or any medical imaging system. In addition, there is no precedent for commercialization of technology like ours. Even with a fully functional prototype, the commercial scale production and deployment of Nanox.ARC will require significant additional development, sales and marketing efforts, and we may not be able to ensure the effectiveness, accuracy, consistency and safety of the Nanox.ARC in commercial settings. Any unanticipated technical or other problems and the possible insufficiency of funds and other resources needed to complete the development and commercialization of our X-ray source, the Nanox.ARC or the Nanox.CLOUD may result in delays and cause us to incur additional expenses that would increase our losses. If our X-ray source is not commercially feasible now or in the long term, our business may fail.

Two of our business models depend on the successful commercial application of the Nanox.CLOUD, which is subject to numerous risks and uncertainties.

In addition to the Nanox.ARC, we are also developing the Nanox.CLOUD, a companion cloud software designed to deliver MSaaS. We have developed a prototype of the Nanox.CLOUD. The development and commercialization of the Nanox.CLOUD has a number of risks, including:

- the Nanox.CLOUD requires a considerable investment of technical, financial, and legal resources, which may not be available to us;
- it may require separate regulatory clearances or approvals;
- it may not be technically viable to integrate the Nanox.CLOUD with the businesses of our potential customers and collaborators, such as local operators, radiologists, cloud storage providers, medical AI software providers and others;
- market acceptance of the MSaaS model is affected by a variety of factors, including security, reliability, scalability, customization, performance, customer preference, patients' concerns with entrusting a third party to store and manage their health data, public concerns regarding privacy and compliance with restrictive laws or regulations;
- our cloud-based service may raise concerns among our customer base, including concerns regarding changes to pricing over time, service availability, information security of a cloud-based solution and access to medical images while offline;
- the Nanox.CLOUD may be subject to computer system failures, cyber-attacks or other security breaches;
- incorrect or improper implementation or use of the Nanox.CLOUD by third-party cloud-service providers under our Sales Model could result in customer dissatisfaction and harm our business and reputation;

- undetected software errors or flaws in the Nanox.CLOUD could harm our reputation or decrease market acceptance of the MSaaS model; and
- we may incur higher costs than we expected as we expand our cloud-based services.

If we are unable to successfully develop and commercialize the Nanox.CLOUD, our business, financial condition, results of operations and prospects could be negatively impacted.

We are highly dependent on the successful development, marketing and sale of our X-ray source technology and the related products and services.

Our core digital X-ray source technology is the basis of our business. The Nanox.ARC currently under development is being designed to integrate our X-ray source technology into a medical imaging device for commercial use. As a result, the success of our business plan is highly dependent on our ability to develop, manufacture and commercialize our X-ray source technology and related products and services, such as the Nanox.ARC and the Nanox.CLOUD, and our failure to do so could cause our business to fail. Successful commercialization of medical imaging devices is a complex and uncertain process, dependent on the efforts of management, manufacturers, local operators, integrators, medical professionals, third-party payors, as well as general economic conditions, among other factors. Any factor that adversely impacts the development and commercialization of our X-ray source technology or related products and services, including the Nanox.ARC, the Nanox.CLOUD and the Nanox System, will have a negative impact on our business, financial condition, results of operations and prospects. Some potential factors include:

- our ability to achieve sufficient market acceptance by hospitals and clinics, providers of medical imaging services, medical professionals such as radiologists, third-party payors and others in the medical community;
- our ability to compete with existing medical imaging technology companies;
- our ability to establish, maintain and expand our sales, marketing and distribution networks;
- our ability to obtain and/or maintain necessary regulatory approvals; and
- our ability to effectively protect our intellectual property.

Our inability to successfully obtain clearance or approval for and subsequently commercialize our X-ray source technology or related products and services, and/or successfully develop and commercialize additional products or any enhancements to the products which we may develop would have a material adverse effect on our business, financial condition, results of operations and prospects.

Products utilizing our technology may need to be approved or cleared by the FDA and similar regulatory agencies worldwide. We may not receive, or may be delayed in receiving, the necessary approval or clearance for our future products, which would adversely affect business, financial condition, results of operations and prospects.

We are taking a multi-step approach to the regulatory clearance process. As a first step, we submitted a 510(k) premarket notification to an accredited Review Organization under the FDA's 510(k) Third Party Review Program (the "Third Party Review Program") for the Nanox Cart X-Ray System, which is a single-source version of the Nanox.ARC (the "Nanox Cart X-Ray System"), in January 2020. As part of the review process, in March 2020, we received an information request, referred to as a major deficiency letter, from the Review Organization, which among other things, required us to provide additional data and other information to complete the application and to address certain deficiencies highlighted by the reviewer, including the results of certain performance tests. On September 3, 2020, we submitted our response to the Review Organization. The response included additional data and other information to complete the application and to address certain deficiencies identified by the reviewer, including the results of certain performance tests. On September 10, 2020, the Review Organization requested that we include a second predicate device in our 510(k) premarket notification. On September 26, 2020, we submitted our revised 510(k) premarket notification to the Review Organization, which the Review Organization subsequently recommended to the FDA for clearance on December 28, 2020. On January 1, 2021, we received an informational request from the FDA through the Review Organization regarding our submission, which we responded to on January 4, 2021. On January 30, 2021, we received additional information requests from the FDA which, among other things, require us to address certain deficiencies and questions, including requests that we provide additional support regarding the intended use of the Nanox.ARC and the comparability of the Nanox.ARC to the predicate device. We submitted our response to these requests on March 1, 2021. On April 1, 2021, we received clearance from the FDA to market our Nanox Cart X-Ray System. We will continue to optimize and develop features of the Nanox.ARC, and plan to submit an additional 510(k) premarket notification to the FDA with respect to the multi-source Nanox.ARC and the Nanox.CLOUD during 2021. If cleared by the FDA, we expect to commercialize the multi-source Nanox.ARC and we may seek alternatives for commercialization of our Nanox Cart X-Ray System. The review process may be more costly and time consuming than we expect and we may not ultimately be successful in completing the review process and our 510(k) premarket notification for the multi-source Nanox.ARC may not be cleared by the FDA in a timely manner or at all. We may also need to seek approval from foreign regulatory authorities. With respect to our X-ray source technology, although we believe that it does not require FDA approval or clearance, regulatory agencies may not agree. To date, we have not had any discussion with the FDA or other regulatory authorities regarding the regulatory pathways for the novel digital X-ray source. Efforts to achieve required governmental clearances and approvals could be costly and time consuming, and we may not be able to obtain any such required clearances or approvals in accordance with our anticipated timeline or in a cost-efficient manner. Any delay or failure to obtain necessary regulatory clearances or approvals could have a material negative impact on our ability to generate revenues. Even if the products containing our technology receive the required regulatory clearance or approval, such products will remain subject to extensive regulatory requirements. If we fail to comply with the regulatory requirements of the FDA and other applicable U.S. and foreign regulatory authorities, or previously unknown problems with any approved commercial products, manufacturers or manufacturing processes are discovered, we could be subject to administrative or judicially imposed sanctions.

In addition, the cost of compliance with new laws or regulations governing our technology or future products could adversely affect our business, financial condition, results of operations and prospects. New laws or regulations may impose restrictions or obligations on us that could force us to redesign our technology or other future products or services, and may impose restrictions that are not possible or practicable to comply with, which could cause our business to fail. See "—Risks Related to Government Regulation."

We may need to obtain additional financing to fund our future operations. If we are unable to obtain such financing, we may be unable to complete the development and commercialization of our technology and our products and services.

Our operations have consumed substantial amounts of cash since inception. Our net losses were \$43.8 million, \$22.6 million and \$1.9 million for the years ended December 31, 2020, 2019 and 2018, respectively. In addition, significant resources were invested in the development of our X-ray source technology prior to us acquiring the technology. We anticipate that our future cash requirements will continue to be significant. We may need to obtain additional financing to implement our business plan as described in this annual report on Form 20-F. Specifically, although we believe our cash on hand is sufficient to complete the manufacture, shipping, installation and deployment of the initial wave of approximately 15,000 Nanox.ARC units, as well as to support the continued research and development of the Nanox.ARC and the development of the Nanox.CLOUD, we may need to raise additional funds for such purposes, including in the case of unforeseen events. Such financings could include equity financing, which may be dilutive to shareholders, or debt financing, which would likely restrict our ability to borrow from other sources. In addition, such securities may contain rights, preferences or privileges senior to those of the rights of our current shareholders. Additional funds may not be available when we need them, on terms attractive to us, or at all. If adequate funds are not available on a timely basis, we may be required to curtail the development of our technology, products or services, or materially delay, curtail, reduce or terminate our research and development and commercialization activities. We could be forced to sell or dispose of our rights or assets. Any inability to raise adequate funds on commercially reasonable terms could have a material adverse effect on our business, financial condition, results of operation and prospects, including the possibility that a lack of funds could cause our business to fail and liquidate with little or no return to investors.

The success of our primary business model, the Subscription Model, is subject to numerous risks and uncertainties.

We expect the Subscription Model to be our primary business model and the key to achieving our vision of increasing early-detection of medical conditions that are discoverable by X-ray. Even if we are able to successfully implement our Sales Model and/or our Licensing Model, the sustainability of our general business plan depends substantially on the sustainability of our Subscription Model. We believe that effectively stimulating market interest in our Nanox System will require deploying 5,000 to 10,000 Nanox.ARC units. In addition, we estimate that a minimum installed base of at least 1,000 Nanox.ARC units will be needed to support our business during the initial deployment, assuming we enter into at least one licensing agreement on commercially reasonable terms. The success of our Subscription Model will also depend on each device, once deployed, performing a sufficient number of scans per day to be fully utilized. We may not be successful in achieving these goals for various reasons, including:

- the process of manufacturing and deploying the Nanox System is a complex, multi-step process that depends on factors outside our control, and could cause us to expend significant time and resources prior to earning associated revenues;
- the manufacturing cost of the Nanox.ARC may be higher than we expect, may increase significantly, or may increase at a higher rate than anticipated, and we may not be able to set or timely adjust our pay-per-scan pricing to compensate for any increased costs;
- the manufacturing of the Nanox.ARC may take longer than we expected, and we may have insufficient manufacturing capacity and experience delays in the manufacturing and deployment of the Nanox System, which would have a negative impact on the timing of our revenues;
- deployment and full utilization of the Nanox System may not be achieved or may take substantially longer than we expect, and we may not be able to deploy a sufficient number of units of the Nanox System to support our business or to effectively stimulate market interest;
- a Nanox System may perform fewer scans per day than our estimates due to a number of factors, including low market acceptance rate, technical failures and downtime, service disruptions, outages or other performance problems, which would have a negative impact on our revenues and our ability to recover costs;
- the implementation, integration and testing of the Nanox.CLOUD with our potential customers and collaborators can be complex, time-consuming and expensive for them, which may have a negative impact on the timing of our revenues;
- the inability or unwillingness of potential customers to invest in the required safety infrastructure, including customary X-ray shielding, to allow the Nanox.ARC to be safely operated;
- as part of the Subscription Model, we will be responsible for maintenance of the Nanox System units we deploy, which may be more costly and time-consuming than we expect;
- our customers may not be able to find or retain a sufficient number of radiologists to review the images generated by the Nanox System, especially as we deploy additional Nanox Systems and the volume of scans increases;
- the portion of our pay-per-scan pricing allocated to our collaborators may not be acceptable to them, either now or in the future, and pricing negotiations with such collaborators may be a complex and time-consuming process;
- the availability of insurance coverage and the level of reimbursement for the Nanox.ARC provided by third-party payors may not be sufficient for our customers;
- our pay-per-scan pricing may not be sufficient to recover our costs and may not be adjusted in a timely manner, which could negatively affect our revenues or cause our revenues and results of operations to vary significantly from period to period;
- we may be unsuccessful in maintaining our target price per scan because we do not control the price charged by local operators and higher prices may adversely affect market acceptance of the Nanox System; and
- regulatory authorities may challenge our Subscription Model altogether, and impose significant civil, criminal, and administrative penalties, damages, fines, and/or exclusion from government funded healthcare programs, which could adversely affect our revenues and results of operations.

Any of the above factors may negatively affect the implementation of our Subscription Model, or cause our Subscription Model to fail.

We may not be successful in tailoring our X-ray source to the specific systems of other medical imaging companies under our Licensing Model, and/or entering into licensing agreements on terms favorable to us.

Under our proposed Licensing Model, we expect to be engaged to tailor our X-ray source to other medical imaging companies' specific systems to replace the legacy X-ray source or to license our X-ray source technology to them to develop new types of imaging systems, and we expect to receive a one-time, non-recurring licensing fee upfront, as well as recurring royalty payments for each imaging system sold by such companies. We expect customization to be a complex and multi-step process that varies for each project, which will require significant research and testing activities. We may also not be able to demonstrate the feasibility, functionality or safety of our technology in other medical imaging systems, meet the potential licensees' design and manufacturing requirements, or satisfy their marketing and product needs. In addition, we may not be successful in entering into licensing agreements with favorable terms as a result of a numbers of factors, many of which are outside of our control, including willingness of, and the resources available to, other medical imaging companies to in-license our novel X-ray source technology, our ability to agree with a potential partner on the value of our technology, or on the related terms, as well as the availability of other technologies at lower cost or other alternative technologies at the time. We have not entered into any licensing agreements; however, we expect to enter into negotiations regarding a commercial arrangement with FUJIFILM Corporation for the licensing of our Nanox System. Any of the above factors may negatively affect the implementation of our Licensing Model, or cause our Licensing Model to fail.

To the extent that we license our X-ray source technology to other medical imaging companies, the products integrating our technology may need to be approved or cleared by the FDA or similar regulatory agencies.

The FDA may require products developed by other medical imaging companies under the Licensing Model to go through lengthier or more rigorous processes than we expected. These products may also be subject to regulations by governmental agencies in other jurisdictions, or regulation by other federal, state and local agencies. In addition, we may not have control with respect to any such further regulatory approval strategies or process. If such products do not receive, or are delayed in receiving, the necessary clearances or approvals, or if the performance of one or more clinical trials are required in connection with such clearances or approvals, the prospects of our Licensing Model may be materially affected, which could have a material adverse impact on our business and our revenues.

A pandemic, epidemic or outbreak of an infectious disease, such as COVID-19, may materially and adversely affect our business and our financial results and could cause a disruption to the development or deployment of the Nanox System.

Public health crises such as pandemics or similar outbreaks could adversely impact our business. Beginning in 2019, a novel strain of a virus named SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2), or coronavirus, which causes COVID-19, has spread to most countries across the world, including Israel, Japan and all 50 states within the U.S. The COVID-19 pandemic is evolving, and to date has led to the implementation of various responses, including government-imposed quarantines, travel restrictions and other public health safety measures. The COVID-19 pandemic has adversely impacted our operations in various ways. For example, our engineers have limited ability to make work-related trips to Korea or Israel to test and optimize the Nanox.ARC or to begin development of MEMs X-ray chip manufacturing in Korea. Our potential business partners have limited ability to make on-site visits to our facilities or attend industry conferences and meetings in person to experience the Nanox.ARC, which has negatively impacted our business development and deployment activities. Due, in part, to travel restrictions as a result of the COVID-19 pandemic, we expect to manufacture a small number of Nanox.ARC units in Israel on a purchase order basis that will be used for the acceptance tests under our MSaaS agreements, demonstrations, regulatory approvals and for the initial global deployment, among other purposes. The external labs we work with have been affected by COVID-19, resulting in delays in our timeline for obtaining regulatory clearance and approval. Our FDA and other regulatory approvals and clearances may be delayed due to prioritization of vaccines for COVID-19. COVID-19 has also caused shutdowns or disruptions of business for our manufactures and suppliers.

The extent to which the COVID-19 pandemic impacts our operations or those of our third-party partners will depend on future developments, which are highly uncertain and cannot be predicted with confidence, including the duration of the pandemic, new information that will emerge concerning the severity of the coronavirus and the actions to contain the coronavirus or treat its impact, among others. In addition, if any treatment or vaccine for COVID-19 is ineffective or underutilized, any impact on our business may be prolonged. The continued spread of COVID-19 globally could adversely impact our development, manufacture or deployment of the Nanox System, which could adversely affect our ability to obtain regulatory clearance and approval for and to commercialize the Nanox System, increase our operating expenses and have a material adverse effect on our financial results.

These and other factors arising from the COVID-19 pandemic could worsen in countries that are afflicted with the coronavirus. Any of these factors, and other factors related to any such disruptions that are unforeseen, could have a material adverse effect on our business and our results of operations and financial condition. Further, uncertainty around these and related issues could lead to adverse effects on the economy of the United States and other economies, which could impact our ability to raise the necessary capital needed to develop and commercialize the Nanox System.

Our industry is highly competitive and is subject to technological change, which may result in new products or solutions that are superior to our technology or other future products we may bring to market from time to time. If we are unable to anticipate or keep pace with changes in the marketplace and the direction of technological innovation and customer demands, our technology may become less useful or obsolete and our operating results will suffer.

The medical imaging industry is rapidly evolving and subject to intense and increasing competition. To compete successfully and to be able to establish and maintain a competitive position in current and future technologies, we will need to demonstrate the advantages of our technology over well-established alternative solutions, products and technologies, such as computed tomography (“CT”), as well as newer methods of medical imaging and early detection. We believe that effectively stimulating market interest for the Nanox System will require deploying 5,000 to 10,000 Nanox.ARC units. To achieve this, we will need to raise or develop financial resources, technical expertise, marketing, distribution or support capabilities and we may not be successful in doing so.

Also, companies offering traditional medical imaging systems, such as General Electric, Siemens, Philips, Hologic, Varian, Fuji, Toshiba and Hitachi, may be better established in the market than we are, have greater corporate, financial, operational, sales and marketing resources than we do, or have more experience in research and development than we have. In particular, the field emission technology has been used by a wide range of leading market players in an attempt to create an alternative digital source of X-ray, the most well-known attempt being the use of carbon nano tubes as the base materials for a potential field emission-based solution. In addition, early-detection technologies developed by other companies, such as blood testing and DNA screening, may also reduce the attractiveness of our technology for early detection or render it obsolete. Successful developments of these or other technologies by competitors resulting in new approaches for medical imaging, including technologies, products or services that are more effective or commercially attractive, could make our technology less useful or obsolete. We may also face opposition from certain industry leaders, who may have political influence and the ability to delay deployment of the Nanox System in certain geographical areas.

Furthermore, as the market expands, we expect the entry of additional competitors, such as cloud computing companies or leading IT companies, who may have longer operating histories, more extensive international operations, greater name recognition, and/or substantially greater technical, marketing and financial resources.

Our competitive position also depends on our ability to:

- generate widespread awareness, acceptance and adoption of our technology and future products or services;
- develop new or enhanced technologies or features that improve the convenience, efficiency, safety or perceived safety, and productivity of our technology and future products or services;
- properly identify customer needs and deliver new products or services or product enhancements to address those needs;
- limit the time required from prototype development to commercial production;
- limit the timing and cost of regulatory approvals;
- attract and retain qualified personnel and collaborators;
- protect our inventions with patents or otherwise develop proprietary products and processes; and
- secure sufficient capital resources to expand both our continued research and development, and sales and marketing efforts.

If our technology is not, or our future products or services are not, competitive based on these or other factors, our business would be harmed.

We expect to depend on third parties to manufacture the Nanox.ARC and to supply certain component parts. Our reliance on third-party manufacturers and suppliers involve certain risks that may result in, among others, increased costs, quality or compliance issues, or failure to timely manufacture the Nanox.ARC, any of which could materially harm our business.

If cleared, we expect to rely on third-party manufacturers and suppliers for the commercial production of the multi-source Nanox.ARC. We have entered into direct arrangements on a purchase order basis with a manufacturer for the production of our X-ray tubes. We are evaluating, subject to completion of testing, a transition from glass-based X-ray tubes to ceramics-based tubes for cost efficiency purposes, which are the tubes to be used in the multi-source version of the Nanox.ARC, and we intend to enter into an agreement for such ceramics-based tubes with a new manufacturer in the future. In addition, we have entered into a contract manufacturing agreement with FITI to manufacture the multi-source Nanox.ARC, with a goal to enable the commercial production of the initial approximately 15,000 units planned for global deployment by the end of 2024. Under the contract manufacturing agreement with FITI, FITI will negotiate and contract with other parties for the supply of the various other components of the Nanox.ARC in accordance with the pre-approved supplier list and on the terms to be agreed upon by both parties. Our dependence on such third-party manufacturers and suppliers involves a number of risks, including:

- insufficient capacity or delays in meeting our demand;
- inadequate manufacturing yields, inferior quality and excessive costs;
- inability to manufacture products that meet the agreed upon specifications;
- inability to obtain an adequate supply of materials;
- inability to comply with the relevant regulatory requirements for the manufacturing process;
- limited warranties on products supplied to us;

- inability or failure to comply with our contractual obligations;
- potential increases in prices; and
- increased exposure to potential misappropriation of our intellectual property.

Due, in part, to travel restrictions as a result of the COVID-19 pandemic, we expect to manufacture a small number of Nanox.ARC units in Israel on a purchase order basis that will be used for the acceptance tests under our MSaaS agreements, demonstrations, regulatory approvals and for the initial global deployment, among other purposes. Although we expect to formalize our arrangement in writing, we have not yet done so, and we may not establish a formal agreement or be able to enforce the obligations under such arrangements. Furthermore, we currently expect to engage only one general manufacturer for the mass production of the Nanox.ARC. As we further expand our business in connection with the commercialization of our technology, we expect to seek to engage alternative manufacturers of the Nanox.ARC. If any of our manufacturers or suppliers breach their agreements, are unable to meet their contractual or quality requirements, or become unwilling to perform for any reason, we may be unable, or may be unable in a timely manner, to locate alternative acceptable manufacturers or suppliers and enter into favorable agreements with them.

As mentioned above, we currently manufacture the MEMs X-ray chips in the clean rooms located in Tokyo, Japan. While we intend to expand our manufacturing capacity, including through the establishment of the Korean Subsidiary, to meet our currently anticipated needs, we may not have sufficient capacity to manufacture the MEMs X-ray chips as our business expands. In addition, we rely on third parties to supply the raw materials and certain component parts. Disruptions of our relationships with such suppliers could negatively impact our production for an extended period of time. Any inability to acquire sufficient quantities of any raw materials or components in a timely manner from these third-party suppliers could have a material negative impact on our business.

In addition, if we change the manufacturer of a critical component of our products, such as our proposed transition from using glass-based tubes to ceramics-based tubes, we will be required to verify that the new manufacturer maintains facilities, procedures and operations that comply with our quality and applicable regulatory requirements, which could further impede our ability to manufacture our products in a timely manner.

Transitioning to a new supplier could be time-consuming and expensive, may result in interruptions in our operations and product delivery, could affect the performance specifications of our products or could require that we modify the design of those systems. If the change in manufacturer results in a significant change to any product, a new 510(k) clearance or approval from the FDA or similar international regulatory authorization may be necessary before we implement the change, which could cause substantial delays. The occurrence of any of these events could harm our ability to meet the demand for our products in a timely or cost-effective manner. See “—Risks Related to Government Regulation.”

We may experience development or manufacturing problems and higher costs, or delays that could limit our revenue, if any, or increase our losses.

Developing manufacturing procedures for new products requires developing specific production processes for those products. Developing such processes could be time consuming, and any unexpected difficulty in doing so can delay the introduction of the Nanox.ARC. Moreover, difficulties associated with adapting our technology and product design to the proprietary process technology and design rules of outside manufacturers can lead to reduced yields. Since low yields may result from either design or process technology failures, yield problems may not be effectively determined or resolved until an actual product exists that can be analyzed and tested to identify process sensitivities relating to the design rules that are used. As a result, yield problems may not be identified until well into the production process, and resolution of yield problems may require cooperation between our manufacturers and us. This risk could be compounded by the offshore location of our manufacturers, increasing the effort and time required to identify, communicate and resolve manufacturing yield problems. Manufacturing defects that we do not discover during the manufacturing or testing process may lead to costly product recalls. These risks may lead to increased costs or delayed product delivery, which would harm our profitability and customer relationships. Furthermore, our, our manufacturers’ or our suppliers’ production processes and assembly methods may have to change to accommodate any significant, future expansion of our manufacturing capacity, which may increase the manufacturing costs, delay production of our products, reduce our product margin, require supplemental filings with the FDA or other regulatory authorities, any of which may adversely impact our business. If we are unable to keep up with demand for our products by successfully manufacturing and shipping our products in a timely manner, our revenue could be impaired, and market acceptance for our products could be adversely affected.

We may not be able to successfully execute our business models.

We are pursuing three simultaneous business models to maximize the commercial potential of our X-ray source technology, each of which requires significant time and resources, in particular, our primary business model, the Subscription Model. We are a company with limited operating history and we may not have the necessary resources, expertise and experience to successfully execute any of our business models on a global scale, such as obtaining the necessary approvals or clearances from the regulatory agencies of our target markets. Our ability to execute our models is dependent on a number of factors, including the ability of our senior management team to execute our models, our ability to engage local operators and integrators in different geographic regions, our ability to begin or maintain our pace of product development, manufacturing and commercialization, our ability to meet the changing needs of the medical imaging market, and the ability of our employees to perform at a high-level. If we are unable to execute our models, if our models do not drive the growth that we anticipate, or if our market opportunity is not as large as we have estimated, it could adversely affect our business and our prospects.

We have a limited operating history. If we successfully commercially launch the Nanox.ARC or the Nanox.CLOUD, and they do not achieve widespread market acceptance, we will not be able to generate the revenue necessary to support our business.

We have a limited operating history and have no history of marketing our X-ray source technology, the Nanox.ARC, the Nanox.CLOUD or any other product using our technology. We may fail to generate significant interest in our X-ray source technology, the Nanox.ARC, the Nanox.CLOUD or the imaging products using our technology, or any other product we may develop. These and other factors, including the following, may affect the rate and level of market acceptance:

- effectiveness of the sales and marketing efforts of us, and our partners such as the local partners;
- perception by medical professionals and patients of the convenience, safety, efficiency and benefits of the Nanox.ARC, the Nanox.CLOUD or products using our technology, compared to competing methods of medical imaging, such as the time and skill required to read the tomographic images produced by the Nanox.ARC and our X-ray source;
- opposition from certain industry leaders, which may limit our ability to promote the Nanox.ARC or the Nanox.CLOUD and to penetrate into the medical imaging market in certain geographical areas;
- the existence of established medical imaging technology;
- willingness of market participants to accept the MSaaS model;
- the changing and volatile U.S. and global economic environments, including as a result of the COVID-19 pandemic;
- timing of market introduction of competing products, and the sales and marketing initiatives of such products;
- press and blog coverage, social media coverage, and other publicity and public relations factors by others;
- lack of financing or other resources to successfully develop and commercialize our technology and implement our business plan;
- the level of commitment and support that we receive from our partners, such as local operators, cloud storage providers and medical AI software providers, as well as medical professionals such as radiologists; and
- coverage determinations and reimbursement levels of third party payors.

If cleared or approved for marketing by the FDA or other regulatory agencies, depending on the approved clinical indication, the multi-source Nanox.ARC will be competing with existing and future imaging products and similar offerings. The technology underlying our X-ray source and the Nanox.ARC may be perceived as inferior or inaccurate and patients may be unwilling to undergo medical screening using the Nanox.ARC or other products using our technology. Moreover, patients and medical professionals may be unwilling to depart from the current medical imaging technology. Medical professionals tend to be slow to change their medical diagnostic practices because of perceived liability risks arising from the use of new technology or products, and they may not recommend medical imaging using the Nanox.ARC or other products using our technology until there is long-term clinical evidence to convince them to alter or modify their existing imaging methods. Our efforts to educate patients, radiologists and other members of the medical community on the benefits of our products require significant resources and may not be successful. Our efforts to educate the marketplace may require more resources than are required by conventional technologies marketed by our competitors. In particular, gaining market acceptance for our products in nascent markets, such as China, India, and certain countries in Latin America, could be challenging. Moreover, in the event that the Nanox.ARC or other products using our technology are the subject of guidelines, clinical studies or scientific publications that are unfavorable or damaging, or otherwise call into question their benefits, we may have difficulty in convincing market participants to adopt our products. In addition, medical professionals, patients, providers of medical imaging services and third-party payors may not adopt or reimburse the use of the Nanox.ARC in the near term or at all. If we are unable to achieve or maintain an adequate level of market acceptance, we may not generate significant revenue or become profitable and our business, financial condition, results of operations and prospects would be significantly harmed.

We plan to do business globally, including in certain countries where we might have limited resources and would be subject to additional regulatory burdens and other risks and uncertainties.

We expect to do business globally, including in North America and certain countries in Asia, Europe, Africa, Latin America and Australia. Commercialization of our X-ray source technology, the Nanox.ARC or the Nanox System in foreign markets, either directly or through third parties, is subject to additional risks and uncertainties, including:

- reimbursement and insurance coverage;
- our inability to find agencies, dealers or distributors in specific countries or regions;
- our inability to directly control commercial activities of third parties;
- limited resources to be deployed to a specific jurisdiction;
- the burden of complying with complex and changing regulatory, tax, accounting and legal requirements;
- different medical imaging practice and customs in foreign countries affecting acceptance in the marketplace;
- import or export licensing and other requirements;
- longer accounts receivable collection times;
- longer lead times for shipping;
- language barriers for technical training;
- reduced protection of intellectual property rights in some foreign countries;
- foreign currency exchange rate fluctuations; and
- interpretations of contractual provisions governed by foreign laws in the event of a contract dispute.

Specifically, we are subject to the U.S. Foreign Corrupt Practices Act of 1977, as amended, the U.S. domestic bribery statute contained in 18 U.S.C. § 201, the U.S. Travel Act, the USA PATRIOT Act, the United Kingdom Bribery Act 2010, the Proceeds of Crime Act 2002, Chapter 9 (sub-chapter 5) of the Israeli Penal Law, 1977, the Israeli Prohibition on Money Laundering Law–2000 and possibly other anti-bribery and anti-money laundering laws in countries outside of the United States in which we conduct our activities. As we engage finders to obtain MSaaS agreements in certain countries, we and our finders may have direct or indirect interactions with officials and employees of government agencies or state-owned or affiliated entities. We may be held liable for the corrupt or other illegal activities of these third-party business partners and intermediaries, our employees, representatives, contractors, partners and agents, even if we do not explicitly authorize such activities. As we expand our international business, our risks under these laws may increase.

We also may sell the Nanox.ARC, the Nanox.CLOUD or the Nanox System to government entities, which are subject to a number of challenges and risks. Any actual or perceived privacy, data protection, or data security incident, or even any perceived defect with regard to our practices or measures in these areas, may negatively impact public sector demand for our products. Government entities may also have statutory, contractual or other legal rights to terminate contracts with us for convenience or due to a default, and any such termination may adversely affect our future results of operations. Governments routinely investigate and audit government contractors' administrative processes, and any unfavorable audit could result in the government refusing to continue buying our subscriptions, a reduction of revenue, or fines or civil or criminal liability if the audit uncovers improper or illegal activities. In addition, sales of the Nanox.ARC, the Nanox.CLOUD or the Nanox System in foreign markets could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs, any of which may adversely affect our business, financial condition, results of operations and prospects.

Because the Nanox System is still in the development stage, it is not yet approved for third-party payor coverage or reimbursement. If in the future we are approved for and are otherwise able to commercialize it, but are unable to obtain adequate reimbursement or insurance coverage from third-party payors, we may not be able to generate significant revenue, in which case we may need to obtain additional financing.

Because the Nanox System is still in the development stage, it is not yet approved for third-party payor coverage or reimbursement. Coding and coverage determinations as well as reimbursement levels and conditions are important to the commercial success of an imaging product or offering. The future availability of insurance coverage and reimbursement for newly approved medical devices is highly uncertain, and our future business will be greatly impacted by the level of reimbursement provided by third-party payors. In the United States, third-party payors decide which imaging products and services they will cover, how much they will pay and whether they will continue reimbursement. Third-party payors may not cover or provide adequate reimbursement for the Nanox System or the imaging services using the Nanox System, assuming we are able to fully develop and obtain all regulatory approvals and clearances to market it in the United States or other geographies. To date, we have not had any discussions with any third-party payors, including any regulatory agencies administering any government funded healthcare programs, regarding the coding, coverage or reimbursement for imaging services using the Nanox System. Accordingly, unless government and other third-party payors provide coverage and reimbursement for our services, patients and healthcare providers may choose not to use them, which would cause investors to lose their entire investment. A primary trend in the United States healthcare industry and elsewhere is cost containment. Government authorities and other third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular products and services. Reimbursement may not be available, or continue to be available, for the Nanox System or the imaging services using the Nanox System, other products or systems using our X-ray source technology or any other products we may develop in the future, or even if reimbursement is available, such reimbursement may not be adequate. We also will be subject to foreign reimbursement policies in the international markets we expect to enter. Decisions by health insurers or other third-party payors in these markets not to cover, or to discontinue reimbursing, our products could materially and adversely affect our business. If such decisions are made, they could also have a negative impact on our ability to generate revenues, in which case we may need to obtain additional financing.

Recent changes in the United States related to payment policies for imaging procedures could have a negative impact on the utilization of our imaging services.

In the United States, over the past several years, the Centers for Medicare & Medicaid Services (“CMS”), the federal agency responsible for administering the Medicare program, has implemented numerous changes to payment policies for imaging procedures in both the hospital setting and non-hospital settings, which include physician offices and freestanding imaging facilities. Some of these changes have had a negative impact on utilization of imaging services. Examples of these changes include:

- limiting payments for imaging services in physician offices and free-standing imaging facility settings based upon rates paid to hospital outpatient departments;
- reducing payments for certain imaging procedures when performed together with other imaging procedures in the same family of procedures on the same patient on the same day in the physician office and free-standing imaging facility setting;
- making significant revisions to the methodology for determining the practice expense component of the Medicare payment applicable to the physician office and free-standing imaging facility setting which results in a reduction in payment; and
- revising payment policies and reducing payment amounts for imaging procedures performed in the hospital outpatient setting.

We also expect increased regulation and oversight of advanced diagnostic testing. One provision in the Protecting Access to Medicare Act requires CMS to develop appropriate use criteria (“AUC”) that professionals must consult when ordering advanced diagnostic imaging services (which include magnetic resonance imaging (“MRI”), CT, nuclear medicine (including positron emission tomography) and other advanced diagnostic imaging services that the Secretary of the Department of Health and Human Services (“HHS”) may specify). Under this provision, which is currently set to be fully implemented on January 1, 2022, payment is to be made to the furnishing professional for an applicable advanced diagnostic imaging service only if the claim indicates that the ordering professional consulted a qualified clinical decision support mechanism, as identified by HHS, as to whether the ordered service adheres to the applicable AUC. To the extent that these types of changes have the effect of reducing the aggregate number of diagnostic medical imaging procedures performed in the United States, our business, results of operations, financial condition and cash flows would be adversely affected.

Billing complexities associated with obtaining payment or reimbursement may negatively affect our revenue, cash flow and profitability.

Billing for imaging services is complex. Payment is provided by individual patients and from a variety of payors, such as commercial insurance carriers, managed care organizations and governmental programs. Each payor typically has different billing requirements, and the billing requirements of many payors have become increasingly stringent.

Among the factors complicating our customers’ ability to bill and receive reimbursement from third-party payors are:

- disputes among payors as to which party is responsible for payment;
- disparity in coverage among various payors;
- disparity in information and billing requirements among payors; and
- incorrect or missing billing information, which is required to be provided by the ordering physician.

In addition, we may be required to seek new billing codes for imaging services using the Nanox System, and regulatory authorities may not approve the creation of separate codes. Additionally, even if we are successful, these billing codes or the payment amounts associated with such codes may change in the future.

The impact of these factors may be compounded by our use of the novel Subscription Model. These billing complexities, and the related uncertainty in obtaining payment for our products, could negatively affect our revenue, cash flow and profitability.

Any collaborative and MSaaS arrangements that we have established or may establish in the future may not be successful or we may otherwise not realize the anticipated benefits from these collaborations. We do not control third parties with whom we have or may have collaborative or MSaaS arrangements, and we will rely on them to achieve results which may be significant to us. In addition, any current or future collaborative and MSaaS arrangements may place the development and commercialization of our technology outside our control, may require us to relinquish important rights or may otherwise be on terms unfavorable to us.

We have entered into certain, and expect to enter into additional, collaborative arrangements and MSaaS agreements with respect to the research, development, manufacture and commercialization of our technology with different relevant industry participants, including, among others, local operators, integrators, radiologists, cloud storage providers and medical AI software providers and third-party payors. See “Item 4. Information on the Company—B. Business Overview—Commercial Agreements.” Any future potential collaborative or MSaaS arrangements may require us to rely on external consultants, advisors and experts for assistance in several key functions, including research and development, manufacturing, regulatory, intellectual property, commercialization and distribution. We cannot and will not control these third parties, but we may rely on them to achieve results, which may be significant to us. Relying upon these collaborative arrangements subjects us to a number of risks, including:

- we may not be able to control the amount and timing of resources that our collaborators may devote to our technology;
- should a collaborator fail to comply with applicable laws, rules or regulations when performing services for us, we could be held liable for such violations;
- our collaborators may have a shortage of qualified personnel, particularly radiologists who can review the medical images generated by the Nanox System, especially as we deploy additional Nanox Systems and the volume of scans increases;
- we may be required to relinquish important rights, such as marketing and distribution rights;
- business combinations or significant changes in a collaborator’s business strategy may adversely affect a collaborator’s willingness or ability to complete its obligations under any arrangement;
- our collaborators may default on their payments to us or fail to deliver standby letters of credit or financial guarantees, and it may be time consuming and difficult to enforce such payment obligations and obligations to provide standby letters of credit and financial guarantees in various jurisdictions, and we may be unsuccessful in enforcing such obligations;
- our collaborative arrangements are subject to conditionality, including receipt of regulatory clearance and material compliance with acceptance test protocol, among other things, for the Nanox.ARC;
- under certain circumstances, a collaborator could move forward with a competing product developed either independently or in collaboration with others, including our competitors;
- our current or future collaborators may utilize our proprietary information in a way that could expose us to competitive harm;
- our collaborators could obtain ownership or other control over intellectual property that is material to our business; and
- collaborative arrangements are often terminated or allowed to expire or remain unformalized by a written agreement, which could delay the ability to commercialize our technology.

In addition, if disputes arise between us and any of our collaborators, it could result in the delay or termination of the development, manufacturing or commercialization of products containing our technology, lead to protracted and costly legal proceedings, or cause collaborators to act in their own interest, which may not be in our interest. As a result, the collaborative arrangements that we may enter into, may not achieve their intended goals.

If any of these scenarios materialize, they could have a material adverse effect on our business, financial condition, results of operations and prospects.

We also may have other future products where it is desirable or essential to enter into agreements with a collaborator who has greater financial resources or different expertise than us, but for which we are unable to find an appropriate collaborator or are unable to do so on favorable terms. If we fail to enter into such collaborative agreements on favorable terms, it could materially delay or impair our ability to develop and commercialize, and increase the costs of development and commercialization of, our technology.

We could become subject to product liability claims, product recalls, and warranty claims that could be expensive, divert management's attention and harm our business reputation and financial results.

Our business exposes us to potential liability risks that are inherent in the marketing and sale of products used in patient care. We may be held liable if the Nanox System or if any other product that integrates our X-ray source technology causes injury or death or is found otherwise unsuitable during usage. The Nanox System currently under development incorporates sophisticated components and computer software. Complex software can contain errors, particularly when first introduced. In addition, new products or enhancements may contain undetected errors or performance problems that, despite testing, are discovered only after installation. Patients could allege or possibly prove defects of our products or other products that integrate our technology.

A product liability claim, regardless of its merit or eventual outcome, could result in significant legal defense costs and divert management's attention. Regardless of merit or eventual outcome, liability claims may result in:

- decreased demand for the Nanox System;
- injury to our reputation;
- costs of related litigation;
- substantial monetary awards to patients and others;
- loss of revenue; and
- the inability to commercialize future products.

Any of these outcomes may have an adverse effect on our business, financial condition and results of operations, and may increase the volatility of our share price.

The coverage limits of our insurance policies we may choose to purchase to cover related risks may not be sufficient to cover future claims. If sales of the Nanox System or other products integrating our technology increase or we suffer future product liability claims, we may be unable to maintain product liability insurance at satisfactory rates or with adequate amounts or at all. A product liability claim, any product recalls or excessive warranty claims, whether arising from defects in design or manufacture or otherwise, could negatively affect our sales or require a change in the design or manufacturing process, any of which could harm our relationship with our customers and partners, and have a material adverse impact on our reputation and business, financial condition, results of operations and prospects.

In addition, if the Nanox System or other products integrating our technology are defective, we, our future customers or partners may be required to notify regulatory authorities and/or to recall the products. See “—Risks Related to Government Regulation—Our products may cause or contribute to adverse medical events or be subject to failures or malfunctions that we are required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us.” Any recall would divert management’s attention and financial resources and harm our reputation with customers, patients, medical professionals and third-party payors. A recall involving the Nanox System would be particularly harmful to our business. The adverse publicity resulting from any of these actions could adversely affect the perception of our customers or partners. These investigations or recalls, especially if accompanied by unfavorable publicity, could result in our incurring substantial costs, losing revenues and damaging our reputation, each of which would harm our business, financial condition, results of operations and prospects.

We are highly dependent on key members of our executive management team. Our inability to retain these individuals could impede our business plan and growth strategies, which could have a negative impact on our business and the value of your investment.

Our ability to implement our business plan depends on the continued services of key members of our senior management. In particular, and to a critical extent, we are dependent on the continued efforts and services of the members of management named under “Item 6. Directors, Senior Management and Employees.” If we lose the services of such key members of our management team, we would likely be forced to expend significant time and money in the pursuit of replacement individuals, which may result in a delay in the implementation of our business plan and plan of operations. We may not be able to find satisfactory replacements on terms that would not be unduly expensive or burdensome to us. We do not currently carry a key-man life insurance policy that would assist us in recouping our costs in the event of the death or disability of a member of our management team. The loss of members of our management team, or our inability to attract or retain other qualified individuals, could have a material adverse effect on our business, results of operations and financial condition.

The mishandling or the perceived mishandling of sensitive information, or the occurrence of data security breaches, could harm our business.

We expect that the Nanox System will enable us to accumulate a significant amount of highly sensitive and/or confidential information, including medical images and other medical information. These images could be received by our customers or collaborators, such as medical AI-analytics companies, to increase the probability of early disease detection. While employee contracts generally contain standard confidentiality provisions, our employees, customers or collaborators may not properly handle or process sensitive or confidential data. The improper handling of sensitive or confidential data, or even the perception of such mishandling (whether or not valid), or other security lapses by us, our customers or collaborators, could reduce demand for such products or otherwise expose us to financial or reputational harm or legal liability.

In addition, any security breach, including personal data breaches, or incident, including cybersecurity incidents, that we experience could result in unauthorized access to, misuse of, or unauthorized acquisition of the sensitive or confidential information and data (including medical information), the loss, corruption, or alteration of this data, interruptions in our operations, or damage to our systems. Any such incidents could expose us to claims, litigation, regulatory or other governmental investigations, administrative fines and potential liability. An increasing number of digital platforms have disclosed breaches of their security, some of which have involved sophisticated and highly targeted attacks on portions of their services. Because the techniques used to obtain unauthorized access, disable or degrade service, or sabotage systems change frequently and often are not foreseeable or recognized until launched against a target, we may be unable to anticipate these techniques or to implement adequate preventative measures. If an actual or perceived breach of our security occurs, public perception of the effectiveness of our security measures and brand could be harmed and our results of operations could be negatively affected. Data security breaches and other incidents may also result from non-technical means (e.g., actions by employees or contractors). Any compromise of our security could result in a violation of applicable security, privacy or data protection, consumer and other laws, regulatory or other governmental investigations, enforcement actions, and legal and financial exposure, including potential contractual liability. Any such compromise could also result in damage to our reputation and a loss of confidence in our security and privacy or data protection measures. Any of these effects could materially and adversely affect our business, financial condition and results of operations.

Our business and operations would suffer in the event of computer system failures, cyber-attacks or deficiencies in our cyber-security.

Our ability to execute our business strategy depends, in part, on the continued and uninterrupted performance of our IT systems, which support our operations. Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from, among others, computer viruses, malware, natural disasters, terrorism, war, telecommunication and electrical failures, cyber-attacks or cyber-intrusions over the internet, attachments to emails, persons inside our organization, or persons with access to systems inside our organization or similar disruptive problems. The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. If such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our product development programs. Any such security breach may compromise information stored on our networks and may result in significant data losses or theft of personally identifiable information. A cybersecurity breach could also hurt our reputation by adversely affecting the patients' perception of the security of their information. A number of proposed and enacted federal, state and international laws and regulations obligate companies to notify individuals of security breaches involving particular personally identifiable information, which could result from breaches experienced by us or by third parties, including collaborators, vendors, contractors or other organizations with which we expect to form strategic relationships. In addition, a cybersecurity attack could result in other negative consequences, including disruption of our internal operations, increased cyber security protection costs, lost revenue, regulatory actions or litigations.

Exchange rate fluctuations between the U.S. dollar, Japanese Yen, the New Israeli Shekel and the South Korean Won and inflation may negatively affect our results of operations, and we may not be able to hedge our currency exchange risks successfully.

The U.S. dollar is our functional and reporting currency. However, a portion of our operating expenses, including personnel and facilities related expenses, are incurred in NIS, Yen and KRW. As a result, we are exposed to the risks that the NIS, Yen and KRW may appreciate relative to the U.S. dollar, or, if the NIS, Yen and KRW instead devalues relative to the U.S. dollar, that the inflation rate in Israel may exceed such rate of devaluation of the NIS, Yen or KRW, or that the timing of such devaluation may lag behind inflation in Israel. In any such event, the dollar cost of our operations in Israel would increase and our dollar-denominated results of operations would be adversely affected. Given our general lack of currency hedging arrangements to protect us from fluctuations in the exchange rates of the NIS, Yen and KRW and other foreign currencies in relation to the U.S. dollar (and/or from inflation of such foreign currencies), we may be exposed to material adverse effects from such movements. Our exchange rate exposure may change over time as our business evolves and could result in increased costs or reduced revenue and could affect our actual cash flow. Changes in the relative values of currencies occur regularly and, in some instances, may have a significant impact on our operating results. The rate of inflation in Israel or in currency exchange rates may materially change and we might not be able to effectively mitigate these risks.

If significant tariffs or other restrictions related to "trade wars" are placed on Chinese imports or any related counter-measures are taken by China, our revenue and results of operations may be materially harmed.

We have, and expect to enter into, agreements with manufacturers and/or suppliers in China for the production of our X-ray tube, the Nanox.ARC and some of their respective components. If significant tariffs or other restrictions are placed by the United States government on Chinese imports or any related counter-measures are taken by China, our business, financial condition and results of operations may be materially harmed. In July 2018, the Trump Administration announced a list of thousands of categories of goods that could face tariffs. If these duties or any other forms of duties or tariffs are imposed on the Nanox.ARC, our X-ray tube or their components, we may be required to charge higher prices in the United States than we expect, which may result in fewer customers and harm our operating performance. Alternatively, we may seek to shift production outside of China, resulting in significant costs and disruption to our operations and business. Our business could also be impacted by retaliatory trade measures taken by China or other countries in response to existing or future tariffs, causing us to raise prices or make changes to our operations, any of which could materially harm our business, financial condition and results of operations.

Our business may be impacted by changes in general economic conditions.

Our business is subject to risks arising from changes in domestic and global economic conditions, including adverse economic conditions in markets in which we operate, which may harm our business. For example, the current COVID-19 pandemic has caused significant volatility and uncertainty in U.S. and international markets.

If our future customers significantly reduce spending in areas in which our technology and products are utilized, or prioritize other expenditures over our technology and products, our business, financial condition, results of operations and prospects would be materially adversely affected.

Disruption to the global economy could also result in a number of follow-on effects on our business, including a possible slow-down resulting from lower customer expenditures; inability of customers to pay for products, solutions or services on time, if at all; more restrictive export regulations which could limit our potential customer base; negative impact on our liquidity, financial condition and share price, which may impact our ability to raise capital in the market, obtain financing and secure other sources of funding in the future on terms favorable to us.

In addition, the occurrence of catastrophic events, such as hurricanes, storms, earthquakes, tsunamis, floods, medical epidemics and other catastrophes that adversely affect the business climate in any of our markets could have a material adverse effect on our business, financial condition and results of operations. Some of our operations are located in areas that have been in the past, and may be in the future, susceptible to such occurrences.

We are currently subject to securities class-action litigation and may be subject to similar or other claims and litigation in the future, all of which will require significant management attention, could result in significant legal expenses and may result in unfavorable outcomes, all or any of which could have a material adverse impact on our financial condition and results of operations, harm our reputation or otherwise negatively impact our business.

We are, and may in the future become, subject to litigation or claims arising in or outside the ordinary course of business that could negatively affect our business operations and financial condition, including securities class actions and shareholder derivative actions, both of which are typically expensive to defend. Such claims and litigation proceedings may be brought by third parties, including our customers, competitors, advisors, service providers, partners or collaborators, employees, and governmental or regulatory bodies. For example, we currently have a securities class-action complaint pending against us and certain current officers and a director, asserting violations of federal securities laws and seeking unspecified damages. We believe this lawsuit is without merit and intend to defend this case vigorously. See “Item 4. Information on the Company—B. Business Overview—Legal Proceedings.”

The outcome of any litigation, regardless of its merits, is inherently uncertain and may differ substantially from our expectations. Any claims and lawsuits, and the disposition of such claims and lawsuits, could be time-consuming and expensive to resolve, divert management attention and resources, and lead to attempts on the part of other parties to pursue similar claims. We may not be able to determine the amount of any potential losses and other costs we may incur due to the inherent uncertainties of litigation and settlement negotiations. In the event we are required or decide to pay amounts in connection with any claims or lawsuits, such amounts could be significant and could have a material adverse impact on our liquidity, business, financial condition and results of operations. In addition, depending on the nature and timing of any such dispute, a resolution of a legal matter could materially affect our future operating results, our cash flows or both.

We do not expect to carry any business interruption insurance or any other insurance (except for director and officer, property and product liability insurance). As a result, we may incur uninsured losses, increasing the possibility that you would lose your entire investment in our company.

Our products and services are in the medical imaging field and so may be subject to claims. We are not immune from product liability or other product claim risks, and we may not be able to maintain insurance on acceptable terms against such risks or that such insurance will be sufficient to protect us against potential claims or that insurance will be available in the future in amounts sufficient to protect us. A product liability claim or other claim, as well as any claims for uninsured liabilities or in excess of insured liabilities, could have a material adverse effect on our business, financial condition, results of operations and prospects.

Certain of our directors and/or officers may have interests that compete with ours.

Certain of our directors currently own, operate and manage other entities, which may have similar or different objectives than ours. Such activities could detract from the time these people have to allocate to our affairs. We had previously entered into a consulting agreement and a service agreement with an entity owned by Ran Poliakine, and we are currently party to a service agreement with an entity of which Onn Fenig and Ran Poliakine each serves as a director and Ran Poliakine is a significant shareholder. Furthermore, Ran Poliakine is a director and Onn Fenig manages the operations of such entity's controlled subsidiary. See "Item 7. Major Shareholders and Related Party Transactions—B. Related Party Transactions—Agreements With Directors and Officers—Relationship With Six-Eye Interactive Ltd." and "—Relationship with SixAI Ltd." Additionally, we lease office space to an entity of which Ran Poliakine serves as a member of senior management, Richard Stone serves as a director and Anat Kaphan serves as a consultant. Each of Ran Poliakine and Richard Stone is also a significant shareholder. See "Item 7. Major Shareholders and Related Party Transactions—B. Related Party Transactions—Agreements with Directors and Officers—Relationship with Illumigyn, Ltd." Additionally, we lease office space to an entity of which each of Ran Poliakine and Richard Stone is a shareholder of its parent company. See "Item 7. Major Shareholders and Related Party Transactions—B. Related Party Transactions—Agreements With Directors and Officers—Relationship with Wellsense Technologies, Ltd." The terms of such agreements may not be as favorable to us as those that could be obtained from a third party. Moreover, certain of our directors and officers are affiliated with our current shareholders, and may have different interests than other shareholders. For additional information regarding related party transactions and potential conflicts of interest, see "Item 7. Major Shareholders and Related Party Transactions—B. Related Party Transactions." Under the Israeli Companies Law, 5759-1999 (the "Companies Law"), office holders must promptly disclose to us any direct or indirect personal interest that he or she may have and all related material information or documents known to him or her relating to any existing or proposed transaction by us. In addition, we have adopted a code of ethics and conduct that requires our employees, officers and directors to disclose any situation that reasonably would be expected to give rise to a conflict of interest.

Our management team has limited experience managing a public company.

Most members of our management team have limited experience managing a publicly traded company, interacting with public company investors and complying with the increasingly complex laws pertaining to public companies in the United States. Our management team may not successfully or efficiently manage our operations as a public company subject to significant regulatory oversight and reporting obligations under the U.S. federal securities laws and the continuous scrutiny of securities analysts and investors. These obligations and constituents require significant attention from our senior management and could divert their attention away from the day-to-day management of our business, which could adversely affect our business, financial condition, results of operations and prospects.

Risks Related to Our Intellectual Property

It is difficult and costly to protect our intellectual property and our proprietary technologies, and we may not be able to ensure their protection.

We rely upon a combination of patents and trade secrets to protect the intellectual property related to our proprietary technologies. Our success depends significantly on our ability to obtain and maintain intellectual property protection with respect to our technology and products. Patents and other proprietary rights provide uncertain protections, and we may be unable to protect our intellectual property for reasons including those that result from complex factual and legal issues such as those that create uncertainty as to the validity, scope and enforceability of any particular patent that we hold or for which we have applied. As a result, we may be unsuccessful in defending our patents and other proprietary rights against third-party challenges, which could have a material adverse effect on our business.

Although we are attempting to obtain patent coverage for our technology where available and where we believe appropriate, there are aspects of the technology for which patent coverage may never be sought or received. Additionally, we have obtained, and may in the future obtain, certain intellectual property related to our technology from third parties, and we cannot be certain that such third parties took the necessary actions to maintain such rights or that the transfer of such rights to us was proper and effective. We may, as a result, be subject to claims challenging the ownership or enforceability of such rights. Furthermore, we may not possess the resources to, or for other reasons may not choose to, pursue patent protection on every invention or in any or every country where we may eventually decide to sell our future products. Our ability to prevent others from making or selling duplicate or similar technologies will be impaired for those technologies with respect to which, and in those countries where, we have no patent protection. In addition, there is no assurance that all potentially relevant prior art relating to our patents and patent applications has been found, which can prevent a patent from issuing from a pending patent application or later invalidate or narrow the scope of an issued patent. Even if patents do successfully issue and even if such patents cover our technology, third parties may challenge their validity, enforceability or scope, which may result in such patents being narrowed, invalidated, or held unenforceable. Any successful challenge to these patents or any other patents owned by or licensed to us could deprive us of rights necessary for the successful commercialization of our technology.

In addition, for patents that do issue based on our applications or future applications, any issued patents may not provide us with any competitive advantages. Competitors may be able to design around our patents and develop products that provide outcomes comparable or superior to ours. Any changes we make to our product or any future products, including designs that may be required for commercialization or that cause them to have what we view as more advantageous properties, may not be covered by patents and patent applications we have licensed or own, and we may be required to file new applications and/or seek other forms of protection for any such altered products if any such protection is available. In addition, the patent prosecution process is expensive, time-consuming and complicated, and we and our current or future licensors, licensees or collaborators may not be able to prepare, file, prosecute and maintain all necessary or desirable patents or patent applications at a reasonable cost or in a timely manner. It is also possible that we or our current or future licensors, licensees or collaborators will fail to identify patentable aspects of inventions before it is too late to obtain patent protection for them. In addition, if we choose to and are able to secure patent protection in countries outside the U.S., the laws of some foreign countries may not protect our intellectual property rights to the same extent as do the laws of the United States. For instance, the legal systems of some countries, including India, China and other developing countries, do not favor the enforcement of patents and other intellectual property rights. This could make it difficult for us to stop the infringement of our patents or the misappropriation of our other intellectual property rights.

Some countries also have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In addition, some countries limit the enforceability of patents against government agencies or government contractors. In these countries, the patent owner may have limited remedies, which could materially diminish the value of such patent. If we or any of our licensors is forced to grant a license to third parties with respect to any patents relevant to our business, our competitive position may be impaired.

Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions and enforce our intellectual property rights, and more generally could affect the value of our intellectual property. Our efforts to seek patent protection for our technology could be negatively impacted by any such changes, which could have a material adverse effect on our existing patent rights and our ability to protect and enforce our intellectual property in the future. In particular, our ability to stop third parties from making, using, selling, offering to sell or importing products that infringe our intellectual property will depend in part on our success in obtaining and enforcing patent claims that cover our technology, inventions and improvements.

We may come to believe that third parties are infringing on, or otherwise violating, our patents or other proprietary rights. To prevent infringement or unauthorized use, we may need to file infringement and/or misappropriation suits, which are very expensive and time-consuming, could result in meritorious counterclaims against us and would distract management's attention. Also, in an infringement or misappropriation proceeding, a court may decide that one or more of our patents is invalid, unenforceable, or both, in which case third parties may be able to use our technology without paying license fees or royalties. Even if the validity of our patents is upheld, a court may refuse to stop the other party from using the technology at issue on the grounds that the other party's activities are not covered by our patents.

In addition to patents, we rely on trade secrets to protect our technology; however, the policies we use to protect our trade secrets may not be effective in preventing misappropriation of our trade secrets by others. In addition, confidentiality agreements executed by our employees, consultants and advisors may not be enforceable or may not provide meaningful protection for our trade secrets or other proprietary information in the event of unauthorized use or disclosure. Litigating a trade secret claim is expensive and time consuming, and the outcome may be unexpected. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop knowledge, methods and know-how that allow them to create substantially similar products or services without misappropriating our trade secrets. If we are unable to protect our trade secrets, we may be unable to prevent competitors from using our own inventions and intellectual property to compete against us, and our business may be harmed.

Patent terms may be inadequate to protect our competitive position on our future products for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our future products are obtained, once the patent life has expired, we may be open to competition from competitive products.

Given the amount of time required for the development, testing and regulatory review of new products, patents protecting our future products might expire before or shortly after we or our future partners commercialize those products. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours for a sufficient amount of time, and, as a result, we may not be able to obtain adequate protection from our patent portfolio against competition, in spite of the time and effort invested in the commercialization of our future products.

Claims that our technology or our future products or the sale or use of our future products infringe the patents or other intellectual property rights of third parties could result in costly litigation or could require substantial time and money to resolve, even if litigation is avoided.

Because our industry is characterized by competing intellectual property, we may be subject to legal actions for violating the intellectual property rights of others, including claims that former employees, collaborators or third parties have an interest in our patents, trade secrets or other intellectual property. For example, we may have inventorship or ownership disputes arising from conflicting obligations of employees, consultants or others who are involved in developing our technology or our products.

We also may be required to participate in interference, derivation or opposition proceedings that concern disputes regarding priority of inventions disclosed in our patents. Determining whether a product infringes a patent, as well as priority of inventions and other patent-related disputes, involves complex legal and factual issues and the outcome is often uncertain. We have not conducted any significant search of patents issued to third parties, and third-party patents containing claims covering our technology or methods that predate our patents may exist. Because of the number of patents issued and patent applications filed in our technical areas or fields (including some pertaining specifically to medical imaging technologies), our competitors or other third parties may assert that our technology and the methods we employ in the use of products incorporating our technology are covered by United States or foreign patents held by them. In addition, because patent applications can take many years to issue and because publication schedules for pending applications vary by jurisdiction, there may be applications now pending of which we are unaware, and which may result in issued patents that our technology or other future products would infringe. Also, because the claims of published patent applications can change between publication and patent grant, there may be published patent applications that may ultimately issue with claims that we infringe.

As the number of competitors in the market for medical imaging technologies increases, and as the number of patents issued in this area grows, the possibility of patent infringement claims against us increases. Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can, including if they have substantially greater resources. Defending against such litigation is costly and time consuming, and would distract our management from our business. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

In the event that we become subject to a patent infringement or other intellectual property lawsuit and if the relevant patents or other intellectual property were upheld as valid and enforceable and we were found to infringe or violate those rights or the terms of a license to which we are a party, we could be prevented from selling any infringing products of ours unless we could obtain a license or were able to redesign the product to avoid infringement. If we were unable to obtain a license or successfully redesign, we might be prevented from selling our technology or other future products. If we are able to redesign, we may need to invest substantial resources in the redesign process. If there is an allegation or determination that we have infringed the intellectual property rights of a competitor or other person, we may be required to pay damages, or a settlement or ongoing royalties, or we may be required to enter into cross-licenses with our competitors. In any of these circumstances, we may be unable to sell our products at competitive prices or at all, and our business, financial condition, results of operations and prospects could be harmed.

In addition, we may be required to indemnify our customers and distributors against claims relating to the infringement of intellectual property rights of third parties related to our products. Third parties may assert infringement claims against our customers or distributors. These claims may require us to initiate or defend protracted and costly litigation on behalf of our customers or distributors, regardless of the merits of these claims. If any of these claims succeed, we may be forced to pay damages on behalf of our customers or distributors, or may be required to obtain licenses for the products or services they use. If we cannot obtain all necessary licenses on commercially reasonable terms, our distributors may be forced to stop distributing our products or services, and our customers may be forced to stop using our products or services.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during discovery. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a material adverse effect on the price of our ordinary shares. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our ordinary shares.

Obtaining and maintaining patent protection depends on compliance with various procedural, document submission, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated if we or our future licensors do not comply with these requirements.

Periodic maintenance fees, renewal fees, annuity fees and various other government fees on a patent and patent application are due to be paid to the patent offices and agencies in several stages over the lifetime of the patent and patent application. The U.S. Patent and Trademark Office and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. In certain circumstances, we may be required to rely on our licensing partners to take the necessary action to comply with these requirements with respect to patents or other intellectual property they have licensed to us. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance, which could include failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents, can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. In such an event, our competitors may be able to enter the market and compete with our products, which would have a material adverse effect on our business.

We may be subject to claims that our employees, consultants or advisers have wrongfully used or disclosed alleged trade secrets of their former employers or claims asserting ownership of what we regard as our own intellectual property.

Many of our employees, consultants and advisers, including our senior management, were previously employed at other companies that may have proprietary rights related to our business. Some of these employees, consultants and advisers, including members of our senior management, executed proprietary rights, non-disclosure and non-competition agreements in connection with such previous employment. Although we try to ensure that such individuals do not use the proprietary information or know-how of others in their work for us, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such individual's former employer. We are not aware of any such disclosures, or threatened or pending claims related to these matters, but in the future, litigation may be necessary to defend against such claims. If we fail in defending any such claims, we may lose valuable intellectual property rights or personnel, in addition to possibly paying monetary damages and being enjoined from conducting our business as contemplated. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management.

Additionally, a licensor, collaborator, employee, consultant, adviser or other third party may dispute our or our licensor's ownership of certain intellectual property rights. We seek to address these concerns in our contractual agreements; however, we may not have contractual arrangements with the party in question and/or such provisions may not be effective. If these provisions prove to be ineffective, we may not be able to achieve our business objectives. If we or our licensors fail in defending any such claims, we may have to pay monetary damages and may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, intellectual property, which could adversely impact our business, financial condition and results of operations.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our unregistered trademarks or trade names are valuable assets and may be challenged, infringed, circumvented or declared generic or determined to infringe third party's marks. We may not be able to protect our rights to these trademarks and trade names, which may be necessary to build name recognition among potential collaborators or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other trademarks or trademarks that incorporate variations of our unregistered trademarks or trade names. We have not conducted any registrability studies for possible future trademarks to assess whether such marks would be successfully registered. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. In addition, we may license our trademarks and trade names to third parties, such as distributors. Though these license agreements may provide guidelines for how our trademarks and trade names may be used, a breach of these agreements or misuse of our trademarks and tradenames by our licensees may jeopardize our rights in or diminish the goodwill associated with our trademarks and trade names. Our efforts to enforce or protect our proprietary rights related to trademarks, trade names, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and adversely affect our competitive position, business, financial condition, results of operations and prospects.

Our rights to develop and commercialize our products may be subject to the terms and conditions of licenses and sublicenses granted to us by third parties.

We rely on licenses and sublicenses to certain patent rights and other intellectual property from third parties that are important or necessary to the development of our products, including the software modules that we expect to integrate into the Nanox.CLOUD. These and other licenses may not provide exclusive rights to use such intellectual property in all relevant fields of use and in all territories in which we may wish to develop or commercialize our products and the underlying patents may fail to provide the intended exclusivity. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in the markets that we hope to address. Moreover, we would not own at least some of the underlying intellectual property rights related to these products, and as a result our rights would be subject to the continuation and compliance with the terms of those agreements. If such in-licenses were terminated, competitors would have the freedom to develop, seek regulatory approval of, and to market, products similar or identical to ours.

In addition, these license agreements may not grant us the right to control the preparation, filing, prosecution or maintenance of patents and patent applications covering our products. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted or maintained in a manner consistent with the best interests of our business. If our current or future licensing partners fail to file, prosecute or maintain such patents, including the payment of applicable fees, or otherwise lose rights to those patents or patent applications, the intellectual property we have licensed or exclusivity we have been granted may be reduced or eliminated, and our right to develop and commercialize any of our future products that are subject of such licensed rights, and our ability to prevent competitors from developing or commercializing such products, could be adversely affected. In addition, even where we have the right to control patent prosecution and maintenance of patents and patent applications we have licensed from third parties, we may still be adversely affected or prejudiced by actions or inactions of our licensees, our licensors and their counsel that took place prior to the date upon which we assumed control over patent prosecution.

Pursuant to the terms of such license agreements, the licensors may also have the right to control enforcement of our licensed patents or defense of any claims asserting the invalidity or unenforceability of these patents. Even if we are permitted to pursue the enforcement or defense of our licensed patents, we may require the cooperation of our future licensors or collaboration partners and any other applicable patent owners and we cannot be certain that such cooperation will be provided to us. We also cannot be certain that our licensors will allocate sufficient resources or prioritize their or our enforcement of such patents or defense of such claims to protect our interests in the licensed patents. Even if we are not a party to these legal actions, an adverse outcome could harm our business because it might prevent us from continuing to license intellectual property that we may need to operate our business. If we lose any of our licensed intellectual property, our right to develop and commercialize any of our products that are subject of such licensed rights could be adversely affected.

In addition, our future licensors may rely on third-party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-license. If other third parties have ownership rights to our in-licensed patents, they may be able to license such patents to our competitors, and our competitors could market competing products and technologies. In addition, if our licensors have not obtained adequate rights from these third parties, we may need to obtain additional rights from these third parties or we could be prevented from developing and commercializing the related products. This could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

In spite of our best efforts, our licensors might conclude that we have materially breached our license agreements and might therefore terminate the license agreements, in which event we may have to cease developing, manufacturing or marketing any product covered by these agreements and we may face other additional penalties or be required to grant our licensors additional rights. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses. Any of these events could have a material adverse effect on our competitive position, business, financial conditions, results of operations and prospects.

We may be required to pay certain milestones and royalties and fulfill other obligations under our license agreements with third-party licensors.

We may be required to pay milestones and royalties related to our development or commercialization activities of our products utilizing the technologies licensed or sublicensed from third parties under license agreements we may enter into with them. These payments could adversely affect our overall profitability related to any future products that we may seek to develop or commercialize. In order to maintain our license rights under our license agreements, we may need to meet certain specified milestones or fulfill certain obligations, including to devote a certain amount of resources, in the development of our products. Failure to satisfy such obligations could result in the termination of our rights under such agreements.

If we choose to license our technology to third parties, this could result in disputes or otherwise limit our future operations.

We may also in the future, as one of our strategies, deploy our technology into the market and license patents and other intellectual proprietary rights to third parties. Disputes with our licensees may arise, including regarding the scope and content of these licenses. Additionally, a licensee may use our intellectual property without our permission, dispute our ownership of certain intellectual property rights or argue that our intellectual property does not cover our product. Regardless of whether we pursue legal action to enforce any such dispute, a dispute with a licensee or customer over intellectual property rights may damage our relationship with that licensee or customer and may also harm our reputation in the industry. Our ability to expand into additional fields with our technologies also may be restricted by licenses or other rights we may grant to third parties in the future, including if the licenses are exclusive, the licensee is assigned ownership of intellectual property that we develop or rights of first negotiation or refusal are granted. For instance, pursuant to the Right of First Negotiation Agreement with FUJIFILM Corporation, dated May 21, 2019, we granted FUJIFILM Corporation a right of first negotiation to obtain an exclusive license to certain of our intellectual property for use in the field of mammography. See “Item 4. Information on the Company—B. Business Overview—Our Business Model—The Licensing Model” for a description of the terms of such agreement. If we choose to use this intellectual property in the field of mammography in the future, our ability would be limited by these rights and any related rights granted in the future to FUJIFILM Corporation.

Risks Related to Government Regulation

Our product candidates and operations are subject to extensive government regulation and oversight both in the United States and abroad, and our failure to comply with applicable requirements could harm our business.

We expect the Nanox.ARC and other future products we develop to be regulated by the FDA as medical devices. Our product candidate is subject to extensive regulation in the United States and elsewhere, including by the FDA and its foreign counterparts, the U.S. Department of Justice (the “DOJ”) and the U.S. Department of Health and Human Services-Office of the Inspector General. The FDA and foreign regulatory agencies regulate, among other things, with respect to medical devices: design, development and manufacturing; testing, labeling, content and language of instructions for use and storage; clinical trials; product safety; establishment registration and device listing; marketing, sales and distribution; pre-market clearance and approval; conformity assessment procedures; record keeping procedures; advertising and promotion; recalls and field safety corrective actions; post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to occur, could lead to death or serious injury; post-market approval studies; and product import and export.

The regulations our product candidate is subject to are complex and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales for any approved product. Failure to comply with applicable regulations could jeopardize our ability to sell our future products, if cleared or approved, and result in enforcement actions such as: warning or untitled letters; fines; injunctions; consent decrees; civil penalties; customer notifications; termination of distribution; recalls or seizures of products; administrative detention of medical devices believed to be adulterated or misbranded; delays in the introduction of products into the market; operating restrictions; total or partial suspension of production; refusal to grant future clearances or approvals for new products, new intended uses or modifications to our products; withdrawals or suspensions of current approvals, resulting in prohibitions on sales of our products; and in the most serious cases, criminal prosecution or penalties. The occurrence of any of these events would have a material adverse effect on our business, financial condition and results of operations and could result in shareholders losing their entire investment.

We may not receive, or may be delayed in receiving, the necessary clearances or approvals for our future products, and failure to timely obtain necessary clearances or approvals for our future products would adversely affect our ability to grow our business.

In the United States, before we can market a new medical device, or a new use of, new claim for or significant modification to an existing product, we must first receive either clearance under Section 510(k) of the Federal Food, Drug, and Cosmetic Act (the “FDCA”) or approval of a pre-market approval application (a “PMA”) from the FDA, unless an exemption applies. In the 510(k) clearance process, before a device may be marketed, the FDA must determine that a proposed device is “substantially equivalent” to a legally-marketed “predicate” device, which includes a device that has been previously cleared through the 510(k) process, a device that was legally marketed prior to May 28, 1976 (pre-amendments device), a device that was originally on the U.S. market pursuant to an approved PMA and later down-classified, or a 510(k)-exempt device. To be “substantially equivalent,” the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data are sometimes required to support substantial equivalence. In the process of obtaining PMA approval, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, pre-clinical, clinical trial, manufacturing and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or implantable devices.

Modifications to products that are approved through a PMA application generally require FDA approval. Similarly, certain modifications made to products cleared through a 510(k) may require a new 510(k) clearance. Both the PMA approval and the 510(k) clearance process can be expensive, lengthy and uncertain. The FDA's 510(k) clearance process usually takes from three to 12 months, but can last longer. The process of obtaining a PMA is generally much more costly and uncertain than the 510(k) clearance process and generally takes from one to three years, or even longer, from the time the application is submitted to the FDA. In addition, a PMA generally requires the performance of one or more clinical trials. Despite the time, effort and cost, a device may not be approved or cleared by the FDA. Any delay or failure to obtain necessary regulatory clearances or approvals could harm our business. Furthermore, even if we are granted regulatory clearances or approvals, they may include significant limitations on the indicated uses for the device or other restrictions or requirements, which may limit the market for the device.

In the United States, we are taking a multi-step approach to the regulatory clearance process. As a first step, we submitted a 510(k) premarket notification for the Nanox Cart X-Ray System to an accredited Review Organization under the Third Party Review Program in January 2020. As part of the review process, in March 2020, we received an information request, referred to as a major deficiency letter, from the Review Organization, which among other things, required us to provide additional data and other information to complete the application and to address certain deficiencies highlighted by the reviewer, including the results of certain performance tests. On September 3, 2020, we submitted our response to the Review Organization. The response included additional data and other information to complete the application and to address certain deficiencies identified by the reviewer, including the results of certain performance tests. On September 10, 2020, the Review Organization requested that we include a second predicate device in our 510(k) premarket notification. On September 26, 2020, we submitted our revised 510(k) premarket notification to the Review Organization, which the Review Organization subsequently recommended to the FDA for clearance on December 28, 2020. On January 1, 2021, we received an information request from the FDA through the Review Organization regarding our submission, which we responded to on January 4, 2021. On January 30, 2021, we received additional information requests from the FDA which, among other things, require us to address certain deficiencies and questions, including requests that we provide additional support regarding the intended use of the Nanox.ARC and the comparability of the Nanox.ARC to the predicate device. We submitted our response to these requests on March 1, 2021. On April 1, 2021, we received clearance from the FDA to market our Nanox Cart X-Ray System. We will continue to optimize and develop features of the Nanox.ARC, and plan to submit an additional 510(k) premarket notification to the FDA with respect to the multi-source Nanox.ARC and the Nanox.CLOUD during 2021. If cleared by the FDA, we expect to commercialize the multi-source Nanox.ARC and we may seek alternatives for commercialization of our Nanox Cart X-Ray System. The review process may be more costly and time consuming than we expect and we may not ultimately be successful in completing the review process and our 510(k) premarket notification may not be cleared by the FDA in a timely manner or at all. If cleared, any modification to these systems that has not been previously cleared may require us to submit a new 510(k) premarket notification and obtain clearance, or submit a PMA and obtain FDA approval prior to implementing the change. Specifically, any modification to a 510(k)-cleared device that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, design or manufacture, requires a new 510(k) clearance or, possibly, approval of a PMA. The FDA requires every manufacturer to make this determination in the first instance, but the FDA may review any manufacturer's decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. We may make modifications or add additional features in the future that we believe do not require a new 510(k) clearance or approval of a PMA. If the FDA disagrees with our determination and requires us to submit new 510(k) notifications or PMA applications for modifications to our previously cleared products for which we have concluded that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, product introductions or modifications could be delayed or canceled, which could adversely affect our ability to grow our business.

The FDA can delay, limit or deny clearance or approval of a medical device for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA or the applicable regulatory entity or notified body that our product candidates are safe or effective for their intended uses or are substantially equivalent to a predicate device;

- the disagreement of the FDA or the applicable foreign regulatory body with the design or implementation of our clinical trials or the interpretation of data from pre-clinical studies or clinical trials;
- serious and unexpected adverse effects experienced by participants in our clinical trials;
- the data from our pre-clinical studies and clinical trials may be insufficient to support clearance or approval, where required;
- our inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- the manufacturing process or facilities we use may not meet applicable requirements; and
- the potential for approval policies or regulations of the FDA or applicable foreign regulatory bodies to change significantly in a manner rendering our clinical data or regulatory filings insufficient for clearance or approval.

In order to sell our products in member countries of the European Economic Area (“EEA”), our products must comply with the essential requirements of the EU Medical Devices Directive (Council Directive 93/42/EEC). Compliance with these requirements is a prerequisite to be able to affix the Conformité Européene (“CE”) mark to our products, without which they cannot be sold or marketed in the EEA. To demonstrate compliance with the essential requirements we must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low-risk medical devices (Class I non-sterile, non-measuring devices), where the manufacturer can issue a European Community (“EC”) Declaration of Conformity based on a self-assessment of the conformity of its products with the essential requirements of the EU Medical Devices Directive, a conformity assessment procedure requires the intervention of an organization accredited by a member state of the EEA to conduct conformity assessments, or a Notified Body. Depending on the relevant conformity assessment procedure, the Notified Body would typically audit and examine the technical file and the quality system for the manufacture, design and final inspection of our devices. The Notified Body issues a certificate of conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the essential requirements. This certificate entitles the manufacturer to affix the CE mark to its medical devices after having prepared and signed a related EC Declaration of Conformity.

As a general rule, demonstration of conformity of medical devices and their manufacturers with the essential requirements must be based, among other things, on the evaluation of clinical data supporting the safety and performance of the products during normal conditions of use. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use, that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device are supported by suitable evidence. If we fail to remain in compliance with applicable European laws and directives, we would be unable to continue to affix the CE mark to our products, which would prevent us from selling them within the EEA.

Failure to comply with post-marketing regulatory requirements could subject us to enforcement actions, including substantial penalties, and might require us to recall or withdraw a product from the market.

If we receive regulatory clearance or approval of the Nanox.ARC or other future products, we will remain subject to ongoing and pervasive regulatory requirements governing, among other things, the manufacture, marketing, advertising, medical device reporting, sale, promotion, import, export, registration, and listing of devices. For example, we will be required to submit periodic reports to the FDA as a condition of 510(k) clearance. These reports include information about failures and certain adverse events associated with the device after its clearance. Failure to submit such reports, or failure to submit the reports in a timely manner, could result in enforcement action by the FDA. Following its review of the periodic reports, the FDA might ask for additional information or initiate further investigation.

The regulations to which we are subject are complex and have become more stringent over time. Regulatory changes could result in restrictions on our ability to continue or expand our operations, higher than anticipated costs, or lower than anticipated sales. Even after we have obtained the proper regulatory clearance or approval to market a device, we have ongoing responsibilities under FDA regulations and applicable foreign laws and regulations. The FDA, state and foreign regulatory authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA, state or foreign regulatory authorities, which may include any of the following sanctions:

- untitled letters or warning letters;
- fines, injunctions, consent decrees and civil penalties;
- recalls, termination of distribution, administrative detention, or seizure of our products;
- customer notifications or repair, replacement or refunds;
- operating restrictions or partial suspension or total shutdown of production;
- delays in or refusal to grant our requests for future clearances or approvals or foreign marketing authorizations of new products, new intended uses, or modifications to existing products;
- withdrawals or suspensions of product clearances or approvals, resulting in prohibitions on sales of our products;
- FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries; and
- criminal prosecution.

Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, financial condition and results of operations.

In addition, the FDA or state or foreign authorities may change their clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay clearance or approval of our future products under development on a timely basis. Such policy or regulatory changes could impose additional requirements upon us that could delay our ability to obtain new clearances or approvals, increase the costs of compliance or restrict our ability to maintain any approvals we are able to obtain. For example, the FDA has announced steps that the FDA intends to take to modernize the premarket notification pathway under Section 510(k) of the FDCA. For more information, see “—Legislative or regulatory reforms in the United States or the EU may make it more difficult and costly for us to obtain regulatory clearances or approvals for our products or to manufacture, market or distribute our products after clearance or approval is obtained.”

Our products must be manufactured in accordance with federal, state and foreign regulations, and we could be forced to recall our devices or terminate production if we fail to comply with these regulations.

The methods used in, and the facilities used for, the manufacture of our products must comply with the Quality System Regulation (“QSR”), which is a complex regulatory scheme that covers the procedures and documentation of the design, testing, production, process controls, quality assurance, labeling, packaging, handling, storage, distribution, installation, servicing and shipping of medical devices. As manufacturers of electron radiation-emitting products, we are also responsible for compliance with the radiological health regulations and certain radiation safety performance standards.

Furthermore, we are required to verify that our suppliers maintain facilities, procedures and operations that comply with our quality standards and applicable regulatory requirements. The FDA enforces the QSR through periodic announced or unannounced inspections of medical device manufacturing facilities, which may include the facilities of subcontractors. Our products are also subject to similar state regulations and various laws and regulations of foreign countries governing manufacturing.

Our third-party manufacturers may not take the necessary steps to comply with applicable regulations, which could cause delays in the delivery of our products. In addition, failure to comply with applicable FDA or state or foreign requirements or later discovery of previously unknown problems with our products or manufacturing processes could result in, among other things: warning letters or untitled letters; fines, injunctions or civil penalties; suspension or withdrawal of approvals; seizures or recalls of our products; total or partial suspension of production or distribution; administrative or judicially imposed sanctions; the FDA's refusal to grant pending or future clearances or approvals for our products; clinical holds; refusal to permit the import or export of our products; and criminal prosecution of us, our suppliers or our employees.

Any of these actions could significantly and negatively affect supply of our products. If any of these events occurs, our reputation could be harmed, we could be exposed to product liability claims and we could lose customers and experience reduced sales and increased costs.

The misuse or off-label use of our products may harm our reputation in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business.

Advertising and promotion of our future products that obtains approval in the United States may be heavily scrutinized by the FDA, the DOJ, HHS, state attorneys general, members of Congress, and the public. In addition, advertising and promotion of any future product that obtains approval outside of the United States will be heavily scrutinized by comparable foreign regulatory authorities.

We expect that, if cleared or approved, our products, including the multi-source Nanox.ARC, will be cleared by the requisite regulatory authorities for specific indications. We expect to train our marketing personnel and direct sales force to not promote our devices for uses outside of the FDA-approved indications for use, known as "off-label uses." We cannot, however, prevent a physician from using our devices off-label, when in the physician's independent professional medical judgment he or she deems it appropriate. There may be increased risk of injury to patients if physicians attempt to use our devices off-label. Furthermore, the use of our devices for indications other than those approved by the FDA or approved by any foreign regulatory body may not effectively treat such conditions, which could harm our reputation in the marketplace among healthcare providers and patients.

If the FDA or any state or foreign regulatory body determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of an untitled letter, which is used for violators that do not necessitate a warning letter, injunction, seizure, civil fine or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action under other regulatory authority, such as false claims laws, if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs and the curtailment of our operations. We may become subject to such actions and, if we are not successful in defending against such actions, those actions may have a material adverse effect on our business, financial condition and results of operations. Equivalent laws and potential consequences exist in foreign jurisdictions.

In addition, if our products are cleared or approved, healthcare providers may misuse our products or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our devices are misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. As described above, product liability claims could divert management's attention from our core business, be expensive to defend and result in sizeable damage awards against us that may not be covered by insurance.

Our products may cause or contribute to adverse medical events or be subject to failures or malfunctions that we are required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could harm our reputation, business, financial condition and results of operations. The discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA or another governmental authority, could have a negative impact on us.

If the Nanox.ARC or our other future products receive clearance or approval, we will be subject to the FDA's medical device reporting regulations and similar foreign regulations, which require us to report to the FDA when we receive or become aware of information that reasonably suggests that one or more of our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. If we fail to comply with our reporting obligations, the FDA or other regulatory bodies could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearance or approval, seizure of our products or delay in clearance or approval of future products.

The FDA and foreign regulatory bodies have the authority to require the recall of commercialized products in the event of material deficiencies or defects in design or manufacture of a product or in the event that a product poses an unacceptable risk to health. The FDA's authority to require a recall must be based on a finding that there is reasonable probability that the device could cause serious injury or death. We may also choose to voluntarily recall a product if any material deficiency is found. A government-mandated or voluntary recall by us could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing defects, labeling or design deficiencies, packaging defects or other deficiencies or failures to comply with applicable regulations. Product defects or other errors may occur in the future.

Depending on the corrective action we take to redress a product's deficiencies or defects, the FDA may require, or we may decide, that we will need to obtain new clearances or approvals for the device before we may market or distribute the corrected device. Seeking such clearances or approvals may delay our ability to replace the recalled devices in a timely manner. Moreover, if we do not adequately address problems associated with our devices, we may face additional regulatory enforcement action, including FDA warning letters, product seizure, injunctions, administrative penalties or civil or criminal fines.

Companies are required to maintain certain records of recalls and corrections, even if they are not reportable to the FDA. We may initiate voluntary withdrawals or corrections for our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, it could require us to report those actions as recalls and we may be subject to enforcement action. A future recall announcement could harm our reputation with customers, potentially lead to product liability claims against us and negatively affect our sales. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results.

Our relationships with customers and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Physicians, other healthcare providers, and third-party payors will play a primary role with respect to any future products for which we obtain marketing approval. Our arrangements with third-party payors and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our product. Restrictions under applicable federal and state healthcare laws and regulations include the following:

- The U.S. federal healthcare program Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under federal healthcare programs such as Medicare and Medicaid. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly and practices that involve remuneration to those who prescribe, purchase, or recommend medical devices, including certain discounts, or engaging consultants as speakers or consultants, may be subject to scrutiny if they do not fit squarely within the exemption or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti-kickback liability. Moreover, there are no safe harbors for many common practices, such as educational and research grants. Liability may be established without a person or entity having actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act. Due to the breadth of these laws, the narrowness of statutory exceptions and regulatory safe harbors available, and the range of interpretations to which they are subject, it is possible that some of our current or future practices might be challenged under one or more of these laws, including, without limitation, our proposed Subscription Model, and our advisory, consulting and royalty agreements with certain physicians who receive compensation, in part, in the form of stock or stock options.

- The federal civil False Claims Act prohibits, among other things, any person from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment of government funds, or knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay money to the government or knowingly concealing or knowingly and improperly avoiding, decreasing, or concealing an obligation to pay money to the federal government. In recent years, several healthcare companies have faced enforcement actions under the federal False Claims Act for, among other things, allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product or causing false claims to be submitted because of the company's marketing the product for unapproved, and thus non-reimbursable, uses. False Claims Act liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties of tens of thousands of dollars per false claim or statement. Healthcare companies also are subject to other federal false claims laws, including, among others, federal criminal healthcare fraud and false statement statutes that extend to non-government health benefit programs.
- The Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), imposes criminal and civil liability for knowingly and willfully executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services. In addition, HIPAA, as amended by HITECH, and their respective implementing regulations impose obligations, including mandatory contractual terms, on covered healthcare providers, health plans, as well as their business associates, with respect to safeguarding the privacy, security and transmission of individually identifiable health information.
- The Physician Payment Sunshine Act, implemented as the Open Payments program, requires manufacturers of certain products reimbursed by Medicare, Medicaid, or the Children's Health Insurance Program to track and report to the federal government payments and transfers of value that they make to physicians and teaching hospitals, certain other healthcare professionals beginning in 2022, group purchasing organizations, and ownership interests held by physicians and their families, and provides for public disclosures of these data. Manufacturers are required to submit annual reports to the government and failure to do so may result in civil monetary penalties for all payments, transfers of value and ownership or investment interests not reported in an annual submission, and may result in liability under other federal laws and regulations.
- Many states have adopted laws and regulations analogous to the federal laws cited above, including state anti-kickback and false claims laws, which may apply to items or services reimbursed under Medicaid and other state programs or, in several states, regardless of the payer. Several states have enacted legislation requiring medical device companies to, among other things, establish marketing compliance programs; file periodic reports with the state, including reports on gifts and payments to individual health care providers; make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities; and/or register their sales representatives. Some states prohibit specified sales and marketing practices, including the provision of gifts, meals, or other items to certain health care providers.

Efforts to ensure that our business arrangements with third parties will comply with applicable healthcare laws and regulations involve substantial costs. Additionally, it is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. Exclusion, suspension and debarment from government funded healthcare programs would significantly impact our ability to commercialize, sell or distribute any product. If any of the physicians or other providers or entities with whom we expect to do business are found not to be in compliance with applicable laws, they may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs.

Changes in laws or regulations relating to data protection, or any actual or perceived failure by us to comply with such laws and regulations or our privacy policies, could materially and adversely affect our business or could lead to government enforcement actions and significant penalties against us, and adversely impact our operating results.

We expect to receive health information and other highly sensitive or confidential information and data of patients and other third parties (e.g., healthcare providers who refer patients for scans), which we expect to compile and analyze. Collection and use of this data might raise privacy and data protection concerns, which could negatively impact our business. There are numerous federal, state and international laws and regulations regarding privacy, data protection, information security, and the collection, storing, sharing, use, processing, transfer, disclosure, and protection of personal information and other data, and the scope of such laws and regulations may change, be subject to differing interpretations, and may be inconsistent among countries and regions we intend to operate in (e.g., the United States, the European Union and Israel), or conflict with other laws and regulations. The regulatory framework for privacy and data protection worldwide is, and is likely to remain for the foreseeable future, uncertain and complex, and this or other actual or alleged obligations may be interpreted and applied in a manner that we may not anticipate or that is inconsistent from one jurisdiction to another and may conflict with other rules or practices including ours. Further, any significant change to applicable laws, regulations, or industry practices regarding the collection, use, retention, security, or disclosure of data, or their interpretation, or any changes regarding the manner in which the consent of relevant users for the collection, use, retention, or disclosure of such data must be obtained, could increase our costs and require us to modify our services and candidate products, possibly in a material manner, which we may be unable to complete, and may limit our ability to store and process patients' data or develop new services and features.

In particular, we will be subject to U.S. data protection laws and regulations (i.e., laws and regulations that address privacy and data security) at both the federal and state levels. The legislative and regulatory landscape for data protection continues to evolve, and in recent years there has been an increasing focus on privacy and data security issues. Numerous federal and state laws, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws, govern the collection, use, and disclosure of health-related and other personal information. Failure to comply with such laws and regulations could result in government enforcement actions and create liability for us (including the imposition of significant civil or criminal penalties), private litigation and/or adverse publicity that could negatively affect our business. For instance, California enacted the California Consumer Privacy Act ("CCPA") on June 28, 2018, which took effect on January 1, 2020. The CCPA creates individual privacy rights for California consumers and increases the privacy and security obligations of entities handling certain personal data. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Further, the California Privacy Rights Act ("CPRA"), recently passed in California. The CPRA will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. The CCPA and the CPRA may increase our compliance costs and potential liability, and many similar laws have been proposed at the federal level and in other states.

In addition, we expect to obtain health information that is subject to privacy and security requirements under HITECH and its implementing regulations. The Privacy Standards and Security Standards under HIPAA establish a set of standards for the protection of individually identifiable health information by health plans, health care clearinghouses and certain health care providers, referred to as Covered Entities, and the business associates with whom Covered Entities enter into service relationships pursuant to which individually identifiable health information may be exchanged. Notably, whereas HIPAA previously directly regulated only Covered Entities, HITECH makes certain of HIPAA's privacy and security standards also directly applicable to Covered Entities' business associates. As a result, both Covered Entities and business associates are now subject to significant civil and criminal penalties for failure to comply with Privacy Standards and Security Standards. As part of our normal operations, we expect to collect, process and retain personal identifying information regarding patients, including as a business associate of Covered Entities, so we expect to be subject to HIPAA, including changes implemented through HITECH, and we could be subject to criminal penalties if we knowingly obtain or disclose individually identifiable health information in a manner that is not authorized or permitted by HIPAA. A data breach affecting sensitive personal information, including health information, also could result in significant legal and financial exposure and reputational damages that could potentially have an adverse effect on our business.

HIPAA requires Covered Entities (like many of our potential customers) and business associates, like us, to develop and maintain policies and procedures with respect to protected health information that is used or disclosed, including the adoption of administrative, physical and technical safeguards to protect such information. HITECH expands the notification requirement for breaches of patient-identifiable health information, restricts certain disclosures and sales of patient-identifiable health information and provides for civil monetary penalties for HIPAA violations. HITECH also increased the civil and criminal penalties that may be imposed against Covered Entities and business associates and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and its implementing regulations and seek attorney's fees and costs associated with pursuing federal civil actions. Additionally, certain states have adopted comparable privacy and security laws and regulations, some of which may be more stringent or broader in scope than HIPAA.

Internationally, many jurisdictions have or are considering enacting privacy or data protection laws or regulations relating to the collection, use, storage, transfer, disclosure and/or other processing of personal data, as well as certification requirements for the hosting of health data specifically. Such laws and regulations may include data hosting, data residency or data localization requirements (which generally require that certain types of data collected within a certain country be stored and processed within that country), data export restrictions, international transfer laws (which prohibit or impose conditions upon the transfer of such data from one country to another), or may require companies to implement privacy or data protection and security policies, enable users to access, correct and delete personal data stored or maintained by such companies, inform individuals of security breaches that affect their personal data or obtain individuals' consent to use their personal data. For example, European legislators adopted the European Union's General Data Protection Regulation (2016/679) ("GDPR"), which became effective on May 25, 2018, and are now in the process of finalizing the ePrivacy Regulation to replace the European ePrivacy Directive (Directive 2002/58/EC as amended by Directive 2009/136/EC). The GDPR, supplemented by national laws and further implemented through binding guidance from the European Data Protection Board, imposes more stringent European Union data protection requirements and provides for significant penalties for noncompliance. Further, following the United Kingdom's withdrawal from the European Economic Area and the European Union, and the expiry of the transition period, companies have to comply with both the GDPR and the GDPR as incorporated into United Kingdom national law, the latter regime having the ability to separately fine up to the greater of £17.5 million or 4% of global turnover. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, for example around how data can lawfully be transferred between each jurisdiction, which may expose us to further compliance risk.

Virtually every jurisdiction in which we expect to operate has established its own data security and privacy legal framework with which we must, and our target customers will need to, comply, including the rules and regulation mentioned above. We may also need to comply with varying and possibly conflicting privacy laws and regulations in other jurisdictions. As a result, we could face regulatory actions, including significant fines or penalties, adverse publicity and possible loss of business.

While we are preparing to implement various measures intended to enable us to comply with applicable privacy or data protection laws, regulations and contractual obligations, these measures may not always be effective and do not guarantee compliance. Any failure or perceived failure by us to comply with our contractual or legal obligations or regulatory requirements relating to privacy, data protection, or information security may result in governmental investigations or enforcement actions, litigation, claims, or public statements against us by consumer advocacy groups or others and could result in significant liability, cause our customers, partners or patients to lose trust in us, and otherwise materially and adversely affect our reputation and business. Furthermore, the costs of compliance with, and other burdens imposed by, the laws, regulations, and policies that are applicable to the businesses of our customers or partners may limit the adoption and use of, and reduce the overall demand for, our products and services. Additionally, if third parties we work with violate applicable laws, regulations, or agreements, such violations may put the data we have received at risk, could result in governmental investigations or enforcement actions, fines, litigation, claims, or public statements against us by consumer advocacy groups or others and could result in significant liability, cause our customers, partners or patients to lose trust in us, and otherwise materially and adversely affect our reputation and business. Further, public scrutiny of, or complaints about, technology companies or their data handling or data protection practices, even if unrelated to our business, industry or operations, may lead to increased scrutiny of technology companies, including us, and may cause government agencies to enact additional regulatory requirements, or to modify their enforcement or investigation activities, which may increase our costs and risks.

If we do not obtain and maintain international regulatory registrations, clearances or approvals for our products, we will be unable to market and sell our products outside of the United States.

Sales of our products outside of the United States are subject to foreign regulatory requirements that vary widely from country to country. Approval procedures vary among countries and can involve additional testing. The time required to obtain approval outside of the United States may differ substantially from that required to obtain FDA approval. In addition, the FDA regulates exports of medical devices from the United States. While the regulations of some countries may not impose barriers to marketing and selling our products or only require notification, others require that we obtain the clearance or approval of a specified regulatory body. Complying with foreign regulatory requirements, including obtaining registrations, clearances or approvals, can be expensive and time-consuming, and we may not receive regulatory clearances or approvals in each country in which we plan to market our products or we may be unable to do so on a timely basis. The time required to obtain registrations, clearances or approvals, if required by other countries, may be longer than that required for FDA clearance or approval, and requirements for such registrations, clearances or approvals may significantly differ from FDA requirements. If we modify our products, we may need to apply for additional regulatory clearances or approvals before we are permitted to sell the modified product. In addition, we may not continue to meet the quality and safety standards required to maintain the authorizations that we have received. If we are unable to maintain our authorizations in a particular country, we will no longer be able to sell the applicable product in that country.

Regulatory clearance or approval by the FDA does not ensure registration, clearance or approval by regulatory authorities in other countries, and registration, clearance or approval by one or more foreign regulatory authorities does not ensure registration, clearance or approval by regulatory authorities in other foreign countries or by the FDA. However, a failure or delay in obtaining registration or regulatory clearance or approval in one country may have a negative effect on the regulatory process in others.

Legislative or regulatory reforms in the United States or the EU may make it more difficult and costly for us to obtain regulatory clearances or approvals for our products or to manufacture, market or distribute our products after clearance or approval is obtained.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulation of medical devices. In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay approval or clearance of our future products under development or impact our ability to modify our currently cleared products on a timely basis. Over the last several years, the FDA has proposed reforms to its 510(k) clearance process, and such proposals could include increased requirements for clinical data and a longer review period, or could make it more difficult for manufacturers to utilize the 510(k) clearance process for their products. For example, in November 2018, FDA officials announced forthcoming steps that the FDA intends to take to modernize the premarket notification pathway under Section 510(k) of the FDCA. Among other things, the FDA announced that it planned to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates. These proposals included plans to potentially sunset certain older devices that were used as predicates under the 510(k) clearance pathway, and to potentially publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. In May 2019, the FDA solicited public feedback on these proposals. The FDA requested public feedback on whether it should consider certain actions that might require new authority, such as whether to sunset certain older devices that were used as predicates under the 510(k) clearance pathway. These proposals have not yet been finalized or adopted, and the FDA may work with Congress to implement such proposals through legislation. Accordingly, it is unclear the extent to which any proposals, if adopted, could impose additional regulatory requirements on us that could delay our ability to obtain new 510(k) clearances, increase the costs of compliance, or restrict our ability to maintain our current clearances, or otherwise create competition that may negatively affect our business.

More recently, in September 2019, the FDA finalized guidance describing an optional “safety and performance based” premarket review pathway for manufacturers of “certain, well-understood device types” to demonstrate substantial equivalence under the 510(k) clearance pathway by showing that such device meets objective safety and performance criteria established by the FDA, thereby obviating the need, in the case of applicable products, for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. The FDA intends to develop and maintain a list device types appropriate for the “safety and performance based” pathway and will continue to develop product-specific guidance documents that identify the performance criteria for each such device type, as well as the testing methods recommended in the guidance documents, where feasible. The FDA may establish performance criteria for classes of devices for which we or our competitors seek or currently have received clearance, and it is unclear the extent to which such performance standards, if established, could impact our ability to obtain new 510(k) clearances or otherwise create competition that may negatively affect our business.

In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new statutes, regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of any future products or make it more difficult to obtain clearance or approval for, manufacture, market or distribute our products. We cannot determine what effect changes in regulations, statutes, legal interpretation or policies, when and if promulgated, enacted or adopted may have on our business in the future. Such changes could, among other things, require: additional testing prior to obtaining clearance or approval; changes to manufacturing methods; recall, replacement or discontinuance of our products; or additional record keeping.

The FDA’s and other regulatory authorities’ policies may change and additional government regulations may be promulgated that could prevent, limit or delay regulatory clearance or approval of our future products. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval or clearance that we may have obtained and we may not achieve or sustain profitability.

On April 5, 2017, the European Parliament passed the Medical Devices Regulation (Regulation 2017/745), which repeals and replaces the EU Medical Devices Directive. Unlike directives, which must be implemented into the national laws of the EEA member states, the regulations would be directly applicable, i.e., without the need for adoption of EEA member state laws implementing them, in all EEA member states and are intended to eliminate current differences in the regulation of medical devices among EEA member States. The Medical Devices Regulation, among other things, is intended to establish a uniform, transparent, predictable and sustainable regulatory framework across the EEA for medical devices and ensure a high level of safety and health while supporting innovation.

The Medical Devices Regulation will, however, only become applicable three years after publication (in 2020). Once applicable, the new regulations will, among other things:

- strengthen the rules on placing devices on the market and reinforce surveillance once they are available;
- establish explicit provisions on manufacturers' responsibilities for follow-up regarding the quality, performance and safety of devices placed on the market;
- improve the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- set up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU; and
- strengthened rules for the assessment of certain high-risk devices, which may have to undergo an additional check by experts before they are placed on the market.

These modifications may have an effect on the way we conduct our business in the EEA.

Healthcare reform laws could adversely affect our products and financial condition.

During the past several years, the U.S. healthcare industry has been subject to an increase in governmental regulation at both the federal and state levels. Efforts to control healthcare costs, including limiting access to care, alternative delivery models and changes in the methods used to determine reimbursement scenarios and rates, are ongoing at the federal and state government levels.

In March 2010, former President Obama signed into law the Patient Protection and Affordable Care Act, and the Health Care and Education Reconciliation Act of 2010 (collectively, the "ACA"), which included measures that significantly changed the way healthcare is financed by both governmental and private insurers. While a primary goal of these healthcare reform efforts was to expand coverage to more individuals, it also involved additional regulatory mandates and other measures designed to constrain medical costs. The ACA significantly impacts the medical device industry. Among other things, the ACA:

- Imposes an annual excise tax of 2.3% on any entity that manufactures or imports medical devices offered for sale in the United States, which, through a series of legislative amendments, was suspended, effective January 1, 2016 and subsequently repealed altogether on December 20, 2019;
- Establishes a new Patient-Centered Outcomes Research Institute to oversee and identify priorities in comparative clinical effectiveness research in an effort to coordinate and develop such research; and
- Implements Medicare payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models.

In addition, the ACA and related healthcare reform laws, regulations and initiatives have significantly increased regulation of managed care plans and decreased reimbursement under Medicare managed care. Moreover, to alleviate budget shortfalls, states have reduced or frozen payments to Medicaid managed care plans. We cannot accurately predict the complete impact of these healthcare reform initiatives, but they could lead to a decreased demand for medical devices and other outcomes that could adversely impact our business and financial results.

Some of the provisions of the ACA have yet to be fully implemented, and certain provisions have been subject to judicial and Congressional challenges. In addition, there have been efforts by the Trump administration to repeal or replace certain aspects of the ACA and to alter the implementation of the ACA and related laws. For example, the Tax Cuts and Jobs Act enacted on December 22, 2017, or TCJA, eliminated the shared responsibility payment for individuals who fail to maintain minimum essential coverage under section 5000A of the Internal Revenue Code of 1986, commonly referred to as the “individual mandate,” effective January 1, 2019. On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or the Texas District Court Judge, ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Cuts and Jobs Act, the remaining provisions of the ACA are invalid as well. This decision was subsequently appealed, and on December 18, 2019, the U.S. Court of Appeals for the Fifth Circuit affirmed the decision of the district court that the individual mandate, as amended by the TCJA, was unconstitutional. The Fifth Circuit remanded the case to the district court to consider a remedy, including to consider and explain which provisions of the ACA are inseverable and invalid. The U.S. Supreme Court is currently reviewing the case. A decision is expected during the current Supreme Court term in 2021, and the ACA remains in effect while judicial review of the decision is pending. It is unclear how this litigation, including all future hearings and appeals, and other efforts to challenge, repeal or replace the ACA, or portions thereof, will affect our future products or our business. It is possible that the ACA, as currently enacted or as it may be amended in the future, and other healthcare reform measures that may be adopted in the future, could have an adverse effect on our industry generally and on our ability to commercialize our future products and achieve profitability.

Disruptions at the FDA and other government agencies caused by funding shortages or global health concerns could hinder their ability to hire, retain or deploy key leadership and other personnel, or otherwise prevent new or modified products from being developed, cleared or approved or commercialized in a timely manner or at all, which could negatively impact our business.

The ability of the FDA to review and clear or approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA’s ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA’s ability to perform routine functions. Average review times at the FDA have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new medical devices or modifications to cleared or approved medical devices to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, including for 35 days beginning on December 22, 2018, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical FDA employees and stop critical activities.

Separately, in response to the COVID-19 pandemic, on March 10, 2020 the FDA announced its intention to postpone most inspections of foreign manufacturing facilities, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020 the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Risks Related to Employee Matters

Under applicable employment laws, we may not be able to enforce covenants not to compete and therefore may be unable to prevent our competitors from benefiting from the expertise of some of our former employees.

Our employment agreements generally include covenants not to compete. These agreements prohibit our employees, if they cease working for us, from competing directly with us or working for our competitors for a limited period. We may be unable to enforce these agreements under the laws of the jurisdictions in which our employees work at all or for a sufficient duration of time to prevent members of our management team from competing with us. For example, Israeli courts have required employers seeking to enforce covenants not to compete to demonstrate that the competitive activities of a former employee will harm one of a limited number of material interests of the employer, such as the secrecy of a company's confidential commercial information or the protection of its intellectual property. In Israel, if we cannot demonstrate that such an interest will be harmed, we may be unable to prevent our competitors from benefiting from the expertise of our former employees or consultants and our competitiveness may be diminished.

We may not be able to attract and retain the highly skilled employees we need to support our planned growth.

To continue to execute our business and our growth plan, we must attract and retain highly qualified personnel. Competition for these personnel is intense. We may not be successful in attracting and retaining qualified personnel. If we fail to attract new personnel or fail to retain and motivate our current personnel, our business, financial condition, results of operations and future growth prospects could be severely harmed.

Risks Related to Owning Our Ordinary Shares

Our share price may be volatile, and you may lose all or part of your investment.

The market price for our shares may be volatile and subject to wide fluctuations in response to factors including the following:

- actual or anticipated fluctuations in results of operations;
- actual or anticipated changes in our growth rate relative to our competitors, as well as announcements by us or our competitors of significant business developments, changes in relationships with our target customers, manufacturers or suppliers, acquisitions or expansion plans;
- failure to meet or exceed financial estimates and projections of the investment community or that we provide to the public, as well as variance in our financial performance from the expectations of market analysts;
- issuance of new or updated research reports or short reports by securities analysts or other market participants;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- additions or departures of key management or other personnel;
- our involvement in litigation, including the securities class-action;
- disputes or other developments related to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technology;
- announcement or expectation of additional debt or equity financing efforts;
- sales of our ordinary shares or other securities by us, our insiders or our other shareholders, or the perception that these sales may occur in the future;
- the trading volume of our ordinary shares;
- market conditions in our industry;
- changes in the estimation of the future size and growth rate of our markets; and
- general economic, market or political conditions in the United States or elsewhere.

In particular, the market prices of pre-commercial-stage companies like ours have been highly volatile due to factors, including, but not limited to:

- our ability to develop and commercialize our technology and future products or services;
- developments or disputes concerning our product's intellectual property rights;
- our or our competitors' technological innovations;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- announcements by us or our competitors of significant contracts, acquisitions, strategic partnerships, joint ventures, capital commitments, new technologies or patents;
- failure to complete significant transactions or collaborate with vendors in manufacturing our product; and
- proposals for legislation that would place restrictions on the price of medical therapies.

These and other market and industry factors may cause the market price and demand for our ordinary shares to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from readily selling their ordinary shares and may otherwise negatively affect the liquidity of our ordinary shares. In addition, the stock market in general, and Nasdaq Global Market and emerging growth companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Such broad market fluctuations, and other factors (such as variations in quarterly and yearly operating results, general trends in the medical imaging industry, and changes in state, federal or other applicable regulations affecting us and our industry) may adversely affect the market price of our ordinary shares, if a market for them develops.

In the past, when the market price of shares has been volatile, holders of those shares have instituted securities class action litigation against the company that issued the shares. If any of our shareholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert resources and the time and attention of our management.

We are an “emerging growth company” under the JOBS Act and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies will make our ordinary shares less attractive to investors.

We are an “emerging growth company,” as defined in the JOBS Act, and for so long as we continue to be an “emerging growth company” we may take advantage of certain exemptions from various reporting requirements that are applicable to other public companies that are not “emerging growth companies” including, but not limited to, not being required to comply with the auditor attestation requirements of section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a non-binding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. In addition, under the JOBS Act, emerging growth companies can delay adopting new or revised financial accounting standards until such time as those standards apply to private companies. We have elected to “opt out” of this provision and, as a result, we will comply with new or revised accounting standards as required when they are adopted for public companies.

Our status as an “emerging growth company” under the JOBS Act may make it more difficult to raise capital as and when we need it.

Because of the exemptions from various reporting requirements provided to us as an “emerging growth company,” we may be less attractive to investors and it may be difficult for us to raise additional capital as and when we need it. Investors may be unable to compare our business with other companies in our industry if they believe that our reporting is not as transparent as the reporting of other companies in our industry. If we are unable to raise additional capital as and when we need it, our financial condition and results of operations may be materially and adversely affected.

We will remain an emerging growth company until the earliest of: (i) the last day of our fiscal year during which we have total annual gross revenue of at least \$1.07 billion; (ii) December 31, 2025; (iii) the date on which we have, during the previous three-year period, issued more than \$1.0 billion in non-convertible debt; or (iv) the date on which we are deemed to be a “large accelerated filer” under the Exchange Act. Once we cease to be an emerging growth company, we will not be entitled to the exemptions provided to emerging growth companies under the JOBS Act.

As a foreign private issuer, we are exempt from certain requirements that apply to domestic issuers and we are permitted to follow certain home country corporate governance practices instead of applicable SEC and Nasdaq requirements, which may result in less protection than is accorded to shareholders under rules applicable to domestic issuers.

We report under the Exchange Act as a non-U.S. company with foreign private issuer status. Because we qualify as a foreign private issuer under the Exchange Act, we are exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including (1) the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act, (2) the sections of the Exchange Act requiring insiders to file public reports of their share ownership and trading activities and liability for insiders who profit from trades made in a short period of time and (3) the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, although we intend to furnish comparable quarterly information on Form 6-K. In addition, foreign private issuers are not required to file their annual report on Form 20-F until 120 days after the end of each fiscal year, while U.S. domestic issuers that are accelerated filers are required to file their annual report on Form 10-K within 75 days after the end of each fiscal year and U.S. domestic issuers that are large accelerated filers are required to file their annual report on Form 10-K within 60 days after the end of each fiscal year. Foreign private issuers are also exempt from Regulation FD, which is intended to prevent issuers from making selective disclosures of material information.

In addition, as a foreign private issuer, we will be permitted to follow certain home country corporate governance practices instead of those otherwise required under the listing rules of the Nasdaq Stock Market for domestic issuers. For instance, we may follow home country practice in Israel with regard to, among other things, composition of the board of directors, director nomination procedure, approval of compensation of officers, and quorum at shareholder meetings. For example, under Israeli law, as currently applicable to us, there is no requirement for a majority of our directors to be independent. In addition, we may follow our home country law, instead of the listing rules of the Nasdaq Stock Market, which require that we obtain shareholder approval for certain dilutive events, such as for the establishment or amendment of certain equity based compensation plans, an issuance that will result in a change of control of the company, certain transactions other than a public offering involving issuances of a 20% or more interest in the company and certain acquisitions of the stock or assets of another company.

As a result of all of the above, you may not have the same protections afforded to shareholders of a company that is not a foreign private issuer.

We may lose our foreign private issuer status which would then require us to comply with the Exchange Act’s domestic reporting regime and cause us to incur significant legal, accounting and other expenses.

As discussed above, we are a foreign private issuer and therefore we are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers. We will remain a foreign private issuer until our board determines that we no longer meet the qualification set forth in Securities Act Rule 405 and Exchange Act Rule 3b-4, with such determinations to be made on an annual basis as of the end of our second fiscal quarter. In order to maintain our current status as a foreign private issuer, either (a) a majority of our ordinary shares must be either directly or indirectly owned of record by non-residents of the United States or (b)(i) a majority of our executive officers or directors must not be U.S. citizens or residents, (ii) more than 50 percent of our assets cannot be located in the United States and (iii) our business must be administered principally outside the United States. If we lose this status, we would be required to comply with the Exchange Act reporting and other requirements applicable to U.S. domestic issuers, which are more detailed and extensive than the requirements for foreign private issuers. We may also be required to make changes in our corporate governance practices in accordance with various SEC and Nasdaq rules. The regulatory and compliance costs to us under U.S. securities laws if we are required to comply with the reporting requirements applicable to a U.S. domestic issuer may be significantly higher than the costs we would incur as a foreign private issuer. As a result, we expect that a loss of foreign private issuer status would increase our legal and financial compliance costs and would make some activities highly time consuming and costly. We also expect that if we were required to comply with the rules and regulations applicable to U.S. domestic issuers, it would make it more difficult and expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified members of our board of directors.

We have not paid dividends in the past and have no immediate plans to pay dividends.

We plan to reinvest all of our future earnings, to the extent we have earnings, in order to develop and commercialize our technology and products and to cover operating costs, finance operations and to otherwise become and remain competitive. We have never declared or paid any dividends on our ordinary shares and we do not plan to pay any cash dividends with respect to our securities in the foreseeable future. As we are a development-stage company with limited operating history, we may not be able to generate, at any time, sufficient surplus cash that would be available for distribution to the holders of our ordinary shares as a dividend. Therefore, you should not expect to receive cash dividends on the ordinary shares we are offering. Consequently, investors may need to rely on sales of their ordinary shares after price appreciation, which may never occur, as the only way to realize any future gains on their investment. In addition, the Companies Law imposes restrictions on our ability to declare and pay dividends. See “Item 8. Financial Information—A. Consolidated Statements and Other Financial Information—Dividend Policy” for additional information.

We incur significant increased costs as a result of operating as a public company that reports to the SEC and our management may be required to devote substantial time to meet compliance obligations.

As a public company reporting to the SEC, we incur significant legal, insurance, director compensation, accounting and other expenses that we did not incur as a private company. We are subject to reporting requirements of the Exchange Act and the Sarbanes-Oxley Act, as well as rules subsequently implemented by the SEC that impose significant requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls and changes in corporate governance practices. In addition, the Dodd-Frank Wall Street Reform and Consumer Protection Act (the “Dodd-Frank Act”) imposes various other requirements on public companies. There are significant corporate governance and executive compensation-related provisions in the Dodd-Frank Act that may increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and may also place undue strain on our personnel, systems and resources. Our management and other personnel may need to devote a substantial amount of time to these compliance initiatives. In addition, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. As a result, it may be more difficult and expensive for us to attract and retain qualified people to serve on our board of directors, our board committees or as executive officers.

We also incur costs associated with corporate governance requirements, including requirements under rules implemented by the SEC and the Nasdaq Global Market, and provisions of Israeli corporate law applicable to public companies. These rules and regulations will increase our legal and financial compliance costs, introduce costs such as investor relations and stock exchange listing fees, and make some activities more time-consuming and costly. Our board and other personnel may need to devote a substantial amount of time to these initiatives. For example, if required by the Companies Law, our board of directors must include at least two external directors who must be nominated within three months of the closing of the initial public offering, and our audit committee and compensation committee must consist of a majority of independent directors. We exceeded this three-month period. However, our shareholders approved the appointment of two external directors during the shareholder meeting in February 2021 and as a result we are now in compliance with the Companies Law. To the extent we are not in compliance with the Companies Law or Nasdaq Global Market rules, we may be subject to additional costs or delisting. We are continuously evaluating and monitoring developments with respect to these rules, and we cannot estimate the amount of additional costs we may incur or the timing of such costs.

As an “emerging growth company,” as defined in the JOBS Act, we may take advantage of certain temporary exemptions from various reporting requirements, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act (and the rules and regulations of the SEC thereunder). When these exemptions cease to apply, we expect to incur additional expenses and devote increased management effort toward ensuring compliance with them. We cannot estimate the amount of additional costs we may incur as a result of being a public company or the timing of such costs.

Pursuant to Section 404 of the Sarbanes-Oxley Act and the related rules adopted by the SEC and the Public Company Accounting Oversight Board, starting with the second annual report that we file with the SEC, our management will be required to report on the effectiveness of our internal control over financial reporting. In addition, once we no longer qualify as an “emerging growth company” under the JOBS Act and lose the ability to rely on the exemptions related thereto discussed above and depending on our status as per Rule 12b-2 of the Exchange Act, our independent registered public accounting firm may also need to attest to the effectiveness of our internal control over financial reporting under Section 404. Irrespective of compliance with Section 404, any failure of our internal controls could have a material adverse effect on our stated results of operations and harm our reputation. As a result, we may experience higher than anticipated operating expenses, as well as higher independent auditor fees during and after the implementation of these changes. If we are unable to implement any of the required changes to our internal control over financial reporting effectively or efficiently or are required to do so earlier than anticipated, it could adversely affect our operations, financial reporting and/or results of operations and could result in an adverse opinion on internal controls from our independent auditors.

Shares eligible for future sale may adversely affect the market for our ordinary shares and the issuance of additional ordinary shares as a result of the exercise of our outstanding warrants and options will dilute the percentage ownership of our other shareholders.

From time to time, certain of our shareholders are eligible to sell all or some of their ordinary shares by means of ordinary brokerage transactions in the open market pursuant to Rule 144, promulgated under the Securities Act, subject to certain limitations. In general, pursuant to Rule 144, non-affiliate shareholders may sell freely after six months subject only to the current public information requirement (which disappears after one year). Of the 47,378,183 ordinary shares outstanding as of March 20, 2021, approximately 33,546,098 ordinary shares have been registered under the Securities Act and are freely transferable by persons other than our “affiliates” without restriction or additional registration; the remaining shares outstanding have not been registered under the Securities Act and may be offered or sold only pursuant to an effective registration statement or pursuant to an available exemption from the registration requirements. As of March 20, 2021, approximately 4,585,726 of our ordinary shares are held by “non-affiliates” and are freely tradable without restriction pursuant to Rule 144, although the shareholders who participated in our secondary offering consummated in February 2021 are subject to the lock-up agreements entered into in connection with such offering. In addition, certain shareholders have the ability to cause us to register the resale of their shares under the Registration Rights Agreement (as defined below) or the terms of certain warrants. See “Item 10. Additional Information—C. Material Contracts” for a description of the registration rights. Any substantial sale of our ordinary shares pursuant to Rule 144 or pursuant to any resale prospectus may have a material adverse effect on the market price of our ordinary shares.

In addition, as of March 20, 2021, there were 13 outstanding warrants to purchase a total of 2,838,496 ordinary shares with exercise prices ranging from \$0.01 per share to \$20.87 per share. As of December 31, 2020, there were 4,689,800 ordinary shares issuable upon the exercise of options to purchase ordinary shares outstanding under our 2019 Equity Incentive Plan (as defined below), at a weighted average exercise price of \$5.73 per share, and 2,978,247 additional ordinary shares reserved for future issuance under our 2019 Equity Incentive Plan. The warrants are exercisable immediately and expire on various dates. More convertible securities may be granted in the future to the Company’s officers, directors, employees or consultants or as part of future financings. The exercise of outstanding stock options and warrants and conversion of notes and debentures will dilute the percentage ownership of the Company’s other shareholders.

The purchase price of the ordinary shares may not reflect our actual value.

The price of our ordinary shares may not be indicative of our actual value or any future market price for our securities. This price may not accurately reflect the value of the ordinary shares or the value that potential investors will realize upon their disposition of ordinary shares. The price does not necessarily bear any relationship to our assets, earnings, book value per share or other generally accepted criteria of value.

If equity research analysts discontinue research or reports about us or our business or if they issue unfavorable commentary or downgrade our ordinary shares, or if other market participants such as short sellers issue unfavorable reports about us, the price of our ordinary shares could decline.

The trading market for our ordinary shares relies in part on the research and reports that equity research analysts publish about us and our business. The analysts' estimates are based upon their own opinions and are often different from our estimates or expectations. If our results of operations are below the estimates or expectations of public market analysts and investors, the price of our ordinary shares could decline. Moreover, the price of our ordinary shares could decline if one or more securities analysts downgrade our ordinary shares or if those analysts issue other unfavorable commentary or cease publishing reports about us or our business.

We have identified material weaknesses in our internal control over financial reporting that could, if not remediated, result in material misstatements in our financial statements. If we fail to maintain an effective system of internal control over financial reporting, we may not be able to accurately report our financial results or prevent fraud. As a result, shareholders could lose confidence in our financial and other public reporting, which would harm our business and the trading price of our ordinary shares.

Effective internal controls over financial reporting are necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures are designed to prevent fraud. Our management will be required to assess the effectiveness of our internal controls and procedures and disclose changes in these controls on an annual basis. However, for as long as we are an "emerging growth company" under the JOBS Act, our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting pursuant to Section 404.

Any failure to implement required new or improved controls, or difficulties encountered in their implementation could cause us to fail to meet our reporting obligations. In addition, any testing by us conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, may reveal deficiencies in our internal controls over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our ordinary shares.

We have identified a material weakness in our internal control over financial reporting in connection with the audit of our financial statements as of and for the years ended December 31, 2019 and 2020. As defined in Regulation 12b-2 under the Exchange Act, a "material weakness" is a deficiency, or combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual financial statements will not be prevented, or detected on a timely basis. Specifically, we determined that the material weakness is related to having an insufficient number of financial reporting personnel with an appropriate level of knowledge, experience and training in application of U.S. GAAP and SEC rules and regulations commensurate with our reporting requirements.

We have taken action toward remediating this material weakness by hiring additional qualified personnel with U.S. GAAP accounting and reporting experience in order to improve our ability to have effective internal control over financial reporting, and we intend to provide enhanced training to existing financial and accounting employees on related U.S. GAAP issues. In addition, to remediate this material weakness, we are implementing measures including the following:

- we have hired a corporate controller with U.S. GAAP and SEC reporting experience, an internal auditor (part-time) and a financial planning and analysis professional and are continuing to seek additional financial professionals to increase the number of qualified financial reporting personnel and to strengthen our finance department;
- we are selecting and implementing a new enterprise resource planning system;

- we are developing, communicating and implementing an accounting policy manual for our financial reporting personnel for recurring transactions and period-end closing processes; and
- we are establishing monitoring and oversight controls for non-recurring and complex transactions to ensure the accuracy and completeness of our consolidated financial statements and related disclosures.

However, the material weakness will not be considered remediated until our applicable controls will have been implemented and operating for a sufficient period of time and our management, including the Chief Financial Officer and Chief Executive Officer, have assessed and concluded, through testing, that these controls are operating effectively.

These controls and other procedures are designed to ensure that information required to be disclosed by us in the reports that we file with the SEC is disclosed accurately and is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms.

Even if we develop effective internal control over financial reporting, these controls may become inadequate because of changes in conditions or the degree of compliance with these policies or procedures may deteriorate, and material weaknesses and deficiencies may be discovered in them. We are working with our legal and financial advisors to identify those areas in which changes should be made to our financial and management control systems to manage our growth and our obligations as a public company. These areas include corporate governance, corporate control, disclosure controls and procedures and financial reporting.

We have made, and will continue to make, changes in these and other areas. In any event, the process of determining whether our existing internal controls are compliant with Section 404 and sufficiently effective will require the investment of substantial time and resources, including by our chief financial officer and other members of our senior management. As a result, this process may divert internal resources and take a significant amount of time and effort to complete, even more so after we are no longer an “Emerging Growth Company.” In addition, we cannot predict the outcome of this process and whether we will need to implement remedial actions in order to implement effective controls over financial reporting. The determination of whether or not our internal controls are sufficient and any remedial actions required could result in us incurring additional costs that we did not anticipate, including the hiring of outside consultants. We may also fail to complete our evaluation, testing and any required remediation needed to comply with Section 404 in a timely fashion. Irrespective of compliance with Section 404, any additional failure of our internal controls could have a material adverse effect on our stated results of operations and harm our reputation. As a result, we may experience higher than anticipated operating expenses, as well as higher independent auditor fees during and after the implementation of these changes. If we are unable to implement any of the required changes to our internal control over financial reporting effectively or efficiently or are required to do so earlier than anticipated, it could adversely affect our operations, financial reporting or results of operations and could result in an adverse opinion on internal controls from our independent auditors.

Furthermore, if we are unable to certify that our internal control over financial reporting is effective and in compliance with Section 404, we may be subject to sanctions or investigations by regulatory authorities, such as the SEC or stock exchanges, and we could lose investor confidence in the accuracy and completeness of our financial reports, which could hurt our business, the price of our ordinary shares and our ability to access the capital markets.

We believe that we will technically be classified as a passive foreign investment company, or PFIC, for U.S. federal income tax purposes for our taxable year ended December 31, 2020, for the current taxable year and possibly for future taxable years, which could result in adverse U.S. federal income tax consequences to U.S. Holders of our ordinary shares.

A non-U.S. corporation will be a PFIC for any taxable year if either (1) at least 75% of its gross income for such year consists of certain types of passive income; or (2) at least 50% of the value of its assets (generally determined based on an average of the quarterly values of the assets) during such year is attributable to assets that produce passive income or are held for the production of passive income. For this purpose, cash and assets readily convertible into cash are categorized as passive assets and our goodwill and other unbooked intangibles will generally be taken into account in determining our asset value.

A non-U.S. corporation's PFIC status is a factual determination made annually after the close of each taxable year. Prior to the commercialization of our medical imaging technology, passive income could constitute more than 75% of gross income for any taxable year. Consequently, we believe that we will technically be classified as a PFIC for the taxable year ended December 31, 2020. Depending upon the composition of our income and assets and the market price of our ordinary shares during 2021 and subsequent taxable years and whether we start generating a substantial amount of active revenue, we could continue to be classified as a PFIC for 2021 and subsequent taxable years if we are classified as a PFIC for 2020. In addition, it is possible that any subsidiary that we own would also be classified as a PFIC for such taxable years.

If we were classified as a PFIC for any taxable year during which a U.S. Holder (as defined below) holds our ordinary shares, certain adverse U.S. federal income tax consequences could apply to such U.S. Holder. See "Item 10. Additional Information—E. Taxation—U.S. Federal Income Tax Considerations."

Risks Related to Our Operations in Israel

Conditions in Israel could materially and adversely affect our business.

Our executive offices are located in Neve Ilan, Israel. In addition, a number of our officers and directors are residents of Israel. Accordingly, political, economic and military conditions in Israel and the surrounding region may directly affect our business and operations. Since the establishment of the State of Israel in 1948, a number of armed conflicts have taken place between Israel and its neighboring countries, as well as terrorist acts committed within Israel by hostile elements. During the last decade, there have been extended hostilities in 2009, 2012 through 2014, with additional small flare-ups as recently as 2018 and 2019.

Since February 2011, Egypt has experienced political turbulence and an increase in terrorist activity in the Sinai Peninsula. Such political turbulence and violence may damage peaceful and diplomatic relations between Israel and Egypt, and could affect the region as a whole. Similar civil unrest and political turbulence has occurred in other countries in the region, including Syria, which shares a common border with Israel, and is affecting the political stability of those countries. Since April 2011, internal conflict in Syria has escalated and chemical weapons have been used in the region. Foreign actors have intervened and may continue to intervene in Syria. This instability and any intervention may lead to deterioration of the political and economic relationships that exist between the State of Israel and some of these countries and may lead to additional conflicts in the region. In addition, Iran has threatened to attack Israel and may be developing nuclear weapons. Iran also has a strong influence among extremist groups in the region, including Hamas in Gaza, Hezbollah in Lebanon and various rebel militia groups in Syria. These situations have escalated at various points in recent years and may escalate in the future to more violent events, which may affect Israel and us. Any armed conflicts, terrorist activities or political instability in the region could adversely affect business conditions and could harm our results of operations and could make it more difficult for us to raise capital. In addition, the political and security situation in Israel may result in parties with whom we have agreements involving performance in Israel claiming that they are not obligated to perform their commitments under those agreements pursuant to force majeure provisions in such agreements.

We currently do not, and we do not expect to, carry any commercial insurance that covers losses resulting from events associated with war and terrorism. Although the Israeli government currently covers the reinstatement value of direct damages that are caused by terrorist attacks or acts of war, we cannot be assured that this government coverage will be maintained or, if maintained, that it will be sufficient to compensate us fully for damages incurred and the government may cease providing such coverage or the coverage might not suffice to cover potential damages. Any losses or damages incurred by us could have a material adverse effect on our business. Any armed conflicts or political instability in the region would likely negatively affect business conditions and could harm our results of operations.

Further, in the past, the State of Israel and Israeli companies have been subjected to economic boycotts. Several countries still restrict business with the State of Israel and with Israeli companies. These restrictive laws and policies may have an adverse impact on our operating results, financial condition or the expansion of our business. A campaign of boycotts, divestment and sanctions has been undertaken against Israel, which could also adversely impact our business.

In addition, many Israeli citizens are obligated to perform several days, and in some cases more, of annual military reserve duty each year until they reach the age of 40 (or older for certain reservists) and, in the event of a military conflict, may be called to active duty. In response to increases in terrorist activity, there have been periods of significant call-ups of military reservists. It is possible that there will be military reserve duty call-ups in the future. Our operations could be disrupted by such call-ups, which may include the call-up of members of our management. Such disruption could materially adversely affect our business, prospects, financial condition and results of operations.

The termination or reduction of tax and other incentives that the Israeli government provides to Israeli companies may increase our costs and taxes.

The Israeli government currently provides tax and capital investment incentives to Israeli companies, as well as grant and loan programs relating to research and development and marketing and export activities (see “Item 10. Additional Information—E. Taxation—Israeli Tax Considerations and Government Programs”). In recent years, the Israeli government has reduced the benefits available under these programs and the Israeli governmental authorities may in the future further reduce or eliminate the benefits of these programs. We may take advantage of these benefits and programs in the future; however, there can be no assurance that such benefits and programs will be available to us. If we qualify for such benefits and programs and fail to meet the conditions thereof, the benefits could be canceled and we could be required to refund any benefits we might already have enjoyed and become subject to penalties. Additionally, if we qualify for such benefits and programs and they are subsequently terminated or reduced, it could have an adverse effect on our financial condition and results of operations.

It may be difficult to enforce a U.S. judgment against us, our officers and directors named in this annual report on Form 20-F in Israel or the United States, or to assert U.S. securities laws claims in Israel or serve process on our officers and directors.

Many of our directors and officers are not residents of the United States and a significant portion of their and our assets are located outside the United States. Service of process upon us or our non-U.S. resident directors and officers may be difficult to obtain within the United States. We have been informed by our legal counsel in Israel that it may be difficult to assert claims under U.S. securities laws in original actions instituted in Israel or obtain a judgment based on the civil liability provisions of U.S. federal securities laws. Israeli courts may refuse to hear a claim based on a violation of U.S. securities laws against us or our directors and officers because Israel may not be the most appropriate forum to bring such a claim. In addition, even if an Israeli court agrees to hear a claim, it may determine that Israeli law and not U.S. law is applicable to the claim. If U.S. law is found to be applicable, the content of applicable U.S. law must be proved as a fact, which can be a time-consuming and costly process. Certain matters of procedure will also be governed by Israeli law. There is little binding case law in Israel addressing the matters described above. Additionally, Israeli courts might not enforce judgments obtained in the United States against us or our directors and officers, which may make it difficult to collect on judgments rendered against us or our directors and officers.

Moreover, an Israeli court will not enforce a non-Israeli judgment if it was given in a state whose laws do not provide for the enforcement of judgments of Israeli courts (subject to exceptional cases), if its enforcement is likely to prejudice the sovereignty or security of the State of Israel, if it was obtained by fraud or in the absence of due process, if it is at variance with another valid judgment that was given in the same matter between the same parties, or if a suit in the same matter between the same parties was pending before a court or tribunal in Israel at the time the foreign action was brought.

Your rights and responsibilities as our shareholder will be governed by Israeli law, which may differ in some respects from the rights and responsibilities of shareholders of U.S. corporations.

We are incorporated under Israeli law. The rights and responsibilities of holders of our ordinary shares are governed by our amended and restated articles of association and the Companies Law. These rights and responsibilities differ in some respects from the rights and responsibilities of shareholders in typical U.S. corporations. In particular, pursuant to the Companies Law, each shareholder of an Israeli company has to act in good faith and in a customary manner in exercising his or her rights and fulfilling his or her obligations toward the company and other shareholders and to refrain from abusing his or her power in the company, including, among other things, in voting at the general meeting of shareholders on amendments to a company's articles of association, increases in a company's authorized share capital, mergers and certain transactions requiring shareholders' approval under the Companies Law. In addition, under Israeli law, a controlling shareholder of an Israeli company or a shareholder who knows that it possesses the power to determine the outcome of a shareholder vote or who has the power to appoint or prevent the appointment of a director or officer in the company or has other powers toward the company has a duty of fairness toward the company. However, Israeli law does not define the substance of this duty of fairness. There is little case law available in Israel to assist in understanding the implications of these provisions that govern shareholder behavior.

Our amended and restated articles of association contains exclusive forum provisions for certain claims, which could limit our shareholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated articles of association provides that the federal district courts of the United States of America will, to the fullest extent permitted by law, be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act (the "Federal Forum Provision"). Our decision to adopt a Federal Forum Provision followed a decision by the Supreme Court of the State of Delaware holding that such provisions are facially valid under Delaware law. While there can be no assurance that U.S. federal or state courts or Israeli courts will follow the holding of the Delaware Supreme Court or determine that the Federal Forum Provision should be enforced in a particular case, application of the Federal Forum Provision means that suits brought by our shareholders to enforce any duty or liability created by the Securities Act must be brought in federal court and cannot be brought in state court. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all claims brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder and the Federal Forum Provision does not apply to suits brought to enforce any duty or liability created by the Exchange Act. Accordingly, actions by our shareholders to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder must also be brought in federal court. Our shareholders will not be deemed to have waived our compliance with the federal securities laws and the regulations promulgated thereunder.

Any person or entity purchasing or otherwise acquiring or holding any interest in any of our securities shall be deemed to have notice of and consented to the Federal Forum Provision. This provision may limit our shareholders' ability to bring a claim in a judicial forum they find favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. Alternatively, if a court were to find the choice of forum provision contained in our amended and restated articles of association to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could harm our business, operating results and financial condition.

Provisions of our amended and restated articles of association and Israeli law and tax considerations may delay, prevent or make difficult an acquisition of us, which could prevent a change of control and negatively affect the price of our ordinary shares.

Israeli corporate law regulates mergers, requires tender offers for acquisitions of shares if such acquisitions cause the acquirer to hold more than specified thresholds, requires special approvals for certain transactions involving directors, officers or significant shareholders and regulates other matters that may be relevant to these types of transactions. For example, under Israeli law, a merger may not be consummated unless at least 50 days have passed from the date that a merger proposal was filed by each merging company with the Israel Registrar of Companies and at least 30 days have passed from the date that the shareholders of both merging companies approved the merger.

Furthermore, Israeli tax considerations may make potential transactions unappealing to us or to our shareholders, especially for those shareholders whose country of residence for tax purposes does not have a tax treaty with Israel which exempts such shareholders from Israeli tax. For example, Israeli tax law does not recognize tax-free share exchanges to the same extent as U.S. tax law. With respect to mergers, Israeli tax law allows for tax deferral in certain circumstances but makes the deferral contingent on the fulfillment of a number of conditions, including, in some cases, a holding period of two years from the date of the transaction during which sales and dispositions of shares of the participating companies are subject to certain restrictions. Moreover, with respect to certain share swap transactions, the tax deferral is limited in time, and when such time expires, the tax becomes payable even if no disposition of the shares has occurred. In order to benefit from the tax deferral, a pre-ruling from the Israeli Tax Authority may be required.

These provisions of Israeli law and Israeli tax laws may delay, prevent or make difficult a merger with, or an acquisition of us, or all or a significant portion of our assets, which could prevent a change of control and may make it more difficult for a third party to acquire us, even if doing so would be beneficial to our shareholders. These provisions may limit the price that investors may be willing to pay in the future for our ordinary shares and therefore depress the price of our shares.

Our amended and restated articles of association provide that our directors (other than external directors) are elected on a staggered basis, such that a potential acquirer cannot readily replace our entire board of directors at a single annual general shareholder meeting.

Item 4. Information on the Company

A. History and Development of the Company

NANO-X IMAGING LTD was incorporated under the laws of the State of Israel on December 20, 2018 and commenced operations on September 3, 2019.

Substantially all of our assets at the time of commencement of our operations were acquired or assigned (the “Asset Purchase”) from our predecessor company, Nanox Imaging PLC (“Nanox Gibraltar”), a Gibraltar public company, under an Asset Purchase Agreement, dated as of September 3, 2019 and as amended on December 3, 2019 and December 31, 2019, between Nanox Gibraltar and us. Pursuant to the Asset Purchase Agreement, substantially all of the assets of Nanox Gibraltar, including all patents, patent applications and all other intellectual property rights, but not including the shares of Nanox Japan, Inc., a wholly owned subsidiary of Nanox Gibraltar (“Nanox Japan (predecessor)”), were sold to the Company for an aggregate consideration of \$13.3 million, reflecting the fair market value of the transferred assets, which was estimated to be \$6.1 million (excluding cash) based on an independent valuation report, plus the cash balance less \$200,000, which cash amount totaled \$7.2 million as of the date of the Asset Purchase Agreement.

Under the terms of the Asset Purchase Agreement, the consideration for the transferred assets will be paid only on the occurrence of one of the following events: (a) the closing of a transaction involving the sale of all or substantially all of the Company’s assets; (b) the acquisition of the Company by, or the merger of the Company with, another entity, consolidation, reorganization, recapitalization, sale, assignment or disposal by the Company of all or substantially all of the issued and outstanding shares of the Company; (c) the transfer, sale, lease, grant or other disposition of or the grant of an exclusive license over all or substantially all of Company’s assets, including, but not limited to, intellectual property, with the same economic effect to that of a sale and/or cessation of its business; (d) any other transaction, except for a financing round, following which the shareholders of the Company prior to the closing of such transaction own, directly or indirectly, less than 50% of the voting power of the surviving entity; (e) the closing of the first underwritten public offering of the Company pursuant to a registration statement under the Securities Act or the Securities Law (or under equivalent securities law of another jurisdiction) or any other securities laws world-wide with the same effects and results; and (f) an equity financing of the Company at a minimum pre-money valuation of \$100.0 million, with proceeds to the Company of at least \$30.0 million. In the events of (e) or (f) above, the Company will have the option to pay the consideration in cash or by the issuance to Nanox Gibraltar of the Company’s securities of the same series to be issued upon such event, in an amount reflecting a 25% discount on the price per share to be determined in connection with (e) and (f) above. If the Company elects to pay such consideration in cash, Nanox Gibraltar will have the right, at its sole discretion and in good faith, to reject such payment in cash, and require that the Company pay such consideration in the form of the Company’s securities in such amount and with such discount described above. In connection with this, the Company recorded a related party liability in an amount of \$17.8 million in its financial statements as of and for the year ended December 31, 2019.

In January 2020, the board of directors of the Company and the board of directors and shareholders of Nanox Gibraltar approved the issuance of shares in accordance with the terms of the Asset Purchase Agreement described above. As a result, 1,109,245 of the Company's ordinary shares were issued to Nanox Gibraltar, representing an aggregate consideration of approximately \$17.8 million, and the Company has no further obligations to Nanox Gibraltar under the Asset Purchase Agreement.

Our principal executive offices are located at Communications Center, Neve Ilan, Israel 9085000, and our telephone number is +972 02 995 0506. Our website address is <http://www.nanox.vision>. The information contained therein or connected thereto shall not be deemed to be incorporated into this annual report on Form 20-F. Our agent for service of process in the United States is CT Corporation System.

Private Placement and Public Offerings

From December 2019 through August 2020, we entered into share purchase agreements with certain investors (together, the "Investors"), under which we sold an aggregate of 4,937,000 ordinary shares to the Investors, at a price per share of \$16.00, for an aggregate purchase price, before fees and expenses, of approximately \$79 million (the "Private Placement"). As part of the Private Placement, we sold 312,500 ordinary shares to Foxconn Singapore Pte Ltd. for an aggregate purchase price of approximately \$5 million, 1,250,000 ordinary shares to SK Telecom TMT Investment Corp. ("SKT") for an aggregate purchase price of \$20 million, 375,000 ordinary shares to certain funds affiliated with Industrial Alliance Investment Management Inc., a Canadian-based financial institution, for an aggregate purchase price of approximately \$6 million, and 2,512,000 ordinary shares to Yozma for an aggregate purchase price of \$40.2 million, in each case before fees and expenses.

On August 25, 2020, we completed our initial public offering of 10,555,556 ordinary shares at a public offering price of \$18 per share, including 1,376,812 additional ordinary shares purchased by the underwriters at the public offering price, less the underwriting discount, pursuant to the exercise in full of their option to purchase additional ordinary shares. Our ordinary shares are listed on the NASDAQ Global Market under the symbol "NNOX."

On February 10, 2021, certain of our shareholders sold an aggregate of 3,091,635 ordinary shares in a public offering pursuant to an Underwriting Agreement by and among us, Cantor Fitzgerald & Co., acting as representative of the underwriters, and the selling shareholders named therein (the "Selling Shareholders"). We did not receive any of the proceeds from the sale of ordinary shares offered by the Selling Shareholders. The Selling Shareholders entered into new lock-up agreements with Cantor Fitzgerald & Co. pursuant to which, subject to certain exceptions, the Selling Shareholders agreed not to sell or otherwise dispose of ordinary shares or any securities convertible into or exchangeable for ordinary shares for a period of 90 days after February 16, 2021 without the prior written consent of Cantor Fitzgerald & Co. In addition, the Selling Shareholders agreed not to sell or otherwise dispose of ordinary shares or any securities convertible into or exchangeable for ordinary shares in an amount that exceeds one third of the remaining ordinary shares or any securities convertible into or exchangeable for ordinary shares such persons hold during each of the subsequent 30-day periods for a total of 90 days without the prior written consent of Cantor Fitzgerald & Co. None of our directors and officers entered into lockup agreements in connection with this offering.

B. Business Overview

Overview

Early detection saves lives—and we at Nanox are focused on applying our proprietary medical imaging technology to make diagnostic medicine more accessible and affordable across the globe. Our vision is to increase early detection of medical conditions that are discoverable by X-ray, which we believe is key to increasing early treatment, improving health outcomes and, ultimately, saving lives.

As a first step to producing a new class of affordable medical imaging systems, we have focused on identifying and developing a novel X-ray source. Our X-ray source is based on a novel digital MEMs semiconductor cathode that we believe can achieve the same functionalities as legacy X-ray analog cathodes, while allowing for lower-cost production than existing medical imaging systems. We developed this technology over eight years to reach commercial applicability. This novel digital X-ray source is the basis of core technology in the Nanox.ARC, the imaging system we are developing, and we believe it also has the potential to replace the legacy X-ray source in other existing imaging systems.

Our solution, which we refer to as the Nanox System, has two integrated components—hardware (Nanox.ARC) and software (Nanox.CLOUD). We have developed a working prototype of the Nanox.ARC, a medical imaging system incorporating our novel digital X-ray source. Subject to receiving regulatory clearance, the first version of the Nanox.ARC that we expect to introduce to the market will be a 3D tomosynthesis imaging system. Tomosynthesis is an imaging technique widely used for early detection, that is designed to produce a high-resolution, 3D X-ray image reconstruction of the scanned human body part for review by a professional diagnostics expert. In parallel, we have developed a prototype of the Nanox.CLOUD, a companion cloud-based software that is designed to provide an end-to-end medical imaging service, including services such as image repository, radiologist matching, online and offline diagnostics review and annotation, connectivity to diagnostic assistive AI systems, billing and reporting. The Nanox System is designed to enable MSaaS to improve accessibility and affordability of early-detection services worldwide.

If cleared, we plan to market and deploy the Nanox System globally at a substantially lower cost than currently available medical imaging systems, such as CT, because our digital X-ray source will allow the Nanox.ARC to have a simpler structure without the costly cooling equipment or the complex rotating mechanism used in legacy CT devices. See “—Our Technology—The Nanox System.” We believe that the Nanox System could increase the accessibility and affordability of early-detection medical imaging systems worldwide.

As we continue to develop the Nanox.ARC, we are taking a multi-step approach to the regulatory clearance process. As a first step, we submitted a 510(k) premarket notification for the Nanox Cart X-Ray System to an accredited Review Organization under the Third Party Review Program in January 2020. As part of the review process, in March 2020, we received an information request, referred to as a major deficiency letter, from the Review Organization which, among other things, required us to provide additional data and other information to complete the application and to address certain deficiencies highlighted by the reviewer, including the results of certain performance tests. On September 3, 2020, we submitted our response to the Review Organization. The response included additional data and other information to complete the application and to address certain deficiencies identified by the reviewer, including the results of certain performance tests. On September 10, 2020, the Review Organization requested that we include a second predicate device in our 510(k) premarket notification. On September 26, 2020, we submitted our revised 510(k) premarket notification to the Review Organization, which the Review Organization subsequently recommended to the FDA for clearance on December 28, 2020. On January 1, 2021, we received an information request from the FDA through the Review Organization regarding our submission, which we responded to on January 4, 2021. On January 30, 2021, we received additional information requests from the FDA which, among other things, require us to address certain deficiencies and questions, including requests that we provide additional support regarding the intended use of the Nanox.ARC and the comparability of the Nanox.ARC to the predicate device. We submitted our response to these requests on March 1, 2021. On April 1, 2021, we received clearance from the FDA to market our Nanox Cart X-Ray System. We will continue to optimize and develop features of the Nanox.ARC, and plan to submit an additional 510(k) premarket notification to the FDA with respect to the multi-source Nanox.ARC and the Nanox.CLOUD during 2021. If cleared by the FDA, we expect to commercialize the multi-source Nanox.ARC and we may seek alternatives for commercialization of our Nanox Cart X-Ray System. We believe that our novel digital X-ray source will not require FDA approval or clearance. However, to date, we have not obtained feedback from the FDA regarding our regulatory strategy with respect to our digital X-ray source. We first demonstrated a working prototype of the Nanox.ARC in February 2020 and, if the multi-source Nanox.ARC is cleared by the FDA and authorized by similar regulatory agencies in other jurisdictions, we are targeting shipment of 1,000 Nanox Systems by the first quarter of 2022, with the goal to finalize deployment of the initial 15,000 Nanox Systems by the end of 2024.

Limitation of Current Medical Imaging Systems and Our Market Opportunity

The main categories of current medical imaging systems that use X-ray sources include CT, mammography, fluoroscopy, angiogram and dental. The analog X-ray source used by these systems produces X-rays by accelerating electrons to high energies, causing them to hit a metal target from which the X-rays are emitted.

This requires a significant amount of electrical energy to be transferred to the X-ray tube. Due to the heat generated by this process, one of the most complex mechanical challenges is cooling the analog X-ray source. In addition, for CTs, the mechanical structure is even more complex because the analog X-ray source needs to rotate in a heavy gantry at high speed. We believe these are key factors leading to the high cost and complexity of existing medical imaging systems, which in turn significantly limits the availability of medical imaging for early detection globally. According to a report from the Pan-American Health Organization and WHO in 2012, approximately two-thirds of the world population did not have access to medical imaging, while many people with access to medical imaging face substantial wait times for scanning.

In addition, most market participants, including medical imaging manufacturing companies, medical imaging providers and radiologists, among others, have not provided the same level of end-to-end medical imaging services. One of the reasons is that the scanning process is currently not integrated with the diagnostics process, which contributes to extended wait times for image diagnostics by experts.

We estimate that the total annual capital expenditures on existing X-ray-based medical imaging systems, not including support, maintenance, insurance and ancillary services, will reach approximately \$21 billion by 2021, which we believe represents a significant market opportunity for the Nanox System.

Our Solution

We believe the Nanox System addresses the limitations of existing medical imaging systems on three levels:

- **Digital X-ray source with the potential to significantly reduce the costs of medical imaging systems.** We believe our digital X-ray source technology will allow us to manufacture the Nanox.ARC, if cleared, at substantially lower costs compared to medical imaging systems that use a legacy analog X-ray source without sacrificing imaging quality. A lower cost device has the potential to substantially increase medical imaging availability and improve accessibility of early-detection services broadly across the globe.
- **Technology designed to improve upon the industry standard with integrated radiology diagnostics via a cloud-based MSaaS platform.** The Nanox.ARC employs our novel digital X-ray source that is designed to be energy-efficient, smaller and can be more precisely controlled compared to existing X-ray source. By integrating the Nanox.CLOUD, we believe the Nanox System could provide a streamlined process where each scanned image is uploaded automatically to the cloud system and matched to a human radiology expert and decision assistive AI algorithms to provide scan reviews and diagnostics in a significantly shorter time frame than current diagnostics, which could substantially reduce wait-times for imaging results and increase early detection rates compared to currently employed imaging process protocols.
- **Business model designed to increase the availability of medical imaging.** Our primary business model is based on a pay-per-scan pricing structure as opposed to the capital expenditure-based business model currently used by medical imaging manufacturing companies. We believe our business model will significantly reduce the price per scan compared to the current global average cost of \$300 per scan, and has the potential to commoditize medical imaging services at prices that are affordable to a greater number of people. We believe our MSaaS business model has the potential to expand the total size of the X-ray-based medical imaging market.

Our Strategy

- **Secure regulatory clearance for our medical imaging system.** We are taking a multi-step approach to the regulatory clearance process. As a first step, we submitted a 510(k) premarket notification for the Nanox Cart X-Ray System to an accredited Review Organization under the Third Party Review Program in January 2020. As part of the review process, in March 2020, we received an information request, referred to as a major deficiency letter, from the Review Organization which, among other things, required us to provide additional data and other information to complete the application and to address certain deficiencies highlighted by the reviewer, including the results of certain performance tests. On September 3, 2020, we submitted our response to the Review Organization. The response included additional data and other information to complete the application and to address certain deficiencies identified by the reviewer, including the results of certain performance tests. On September 10, 2020, the Review Organization requested that we include a second predicate device in our 510(k) premarket notification. On September 26, 2020, we submitted our revised 510(k) premarket notification to the Review Organization, which the Review Organization subsequently recommended to the FDA for clearance on December 28, 2020. On January 1, 2021, we received an information request from the FDA through the Review Organization regarding our submission, which we responded to on January 4, 2021. On January 30, 2021, we received additional information requests from the FDA which, among other things, require us to address certain deficiencies and questions, including requests that we provide additional support regarding the intended use of the Nanox.ARC and the comparability of the Nanox.ARC to the predicate device. We submitted our response to these requests on March 1, 2021. On April 1, 2021, we received clearance from the FDA to market our Nanox Cart X-Ray System. We will continue to optimize and develop features of the Nanox.ARC, and plan to submit an additional 510(k) premarket notification to the FDA with respect to the multi-source Nanox.ARC and the Nanox.CLOUD during 2021. If cleared by the FDA, we expect to commercialize the multi-source Nanox.ARC and we may seek alternatives for commercialization of our Nanox Cart X-Ray System.

- **Jumpstart the MSaaS-based medical imaging market with strategic partnerships.** We plan to produce and deploy an initial wave of approximately 15,000 Nanox.ARC units over the next three to four years to jumpstart the MSaaS-based medical imaging market. We have entered into a contract manufacturing agreement with FITI, a subsidiary of Foxconn for the commercial production and assembly of the Nanox.ARC and we have entered into commercial agreements with strategic regional partners for the deployment, operation and marketing of the Nanox System broadly across the globe, including in the United States and certain countries in Asia, Europe, Africa, Latin America and Australia. Specifically, we have entered into nine multi-year MSaaS agreements with partners for the deployment of Nanox Systems in various regions that obligate the counterparty to obtain standby letters of credit for the amount of the agreed minimum annual fee. See “—Commercial Agreements—MSaaS Agreements” and “Item 3. Key Information—D. Risk Factors—Risk Related to our Business—Any collaborative and MSaaS arrangements that we have established or may establish in the future may not be successful or we may otherwise not realize the anticipated benefits from these collaborations.” In addition, we have entered into a collaboration agreement with USARAD for deploying and operating the Nanox System and establishing connections with the radiologist community in the United States. We plan to work with these partners to achieve local integrations into health maintenance organizations, electronic health record systems, payment methods and insurance coverage companies. In addition, we have entered into collaboration agreements with AI partners and image-transfer partners and are actively seeking collaboration opportunities, as we anticipate an industry shift to a digital and cloud-based subscription model will bring more digital healthcare disruptors into the market. See “—Commercial Agreements—Collaboration Agreements—Collaboration Agreements with our AI Partners” and “—Collaboration Agreement with our Image-Transfer Partner.”
- **Maximize the commercial potential of our technology with simultaneous business models.** We plan to commercialize our novel X-ray source technology by pursuing three simultaneous business models, which we believe will provide us the flexibility and long-term sustainability to monetize our technology.
 - *Subscription Model:* In certain countries, if permitted by the laws in the applicable jurisdiction, our primary sales strategy will be based on a pay-per-scan pricing structure, where we expect to sell the Nanox System at low cost or at no cost, with a suggested retail price per scan that is substantially lower than the current global average charge, and receive a portion of the proceeds from each scan as the right-to-use licensing fee and fees for usage of the Nanox.CLOUD, artificial intelligence capability and maintenance support.
 - *Sales Model:* In certain countries, to accommodate specific local regulatory requirements, we expect to sell the Nanox.ARC for a one-time charge at a price that is substantially less than current market offerings.

- **Licensing Model:** For certain medical imaging market participants, we plan to tailor our X-ray source technology to their specific imaging systems to replace the legacy X-ray source or to license our X-ray source technology to them to develop new types of imaging systems. We expect to charge a one-time licensing fee upfront and receive recurring royalty payments for each system sold.
- **Leverage the Nanox System to bring added value to our collaborators.** We expect that the Nanox System will enable us to accumulate a significant number of medical images, which have the potential to be used by collaborators, such as medical AI-analytics companies, through machine learning algorithms to increase the probability of early disease detection.

Our Technology

Legacy Analog X-ray Source and Limitations of Existing Medical Imaging Systems

The X-ray tube technology has essentially remained unchanged since its inception in 1895. For any type of imaging system to generate X-rays, the system must use X-ray tubes as a source for the X-rays. The X-ray tube converts electrical power into X-rays by accelerating electrons to high energies, causing them to hit a metal target from which the X-rays are emitted. X-rays can only be produced if the X-ray tube is energized, which has historically required a significant amount of electrical energy to be transferred to the X-ray tube. However, only a small amount of the energy deposited into the X-ray tube is actually converted into X-rays; the majority of the energy turns into heat. This is called a thermionic (heat-based) mode of operation where a metal filament needs to be heated up to approximately 2,000°C to generate the electron stream (a “cathode”) that will hit a metal target (an “anode”) to generate the photon-based X-ray stream resulting from that high-energy impact.

Heating the filament to approximately 2,000°C requires the mechanical cathode support systems to withstand high temperatures within a high vacuum, high voltage environment. Tungsten was introduced into the X-ray tube in 1903 for its properties of a high melting point and ductility. The tungsten filaments still used today are critical components of X-ray tubes, but they limit the lifetime of the X-ray tube due to the progressive evaporation of filament material under these high temperatures. At temperatures of up to 2,000°C, the filament evaporates in a hot spot close to the peak temperature location which over time can cause a catastrophic failure of the filament.

We believe that the use of the legacy analog X-ray source is one of the key factors for the high cost of existing medical imaging systems. The main categories of medical imaging systems that use X-ray sources include CT (3D cross-sectional 360° “slicing” X-ray imaging), mammography (2D and 3D breast X-ray imaging), fluoroscopy (real-time X-ray video imaging), angiogram (blood vessels, contrast X-ray imaging) and dental (2D and panoramic X-ray imaging). CT scanners, for example, are complex diagnostic imaging systems that use X-rays to take pictures of a patient’s internal structures and organs. Due to the limitations of the analog X-ray source described above, general radiographic X-ray tubes are not well suited for use in a CT scanner. CT scanners instead use a specialized X-ray tube designed to withstand the excessive amount of heat produced by continuous energization. This X-ray tube is located in the gantry, which is the largest part of a CT scanner and consists of the X-ray detectors, the mechanical supports and the scanner housing. Due to the heat generated by this process, one of the most complex mechanical challenges is cooling the analog X-ray source while rotating it in a heavy gantry at high-speed. One solution used is the rotating anode, where a tungsten metal disk rotates at high revolutions per minute so the electron beam hits a different spot on the disk on a continuous basis to prevent the concentration of heat in one spot on the disk and reduce the likelihood of overheating or burning. In addition, CT scanners require a long continuous exposure time to create 3D photographs of the patient’s body using multiple X-ray images, which means that the X-ray tube must be continually energized and that patients are continuously exposed to radiation throughout that period. As a result of these complexities, most high-quality X-ray tubes for a CT scanner weigh between approximately 50 and 100 kilograms with the cooling mechanism and generally cost over \$150,000 each.

Our Novel Digital X-ray Source

Realizing that the X-ray tube technology has essentially not changed in more than 100 years and remains a significant source of complexity and cost-driver of existing X-ray-based medical imaging systems, we developed a novel digital X-ray source that we believe addresses these drawbacks and will enable a new class of medical imaging systems that can be produced at a significantly lower cost than the existing systems.

Our technology has its roots in field emission display (“FED”) technology. FED technology was originally developed by Sony with other technology partners, for television screens and monitors, offering a novel way of lighting screen pixels compared to traditional cathode-ray tubes that were based on a one-source electron gun beam. The field emission display innovation used multiple nano-scale electron guns to achieve a much higher quality image with significantly reduced motion blur effects. In 2009, after having invested substantial resources in the development of this technology for over a decade including through a joint venture called Field Emission Technologies, Inc. (“FET”), Sony ceased development of the project.

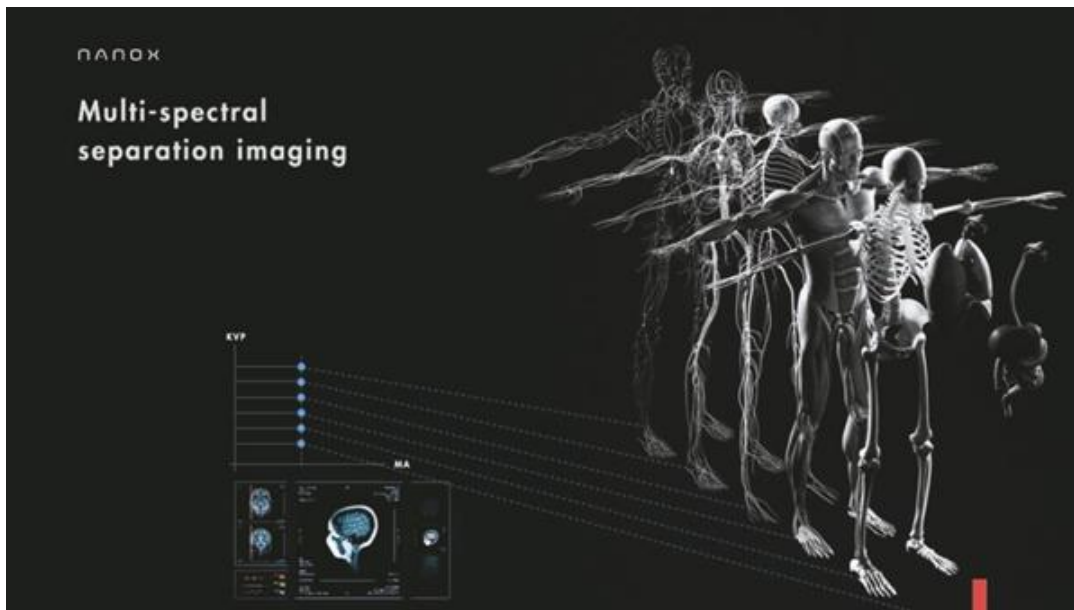
In 2009, FET dissolved and transferred certain assets to FET Japan Inc. (“FETJ”). Scientists on our team, who worked at FETJ, applied their expertise to develop non-display related applications, including our X-ray source technology. In 2011, our predecessor company acquired certain non-display related know-how from FETJ and certain members of the FETJ technical team joined us.

After acquiring the technology, we spent over eight years developing a digital X-ray source for the medical imaging industry that could be produced on a commercial scale. Our X-ray source is a MEMS-based semiconductor cathode that achieves electron emission by a non-thermionic low-voltage trigger to approximately 100 million nano-scale molybdenum cones that act as multiple electron “guns,” instead of a single heated filament. The cathode is housed in a customized X-ray tube.

We believe our X-ray source has the following technological advantages over the analog X-ray source:

Reduced duration of radiation exposure. Our X-ray source uses a digital chip that is designed to provide better control and enables near-instantaneous on/off toggling of the electron beam. This source control also enables a precise “stop and start” operation, which we believe can potentially result in significantly reduced duration of radiation exposure compared to an analog X-ray source that exposes patients to continuous radiation exposure.

Multi-spectral imaging capacity using one X-ray source. Our X-ray source is designed to create multi-spectral imaging using one X-ray source chip because there is complete independence and separation between the strength of X-ray penetration and the amount of photons for illumination (referred to as “KvP / mA”). KvP represents the speed of electrons that gives the X-ray its penetrating power, and higher KvP means the X-rays can penetrate higher density materials such as bones. mA represents the amount of photons or brightness levels of the X-ray image. For legacy X-ray sources, KvP / mA ratios were codependent in a linear relationship and each X-ray source could only produce one set of KvP / mA combinations dedicated for a particular use (for example, either tissue images or bone images, but not both simultaneously). We believe our X-ray source technology can produce multi-spectral imaging from one X-ray source, which allows for variable energy levels to be controlled during one scan. With multi-spectral imaging, one source chip can be used for multiple types of scans, such as head-scans, abdomen, mammography and angiograms, involving both soft and hard tissues at variable densities, simultaneously. We believe this multi-spectral imaging could also be applied to real-time video imaging. The image below is a general illustration of the functionality and capability of multi-spectral imaging. Our working prototype uses 60 KvP / mA, and we intend to commercialize the multi-source Nanox.ARC with a range of 60 - 120 KvP / mA.



Higher frequency use over a longer lifetime. Our X-ray source is based on a field of multiple electron guns on our MEMs-based cathode that spread the load of electron generation among many “producers” compared to a single filament that heats to a high temperature in the analog X-ray tube. As a result, our digital X-ray source is designed to shoot an electron beam at different locations on a stationary anode during each duty cycle without the need for the complex, high precision rotating mechanism. In addition, the near instant on/off toggling feature of our digital X-ray source is designed to allow us to reduce the duration of each operation. As a result, we believe our medical imaging system will have higher stability and a longer lifetime, with a longer mean time between failures.

Simplified hardware structure. Because our X-ray source is designed to direct an electron beam at different locations for each duty-cycle as described above, we are able to have multiple stationary tubes arranged around the patient as opposed to one tube that rotates around the patient. We believe this could reduce the complexity and cost of the Nanox.ARC compared to legacy CT devices. In addition, the current approach to increase durability of the tungsten anode in CT devices, the rotating anode mechanism discussed above, requires both a significant increase in tube size and cost to allow for the complex movements of the components. In contrast, we believe by using our X-ray source we will be able to significantly reduce the size of X-ray tubes and simplify the structure of our medical imaging system.

We believe our X-ray source has the potential to replace the legacy X-ray source in other existing imaging systems, as well as the X-ray source in systems used in other industries, such as security scanners.

Comparative Images from the Nanox.ARC and a Commercial Alternative

We have generated the images below with the Nanox.ARC using a single X-ray tube on an imaging phantom. An imaging phantom is a specially designed object that is scanned or imaged to evaluate and analyze the performance of an imaging device. The comparisons below show the X-ray images taken by our novel X-ray source (single tube) that is expected to be used in the Nanox.ARC and a commercial alternative, the DigitalDiagnost Rel. 3.x by Philips, Germany, each at the same source-to-image distance (100 cm), at the same source-detector angle (90°) and with the same detector. “KvP” represents the penetrating power of the X-ray generated by the device. “mAs” represents the quantity of X-rays used during a given exposure time. The KvP and mAs numbers shown in the images below are based on the machine reading.

Right Foot/Ankle | Lateral | Comparative

kVp: 50
mAs: 0.4
Nanox SOURCE



kVp: 60
mAs: 5
DigitalDiagnost Rel. 3.x; Philips, Germany



Left Hand | Palm | Comparative

kVp: 50
mAs: 0.4
Nanox SOURCE



kVp: 55
mAs: 4
DigitalDiagnost Rel. 3.x; Philips, Germany



Right Foot | Standing | Comparative*

kVp: 50
mAs: 0.4
Nanox SOURCE



kVp: 57
mAs: 4
DigitalDiagnost Rel. 3.x; Philips, Germany



*Due to machine/posture limitations, there is up to 7 degrees angle difference

The Nanox System

The Nanox System has two integrated components — hardware (Nanox.ARC) and software (Nanox.CLOUD).

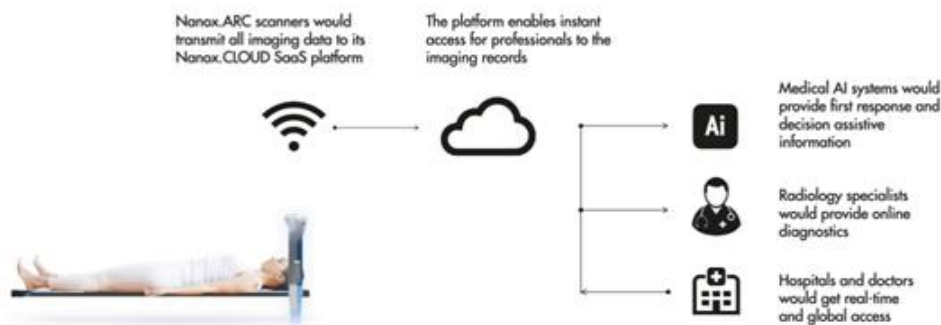
We have developed a working prototype of the Nanox.ARC, a medical device that integrates our proprietary and novel X-ray source. Subject to receiving regulatory clearance, the first version of the multi-source Nanox.ARC that we expect to introduce to the market is expected to be a 3D tomosynthesis imaging system that produces a 3D reconstruction of the scanned human body part, as illustrated in the image below. The Nanox.ARC, using our X-ray source, is being designed to produce partial and full-body scans, with remote operation capability, and to have a full kVp/mA energy throughout range as per industry standards, multi-spectral imaging range, as well as quiet operation, cloud connectivity and standard compliance safety mechanisms. It is being designed for easy setup and operation with multiple stationary X-ray tubes arranged around the patient. The substantial majority of operational software that we anticipate will be used to run the Nanox.ARC will be cloud-computing based and integrated with the Nanox.CLOUD, as further explained below.



In addition to the Nanox.ARC, we have developed a working prototype of the Nanox.CLOUD, a companion cloud software that will allow for the delivery of medical screening as a service. With the Nanox.CLOUD, we anticipate that the high-cost components of existing medical imaging systems, such as analytics and computing software that are traditionally installed via multiple licenses on-premise and on a per-system basis, will become centralized through the cloud. We believe this will significantly reduce on-going software and IT licensing costs and enable a wide range of functionalities, such as per-body-part vertical analysis, multiple AI diagnostics and remote support. The Nanox.CLOUD is also expected to be able to provide an end-to-end medical imaging service, including services such as image repository, radiologist matching, online and offline diagnostics review and annotation, connectivity to medical imaging AI systems and billing and reporting.

A reliable and streamlined, post-scan imaging service is central to the delivery of effective clinical services. Today, even patients in developed countries experience delays of weeks and sometimes months for medical imaging and subsequent diagnostics results. For example, in Canada, access to medical imaging procedures is a growing problem with months of reported wait times for magnetic resonance imaging (“MRI”) and CT screening. Long wait times not only negatively impact patient outcomes but also add significant costs to the Canadian healthcare system each year due to delays in detection and treatment. Wait times for a CT scan can be longer than six weeks in Scotland, over 12 months in Ireland, and in the UK, tens of thousands of suspected cancer patients face month-long wait times to discover whether they have a particular illness due to delays in analyzing scans and X-rays. The Nanox System is designed to address such gaps and inefficiencies between completion of the scan and follow-on diagnostics.

We believe the Nanox System, if successfully developed, will streamline the entire medical screening process ranging from scanning to support diagnostics, and solve the bottleneck of imaging-to-diagnostics. The image below illustrates the potential interplay among the Nanox.ARC, the Nanox.CLOUD and third-party participants.



We also expect to be able to offer the Nanox System for a substantially lower cost than existing medical imaging systems, which we believe is key to achieving our goal of making early-detection medical imaging systems more accessible globally. We believe our novel X-ray source is crucial to our ability to substantially reduce the manufacturing cost of the Nanox.ARC. Our digital X-ray source generates X-ray radiation that is measurably identical in all key metrics to the X-ray radiation generated by existing analog X-ray sources, but without creating the high temperature that results from the filament used in the analog X-ray tube, thereby eliminating the need for the costly cooling equipment. In addition, our digital X-ray source is designed to enable the Nanox.ARC to have multiple stationary tubes arranged around the patient, which allows for a more simplified structure, as opposed to requiring the heavy, complex, high-precision rotating mechanisms used in legacy CT devices. 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.

Our estimated manufacturing costs of the Nanox.ARC are subject to a number of assumptions and uncertainties and the actual cost per unit could vary significantly from our estimate, which would have a negative impact on our business. See “Item 3. Key Information—D. Risk Factors—Risks Related to Our Business—We are a development-stage company with limited operating history. We may never be able to effectuate our business plan or achieve any revenue or reach profitability. Therefore, at this stage of our business, potential investors have a high probability of losing their entire investment,” “—The success of our primary business model, the Subscription Model, is subject to numerous risks and uncertainties,” “—We may experience development or manufacturing problems and higher costs, or delays that could limit our revenue, if any, or increase our losses” and “—We may not be able to successfully execute our business models.”

We do not believe that our novel digital X-ray source will require FDA approval or clearance because we believe it falls within a category of radiology vacuum tubes converting electrical input power into X-rays that utilize the same energy levels, radiation types and throughputs as already existing and approved X-ray tubes applied in a wide range of radiology medical procedures. As a result, we expect that there will be no novel claim or methodology related to the X-ray radiation produced by the digital X-ray source. As we continue to develop the Nanox.ARC, we are taking a multi-step approach to the regulatory clearance process. As a first step, we submitted a 510(k) premarket notification to an accredited Review Organization under the Third Party Review Program in January 2020 to seek clearance of a medical imaging system that incorporates a single digital X-ray source. The submission was based on a predicate filing for an equivalence claim to an existing FDA-approved X-ray imaging system by another market participant. Because our novel digital X-ray source incorporated into this system generates X-ray radiation that is measurably identical in all key characteristics to the X-ray radiation generated by the analog X-ray source incorporated into existing FDA-cleared X-ray imaging systems, we made no new claims as to the operation, image quality or functionality of this system versus the predicate device. As part of the review process, in March 2020, we received an information request, referred to as a major deficiency letter, from the Review Organization which, among other things, required us to provide additional data and other information to complete the application and to address certain deficiencies highlighted by the reviewer, including the results of certain performance tests. On September 3, 2020, we submitted our response to the Review Organization. The response included additional data and other information to complete the application and to address certain deficiencies identified by the reviewer, including the results of certain performance tests. On September 10, 2020, the Review Organization requested that we include a second predicate device in our 510(k) premarket notification. On September 26, 2020, we submitted our revised 510(k) premarket notification to the Review Organization, which the Review Organization subsequently recommended to the FDA for clearance on December 28, 2020. On January 1, 2021, we received an information request from the FDA through the Review Organization regarding our submission, which we responded to on January 4, 2021. On January 30, 2021, we received additional information requests from the FDA which, among other things, require us to address certain deficiencies and questions, including requests that we provide additional support regarding the intended use of the Nanox.ARC and the comparability of the Nanox.ARC to the predicate device. We submitted our response to these requests on March 1, 2021. On April 1, 2021, we received clearance from the FDA to market our Nanox Cart X-Ray System. We will continue to optimize and develop features of the Nanox.ARC, and plan to submit an additional 510(k) premarket notification to the FDA with respect to the multi-source Nanox.ARC and the Nanox.CLOUD during 2021. If cleared by the FDA, we expect to commercialize the multi-source Nanox.ARC and we may seek alternatives for commercialization of our Nanox Cart X-Ray System. To date, we have not obtained feedback from the FDA regarding the regulatory pathways for the novel digital X-ray source.

Our Business Model

We plan to commercialize our X-ray source technology through three simultaneous business models: (i) the Subscription Model, (ii) the Sales Model and (iii) the Licensing Model. The chart below illustrates the various revenue streams we expect to derive from these three business models. We expect the Subscription Model to be our primary business model and the key vehicle to achieving our vision of increasing early-detection of medical conditions that are discoverable by X-ray.

Business model	Upfront Fee	Pay-Per-Scan	Royalty	Maintenance
Subscription Model	● (At low or no cost)	●		● (See comment below*)
Sales Model (e.g. China)	●			
Licensing Model	●		●	

* We expect to contract with third parties to provide maintenance and support services.

The Subscription Model

The foundation of the Subscription Model is our integrated offering of the Nanox.ARC and the Nanox.CLOUD, which we refer to as the “Nanox System.” Under the Subscription Model, we expect to sell the Nanox System, if cleared or approved by the requisite regulatory authorities, either at low cost or at no cost, and to receive a portion of the proceeds from each scan as the right-to-use licensing fee, and fees for usage of the Nanox.CLOUD, artificial intelligence capability and maintenance support, with the remaining amount allocated among our partners, including the local operators, radiologists, cloud storage providers, medical AI software providers and others, on a case by case basis. While the actual pricing charged by local operators may be greater than our suggested retail price, the retail price per scan in all markets other than the United States is still expected to be substantially less than the global average of approximately \$300. In the United States, we expect the retail price to represent a significant reduction compared to the \$3,275 average cost of a CT scan. We expect the Nanox System will be operated by local operators independent from us, but we would contract with third parties to provide the day-to-day maintenance of the Nanox System.

While we believe our novel X-ray source could provide existing market participants with the paradigm shift needed for preventive healthcare disruption, we also believe existing market participants are not likely to undertake the change-leadership route and will be slow to adopt the MSaaS model. Accordingly, we plan to produce and deploy approximately 15,000 Nanox.ARC units broadly across the globe over three to four years to jumpstart the MSaaS-based medical imaging market, including in the United States and certain countries in Asia, Europe, Africa, Latin America and Australia. We estimate that effectively stimulating market interest in our Nanox System will require deploying 5,000 to 10,000 Nanox.ARC units. We believe that this strategy will help initiate market disruption and accelerate the adoption of our novel X-ray source technology by traditional industry leaders.

The Sales Model

In certain countries, such as China, we intend to commercialize our technology using the Sales Model to accommodate specific local regulatory requirements. Under this model, we expect to sell the Nanox System, if cleared or approved by the requisite regulatory authorities, for a one-time charge. We expect this retail price to be higher than the upfront sales price under the Subscription Model but still substantially lower than the cost of existing medical imaging systems. We expect to enter into arrangements with third-party cloud vendors which will be responsible for providing the Nanox.CLOUD services, and be paid separately by the owner-operators of the Nanox Systems. In addition, we expect to contract with third-party service providers to provide maintenance services for the Nanox Systems at the owner-operators' own costs.

The Licensing Model

While we believe the medical imaging industry will eventually migrate towards the recurring revenue-based MSaaS model, we expect certain leading market participants will be slower to adopt this model. For these market participants, we expect to provide an intermediate solution through which they will adopt our X-ray source technology for their existing systems. Under the Licensing Model, we would be engaged to tailor our X-ray source to the specific systems of medical imaging device manufacturers or to license our X-ray source technology to them to develop new types of imaging systems for a one-time licensing fee upfront for the X-ray source, as well as recurring royalty payments for each system sold. The licensees would be responsible for the operation of the medical imaging systems integrating our X-ray source. Although we expect to initially rely on the Licensing Model, in part, we view the Licensing Model as a transitional phase, aimed at maximizing the commercial value of our technology and strategic buy-in from market participants to our vision through partnership and commercial relationships.

FUJIFILM Corporation was the first medical imaging device manufacturer to participate in our licensing model. On May 21, 2019, Nanox Gibraltar, our predecessor company, entered into a Right of First Negotiation Agreement with FUJIFILM Corporation. Under the terms of such agreement, the parties agreed to exclusively negotiate in good faith the terms and conditions of a potential commercial agreement until December 31, 2019. The terms of the commercial agreement are intended to cover the exclusive, worldwide licensing of certain patents and know-hows related to mammography medical devices and solutions owned by us to FUJIFILM Corporation to develop, manufacture, market, distribute, operate and use mammography equipment and services (the "field of use"). Under the Right of First Negotiation Agreement, if such commercial agreement was not entered into by December 31, 2019, and if we later become involved in any negotiation to enter into an agreement for the grant of license of the patents covered by the agreement in the field of use to any third party, FUJIFILM Corporation would have a right of first negotiation for six months with respect to such proposed transaction under terms and conditions no less favorable to us than those proposed or offered by or to such third party. In accordance with the terms of the Right of First Negotiation Agreement, we assumed all of Nanox Gibraltar's obligations under such agreement upon the transfer of Nanox Gibraltar's assets to us. We expect to enter into negotiations regarding the terms of a potential commercial agreement with FUJIFILM Corporation.

Sales and Marketing

We plan to commercialize our technology using the three simultaneous business models described above broadly across the globe by the end of 2024, including in the United States and certain countries in Asia, Europe, Africa, Latin America and Australia. Our sales and marketing strategy varies depending on specific geographical regions, as different regions generally require different marketing approaches.

In most countries, other than the United States, we expect to primarily market through local partnerships with strong national branding and operational market participants in the target region. These local partners would be engaged in deploying and operating our medical imaging systems, training and recruiting a local medical professional workforce to operate the systems and providing medical imaging diagnostics for the systems' scan results.

In the United States, because we expect our systems will be relatively simple and cost effective to deploy compared to existing medical imaging systems, many urgent care units, outpatient clinics and retail locations could potentially become medical imaging service providers with the support of the appropriate partners and radiologists. We have already initiated discussions with some of the largest urgent care units, private clinic chains and retail locations for the potential deployment of thousands of units in the United States.

In addition, we also expect to engage local value-added resellers or integrators in different geographic regions to facilitate the local integration of our systems with health maintenance organizations, electronic health record systems, payment methods and insurance coverage companies. We estimate that it will take approximately three to six months of integration and localization efforts before we can generate sales in a given region.

Manufacturing and Supply

We have optimized the MEMs proprietary manufacturing process and currently use our own equipment in the clean rooms located at the University of Tokyo to manufacture the MEMs X-ray chip, as shown in the picture below. As we further expand our business in connection with the commercialization of our technology, we expect to obtain access to other clean rooms provided by third parties. We plan to retain our core X-ray source technology production activities for the foreseeable future, and we intend to expand our manufacturing capacity, including through the establishment of the Korean Subsidiary, to meet our currently anticipated needs.



We have entered into direct arrangements on a purchase order basis with a manufacturer for the production of our X-ray tubes. In addition, we are evaluating, subject to completion of testing, a transition from glass-based X-ray tubes to ceramics-based tubes for cost efficiency purposes, which are the tubes to be used in the multi-source version of the Nanox.ARC, and we intend to enter into an agreement for such ceramics-based tubes with a new manufacturer in the future. We also expect to rely on third-party manufacturers for the commercial production of the other components of the Nanox.ARC, if cleared or approved by the requisite regulatory authorities.

Due, in part, to travel restrictions as a result of the COVID-19 pandemic, we engaged Dagesh to manufacture a small number of Nanox.ARC units in Israel on a purchase order basis that we expect will be used for the acceptance tests under our MSaaS agreements, demonstrations, regulatory approvals and for the initial global deployment, among other purposes. We expect to enter into a formal agreement for the manufacture of these Nanox.ARC units. Furthermore, we have entered into a contract manufacturing agreement with FITI, as further described below, for mass production of the multi-source Nanox.ARC, with a goal to enable the commercial production of approximately 15,000 Nanox.ARC units that we plan to deploy by the end of 2024. Under the contract manufacturing agreement, FITI will negotiate and subcontract with other third parties for the commercial supply of the components of the Nanox.ARC in accordance with the pre-approved supplier list and on the terms to be agreed upon by both parties, except for the MEMs X-ray chip and the X-ray tube. As we further expand our business in connection with the commercialization of our technology, we also expect to seek to engage alternative manufacturers of the Nanox.ARC.

On May 26, 2020, we entered into a Contract Manufacturing Agreement with FITI. Under the terms of the agreement, FITI agrees to manufacture, package, distribute and ship, and we agree to purchase, certain products and procurement and assembly services, including a minimum of 1,000 Nanox Systems per year. We agree to provide FITI with a rolling forecast of our estimated monthly purchases, which FITI will use to prepare its supply chain to cover the material and manufacturing needs. Subsequently, we will send purchase orders to FITI for certain products and services. Prices for the products will be agreed by the parties at least 90 days prior to the first expected delivery date. FITI will be entitled to order materials in accordance with an approved supplier list and on the terms that the parties agree upon on a quarterly basis, and FITI must obtain our prior written consent if it procures materials from other suppliers. FITI may also purchase materials from us to support orders pursuant to our requests. The parties also agree to enter into a quality agreement, which will set forth the manufacturing standards applicable to FITI. The agreement will be in effect for three years from the date of the agreement and is renewable for successive terms of one year unless or until either party notifies the other in writing of its intention not to renew with 90 days' prior notice. The agreement may be terminated by notice of the non-breaching party in case of a material breach of a party's material obligations, or by either party in case of the bankruptcy or insolvency of the other party.

We have worked with a third party to develop the initial prototype of the Nanox.CLOUD and we plan to continue to develop the Nanox.CLOUD internally.

Commercial Agreements

MSaaS Agreements

We have entered into nine MSaaS agreements to deploy 5,150 Nanox Systems in 13 regions as described in the table below. Under the terms of each agreement, we grant the other party a limited, non-transferable, exclusive, sub-licensable right to access and operate the Nanox System in the region indicated for such party. We undertake to provide the specified number of Nanox Systems to each entity as indicated in the table below based on agreed shipment schedules, subject to local regulatory approval and material compliance with acceptance test protocol (the “conditions precedent”). The other party undertakes to deploy the systems to provide a minimum number of scans per year (based on 7 scans per day and 23 days per month) on a pay-per-scan basis at a minimum of \$14 per scan, and to pay a minimum annual fee (including payments to our partners) in the amount indicated in the table below. The MSaaS agreements require each of our counterparties to deliver to us a standby letter of credit or financial guarantee in the amount equal to the minimum annual fee in favor of us after receipt of the conditions precedent. However, there can be no guaranty that our counterparties will be able to obtain such letters of credit or financial guarantees.

The Nanox Systems provided under each agreement will remain our property, and the other party will only have a limited license to use the Nanox Systems. In addition, we must approve in writing any sublicense granted under this agreement. We undertake to provide billing, radiology and maintenance services and to provide training for a local medical professional workforce to operate the Nanox.ARC.

Each agreement will be in effect for multiple years, ranging from three to seven years from the date of the applicable agreement, and is renewable for an additional multi-year term with both parties’ mutual consent as indicated in the table below. Each agreement may be terminated by notice of the non-breaching party in case of a material breach of a party’s material obligations, or by either party in case of the bankruptcy or insolvency of the other party.

Entity	Date of MsaaS Agreement	Region	Number of Nanox Systems to be Provided	Minimum Annual Fee and Amount of Letter of Credit or Financial Guarantee (approximate)	Initial Term	Renewal Term
The Gateway Group, Ltd.	February 11, 2020	Australia, New Zealand and Norway	1,000	\$58 million	3 years	3 years
Golden Vine International Company, Ltd.	May 28, 2020	Taiwan and Singapore	500	Up to \$29 million	5 years	5 years*
Promedica Bioelectronics s.r.l	May 29, 2020	Italy	500	\$29 million	4 years	3 years
JSC Roel Group	May 29, 2020	Russian Federation	500	\$12.6 million	5 years	5 years
Clarity Medical Solution, a division of “Grodnobioproduct” LLC	June 4, 2020	Belarus	100	\$3.7 million	3 years	4 years
Gold Rush	June 16, 2020	South Africa	500	\$15.5 million	3 years	3 years
LATAM Business Development Group Ltd.	July 6, 2020	Brazil	1,000	\$4.8 million (9 million Letter of Credit) in Year 1 \$14.5 million in Year 2 \$24.2 million in Year 3****	6 years	3 years
APR 1998 S.L	July 25, 2020	Spain	420	\$11.4 million	5 years	5 years**
SPI Medical	August 23, 2020	Mexico and Guatemala	630	\$17.1 million*****	7 years	N/A
TOTAL			5,150	\$180.9 million*****		

* The MSaaS Agreement with Golden Vine International Company, Ltd. may also be terminated by either party upon notice stipulating that the notifying party has come to the conclusion, based on market evidence, that there is no business merit for the Nanox.ARC in Taiwan or Singapore.

- ** The MSaaS Agreement with APR 1998 S.L. may also be terminated by the service provider at the end of a six-month trial period by sending within five days a formal notice to the Company if trial results are not satisfactory.
- *** The enforceability of the standby letter of credit from LATAM Business Development Group Ltd. in our favor is also conditioned upon the parties finalizing within 90 days of the date of the agreement or prior to receipt of regulatory approval, in mutually agreed form, the terms and conditions of the statement of work, the system requirement specifications and the service level agreement.
- **** According to the agreement, SPI issued a performance bond purchased from Aseguradora Aserta, S.A. de C.V., Grupo Financiero Aserta, a top financial institution of Mexico, in favor of us in the amount of approximately \$17.1 million, effective through October 31, 2021, which guarantees the exclusivity of the MSaaS agreement between SPI and us prior to the satisfaction of certain conditions, including receipt of regulatory approval and compliance with acceptance test protocol, and upon satisfaction of those conditions, will be converted into a financial guarantee that guarantees the minimum annual service fee to us.
- ***** The total amount includes payments to be received by our partners. The total amount payable to us would be approximately \$139 million excluding the payments to our partners.

We have entered into certain business development agreements with finders to obtain MSaaS agreements in specified countries. Once the standby letter of credit or financial guarantee has been issued in connection with each MSaaS agreement above, we will grant warrants to purchase our ordinary shares to the finder who caused such MSaaS agreement to be signed between the Company and the entity. The warrants will be granted in an amount equal to 30% of the amount of the standby letter of credit or financial guarantee divided by 35.36 and have an exercise price equal to the fair market value of our ordinary shares at the time of the grant. The finder will also be entitled to 5% of the gross amount that we receive from scans made by the Nanox Systems under the MSaaS agreement. If a finder causes an MSaaS agreement to be signed between us and an entity with a minimum of 23 scans per day at a minimum of \$30 per scan, once the standby letter of credit or financial guarantee has been issued, we will grant the finder warrants to purchase our ordinary shares in an amount equal to 5% of the amount of the standby letter of credit or financial guarantee divided by the fair market value of the ordinary shares at the time of issuance of the warrant. If a finder causes a letter of intent to be signed with an entity that will cooperate to deploy Nanox Systems, we will grant the finder warrants to purchase our ordinary shares in an amount equal to \$300,000 divided by \$18, the market price of our ordinary shares at the time of the closing of our initial public offering.

On October 26, 2020, we entered into an amendment to a certain business development agreement with certain finders in Russia, Belarus, South Africa, Brazil, Mexico and Guatemala, pursuant to which the Company paid the finders an aggregate one-time payment of \$400,000, plus value-added tax and issued to them warrants to purchase an aggregate of 650,000 ordinary shares at an exercise price of \$18 per share, with graded vesting ending ten weeks following the grant date, which may be exercised on a cashless basis. As a result, we recorded an expense of \$6.1 million for the warrants granted. The finders waived any and all past, present and future compensation to which they are or may be entitled pursuant to the agreements and all activities undertaken on our behalf, including the right to a percentage of future revenues we receive from scans made by the Nanox Systems and the issuance of warrants. These finders and their assigns also agree not to sell the shares underlying the warrants in excess of 10% of the daily average trading volume of our shares during the five trading days preceding such sale. In addition, these finders became party to the Registration Rights Agreement with respect to the ordinary shares underlying their warrants. In December 2020, 390,000 of such warrants were exercised for a net of 271,630 ordinary shares and in February 2021, 260,000 of such warrants were exercised for a net of 200,283 ordinary shares.

We believe our MSaaS business model has the potential to expand the total size of the X-ray-based medical imaging market. We plan to measure the success of our MSaaS business model by annual capacity for Above-the-Line (“ATL”) scans which represent the increased capacity of imaging care we can provide to people that originally had no meaningful access to medical imaging. As we expand our operations and deploy more units of the Nanox Systems in an increasing number of countries using the MSaaS model, we expect our ATL scans metric to increase accordingly.

Collaboration Agreements

Collaboration Agreement with Hadasit

We have entered into a Collaboration Agreement, dated September 8, 2019, with Hadasit Medical Research Services and Development Ltd. (“Hadasit”), a wholly owned subsidiary of the Hadassah Medical Organization (“HMO”). Under the terms of the agreement, the parties agreed to collaborate with respect to our medical imaging technology and resulting medical images devices (the “Company Products”), by way of (a) joint research and development projects (each, a “Research Project”); and (b) the provision by Hadasit of services in connection with Company Products, such as testing and consulting work, where no innovative research will be carried out (each, a “Service”). Each Research Project and Service will be rendered under a separate project agreement to be entered into between the parties in writing from time to time (collectively, the “Project Agreements”). Prior to entering into any Project Agreement, a joint steering committee to be established shall be responsible for determining whether such Project Agreement constitutes a Research Project or a Service. The parties envisage the collaboration to continue over a period of five years, unless extended in writing. Under this agreement, Hadasit has agreed to extend competitive prices comparable to prices that it offers to other commercial entities with respect to the Research Projects and Services. We made a non-refundable payment to Hadasit as an advance on account of the Research Projects and Services in the amount of \$250,000, plus value-added tax, which amount will be credited against payments due from time to time to Hadasit under the Project Agreements. We have no obligation to enter into any Project Agreements with Hadasit that will cause us to pay Hadasit any payments in excess of the amount advanced, and we are not permitted to use funding from the Israel Innovation Authority for any Research Projects or Services.

Under this agreement, Hadasit has granted us an exclusive, worldwide license, with the right to sublicense, under Hadasit’s rights in proprietary information created within the framework of a Research Project (collectively, the “Collaboration Intellectual Property”), to develop, have developed, manufacture, have manufactured, use, market, offer for sale, sell, have sold, distribute, export and import Company Products. Notwithstanding the foregoing, Hadasit reserves for itself, HMO and other non-commercial third parties, rights to Collaboration Intellectual Property for teaching or academic research purposes.

In consideration for Hadasit’s license to us, Hadasit is entitled to compensation, on a country-by-country basis, for all commercial scans (each, a “Scan”) carried out with the use of Covered Products (as defined below) throughout the applicable revenue sharing period at the rate of ten cents per Scan, which period commences upon the first Scan conducted in a country and ending on the later of: (i) the expiration of the last to expire valid claim of the applicable jointly owned patent; and (ii) 15 years from the date of the first Scan conducted in such country with a Covered Product after receipt of required regulatory approvals in such country. No royalty is due for Scans that are carried out with the use of Covered Products without consideration for internal, testing, training or demonstration purposes. “Covered Products” are those Company Products which (i) comprise, contain or incorporate, and/or use, in whole or in part, Collaboration Intellectual Property; (ii) the development, production and/or sale of which, is based on, or involves, in whole or in part, the use of the Collaboration Intellectual Property; or (iii) are produced or manufactured in whole or in part, using a process, method or system covered by, or included within the Collaboration Intellectual Property. If we, our affiliate or sublicensee challenges the validity, enforceability or scope of any patents jointly owned by us and Hadasit, Hadasit may terminate such license with respect to Covered Products covered by such patents and double the revenue sharing rate owed Hadasit under the agreement as described above.

In addition, under this agreement, we have granted Hadasit a royalty-free, worldwide, non-exclusive license, with the right to sublicense only to permitted contractors, to use, copy, maintain, modify and prepare derivative works of our intellectual property as necessary to conduct the Research Projects and Services.

The term of the agreement will continue until the expiration of all payment obligations thereunder. The agreement may be terminated by mutual consent, by the non-breaching party in case of a material breach of a party’s material obligations, or by either party in case of the bankruptcy or insolvency of the other party.

We also granted Hadasit a warrant to purchase 23,957 of our ordinary shares at a price of \$20.87 per share with a total exercise price of \$500,000. The warrant was exercised on a cashless basis in September 2020 for a net of 9,163 ordinary shares.

Collaboration Agreement with USARAD

We entered into a Non-Exclusive Collaboration Agreement, dated January 22, 2020, with USARAD. Under the terms of the agreement, USARAD will use best efforts to contact official public health authorities of governments and/or medical center operators in the United States (“Medical System Operators”), to facilitate the closing of commercial agreements between us and the Medical System Operator for the deployment of 3,000 Nanox Systems and to promote the Nanox.CLOUD services with radiologists for joining the Nanox diagnostics services platform. We must approve any engagement of a Medical System Operator that USARAD contacts.

We undertake to provide the deployed Nanox Systems on a pay-per-scan subscription basis using the Nanox.CLOUD. Subject to FDA clearance and a satisfactory Nanox System pilot testing by the Medical System Operator, USARAD undertakes to use best efforts to engage Medical System Operators that will undertake an annual subscription to a minimum number of scans per year. USARAD also undertakes to establish connections with the radiologist community in the United States. USARAD will receive a fee-per-scan, which will be subject to an upfront subscription commitment and fees.

We undertake to fully finance the cost of the Nanox Systems to be deployed in accordance with any commercial agreements between us and a Medical System Operator and their ongoing maintenance, as well as to provide training for the Nanox System operations. USARAD undertakes to make introductions to local maintenance contractors that are qualified to maintain medical equipment for the purpose of providing ongoing maintenance services for the Nanox Systems on our behalf.

The agreement will be in effect for 12 months from the date of the agreement and will be automatically renewed for additional 12-month periods. The agreement may be terminated by 90 days’ advance written notice by either party, by notice of the non-breaching party in case of a material breach of a party’s material obligations, or by either party in case of the bankruptcy or insolvency of the other party.

On January 5, 2021, we announced the extension of our collaboration with USARAD, under which we intend to launch, jointly with USARAD pursuant to an oral agreement, an advanced radiology diagnostics service, combining over 300 expert radiologists and AI decision support algorithms and solutions. We plan to use X-ray based algorithms, including 2D and 3D tomosynthesis, to provide analysis of large datasets combined with expert radiologists’ interpretations through a unique proprietary workflow that prioritizes urgent cases. The service is planned to be launched after strategically partnering with several leading AI companies. We plan to target insurance companies and other key constituents within the healthcare ecosystem, including outpatient imaging centers, throughout United States with the advanced radiology diagnostics service. We aim for this program to become an integral part of our service offering, subject to FDA 510(k) clearance of the multi-source Nanox.ARC.

The program is intended to launch in three categories:

1. Population health screening and predictive analytics for conditions such as coronary arterial disease, stroke prevention and osteoporosis;
2. Post-acute triage for urgent conditions such as pneumothorax, acute fractures and pneumonia (including COVID-19); and
3. Routine peer review and quality assurance cases for conditions such as lung nodules, tumors and incidental vertebral compression fractures.

Collaboration Agreement with SK Telecom

On June 4, 2020, we entered into a collaboration agreement with SK Telecom, pursuant to which we and SK Telecom continue to explore and engage in good faith to develop a definitive agreement for the deployment of 2,500 Nanox Systems in South Korea and Vietnam, and we have established a wholly-owned subsidiary in South Korea with the support of SK Telecom for the purpose of manufacturing MEMs X-ray chips for the Nanox.ARC.

Collaboration Agreements with our AI Partners

In 2019 and 2020, we entered into collaboration agreements with certain AI partners, including Brainomix Limited (“Brainomix”), CureMetrix, Inc. (“CureMetrix”), IMedis AI Ltd. (“IMedis”) and Qure.ai Technologies Pvt. Ltd. (“Qure.ai”). In 2020, we entered into non-binding agreements with Lunit Inc., (“Lunit”) and VUNO Inc. (“VUNO”). CureMetrix will support the development and testing of our technology together with medical imaging scans, in a diagnostic advisory capacity. Brainomix, IMedis and Qure.ai will each collaborate with us in the testing of the Nanox.ARC and the Nanox.CLOUD together with proprietary AI algorithms used for the analysis of brain damage caused by stroke, chest and abdomen X-rays, and chest and head X-rays, respectively, in medical imaging scans. Lunit and VUNO will each cooperate with us to jointly conduct research and development for commercializing medical AI solutions based on digital X-ray and CT technology.

Collaboration Agreement with our Image-Transfer Partner

We entered into a Software-as-a-Service Agreement, dated October 21, 2020, with DICOM Grid, Inc. d/b/a Ambra Health. Ambra is a medical data and image management cloud software company, whose network includes thousands of imaging providers in the U.S., including seven of the top ten hospitals and six of the top ten children’s hospitals, as well as leading radiology practices, subspecialty groups and life sciences companies.

Under the terms of the agreement, Ambra grants us a limited, non-exclusive, non-transferable, non-sublicensable, worldwide, royalty-free and fully paid license to use its software for uploading, viewing, sending and archiving diagnostic imaging and reports to be integrated into the Nanox.CLOUD.

The term of the agreement is for one year from the date of the agreement, and shall be automatically renewed for additional periods of the same duration, unless either party requests termination at least sixty days prior to the end of the then-current term.

Letter Agreement with A-Labs

On January 29, 2019, Nanox Gibraltar and A-Labs Advisory & Finance Ltd. (“A-Labs”) entered into a Letter of Engagement. On October 18, 2019, we entered into an Amendment to the Letter of Engagement with A-Labs, in which we replaced and succeeded Nanox Gibraltar in all matters relating to the agreement. Under the terms of the agreement, A-Labs will provide consulting services to us in connection with various transactions, such as a private placement or our initial public offering.

In October 2019, we paid A-Labs an advanced payment of \$1 million after the signing of the amendment to the agreement, which constituted the full and final payment for A-Labs’ services under the agreement. In addition, in connection with our initial public offering, in August 2020, we paid A-Labs \$4,750,000, representing 2.5% of the gross proceeds received from our initial public offering. The advanced payment and any fees received under the original agreement were set off from the cash payment to A-Labs as part of our initial public offering.

In addition, at the closing of our initial public offering, we issued to A-Labs an amount of warrants to purchase 263,889 ordinary shares, representing 2.5% of all shares issued in our initial public offering, at an exercise price equal to the price per ordinary share in such offering. At that time, A-Labs agreed not to sell or transfer any of our ordinary shares during the one-year period commencing from the closing of our initial public offering, which was later shortened to 180 days in order to align the lock-up period with other locked-up parties.

On December 28, 2020, A-Labs exercised a warrant to purchase 123,426 ordinary shares, pursuant to which A-Labs was issued 83,411 ordinary shares, and on December 31, 2020, A-Labs exercised a warrant to purchase 163,889 ordinary shares, pursuant to which A-Labs was issued 104,257 ordinary shares. In addition, A-Labs transferred a warrant to purchase 50,000 ordinary shares to a third party. On January 27, 2021, A-Labs sold 83,400 ordinary shares to a third party.

Competition

Several large companies, such as General Electric, Siemens, Philips, Hologic, Varian, Fuji, Toshiba and Hitachi currently dominate the medical imaging market. High regulatory, distribution, manufacturing and service-related long-term contractual costs represent significant barriers to entry for any new player. We expect that the existing market participants will remain key players in the future and we aim to form alliances with several of these leading market participants, including through licensing.

Over time, we anticipate that the evolution in the industry will bring new players into the market. Digital healthcare disruptors such as cloud computing companies or leading IT companies may enter the industry and we believe that they may become strong partners through our Subscription Model.

As a general matter, we view competition on two levels:

- Competing digital X-ray sources with same or better attributes; and
- Competing enterprises operating an MSaaS business model.

In terms of digital X-ray sources, the field emission display technology is known and a wide range of industry leaders have used it to attempt to create an alternative, digital source of X-ray. We are not aware of any competing company that has achieved a commercial grade, stable digital X-ray source, either based on field emission display technology or otherwise. The most well-known attempt was the use of carbon nano tubes (“CNT”) as the base material for a potential field emission-based solution. To our knowledge, there are several companies currently in the process of developing this technology, including Carestream, XinRay Systems and Varex Imaging. Branded as a “cold cathode,” CNT solutions have been proven to be unstable and, to date, no commercially available solution has been implemented after significant investment.

There are two main differences between our MEMs-based X-ray source and CNT-based X-ray sources. First, carbon, which is used in CNT-based X-ray sources, is much easier to burn than metal, which is used in our X-ray source. The carbon edges of CNT are extremely small. If these carbon edges are not controlled precisely, so that the maximum current is below their burn temperature, they burn out. Further, the edges of CNT are randomly positioned and cannot position nano-tubes in precise locations. Therefore, the edges burn first under high electric field voltage and cause a chain reaction of all edges burning, which renders the CNT useless. In contrast, we believe our molybdenum cones are a far more resistant base and our X-ray source positions metal cone edges in the precise location of the electric field using our MEMs with negligible positioning error deviation. Second, others have tried to prevent the deterioration of the CNT-based X-ray sources by using “mesh” as an electric field to extract electrons. “Mesh” is a grid-electrode set a few millimeters above of CNTs. However, the distance between the metal edges and their gates is extremely large compared to our X-ray source, and it requires 1,000 volts to extract electrons, while our X-ray source only needs 50 volts. High voltage is costly and imprecise. Moreover, the mesh grid traps 50% of the electron emission, meaning the mesh-based solution is costly and extracts only a small number of electrons, many of which are wasted.

In terms of the MSaaS business model, we currently seek a first-mover advantage by introducing the Subscription Model, as the main pre-requisite for this model is the low cost of the X-ray source. However, the primary competition comes from established market participants. While in developing countries we are experiencing keen interest, the United States and other Western regions already have major market participants that are well entrenched in the market with strong political influence and the ability to delay deployment of our systems.

Security and Data Privacy

The Nanox System is being designed and developed with personal privacy, data security and protection in mind as a top priority for all development parties. Medical imaging information and other health information is highly personal and sensitive and thus regarded as a prime target for hacks and malicious theft. As part of our normal operations, we expect to collect, process and retain personal identifying information regarding patients.

We believe we will likely be subject to U.S. rules and regulations governing data protection, including HIPAA. See “—Government Regulation—Healthcare Regulatory Laws—Data Privacy and Security.”

In addition, we believe we will likely be subject to the GDPR to the extent that our business involves personal data of persons within the EEA. Data protection legislation, including the GDPR, regulates the manner in which we may hold and communicate personal data of our employees and patients (including, in our case, sensitive health data). We are likely to be defined as a “Data Controller” with respect to the personal data of patients that we intend to collect and are therefore likely to be subject to a number of key legal obligations under the GDPR. In addition to reflecting existing requirements that already existed under the old data protection regime, such as, among other things, requirements to provide users with a “fair processing notice” if we process their data, ensure that inaccurate data is corrected, only retain data for so long as is necessary and not transfer data outside the EEA to jurisdictions which do not ensure an adequate level of protection of personal data without taking certain safeguards, the GDPR also implemented new, more stringent operational and procedural requirements for our use of personal data. These include expanded prior information requirements in light of the transparency principle to tell patients how we may use their personal data, increased controls on profiling such persons, increased rights for patients to access, control and delete their personal data and mandatory data breach notification requirements. In addition, there are significantly increased administrative fines of the greater of €20 million and 4% of global turnover (as well as the right to compensation for financial or non-financial damages claimed by any individuals under Article 82 of the GDPR). Further, following the United Kingdom’s withdrawal from the European Economic Area and the European Union, and the expiry of the transition period, companies have to comply with both the GDPR and the GDPR as incorporated into United Kingdom national law, the latter regime having the ability to separately fine up to the greater of £17.5 million or 4% of global turnover. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, for example around how data can lawfully be transferred between each jurisdiction, which may expose us to further compliance risk.

Separate from, and in addition to, the GDPR requirements, certification requirements for the hosting of health data will vary by jurisdiction (and may or may not apply to hosts of health data). As the Nanox System is projected to operate in various EEA countries, we may be required to comply with other national healthcare regulations or regulatory requirements. For example, in France, there is a procedure as of April 1, 2018, for hosts of health data to obtain a prior certification with the competent certification body.

We are dedicated to making our systems and software both HIPAA and GDPR compliant. We intend to submit our systems to an independent external audit on a regular basis as required by HHS. We also intend to develop our privacy protocols to comply with the GDPR. In addition, we are undertaking intendant measures to ensure a high-level of imaging data encryption, complete separation between the imaging data and personal information (anonymization) as well as three-factor authentication procedures during on-boarding and usage of the Nanox System. We also intend to undertake to perform periodic Pen-Tests by external cyber security professionals and publish the results of such audits publicly and without delay on our website and via public relations channels.

Government Regulation

The Nanox System and our operations will be subject to extensive regulation by the FDA, and other federal and state authorities in the United States, as well as comparable authorities in foreign jurisdictions. The Nanox.ARC will be subject to regulation as medical devices and radiation-emitting devices in the United States under the FDCA, as implemented and enforced by the FDA, and under comparable regulatory schemes in foreign jurisdictions.

FDA Regulation of Medical Devices

The FDA regulates the development, design, non-clinical and clinical research, manufacturing, safety, efficacy, labeling, packaging, storage, installation, servicing, recordkeeping, premarket clearance or approval, adverse event reporting, advertising, promotion, marketing and distribution, and import and export of medical devices to ensure that medical devices distributed within the United States are safe and effective for their intended uses or are substantially equivalent to a predicate device and otherwise meet the requirements of the FDCA.

Subject to certain exceptions, each medical device commercially distributed in the United States requires either FDA clearance of a 510(k) premarket notification, or approval of a PMA application. Under the FDCA, medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of manufacturer and regulatory control needed to ensure its safety and effectiveness. Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be assured by adherence to the FDA’s General Controls for medical devices, which include compliance with the applicable portions of QSR, facility registration and product listing, reporting of adverse medical events and truthful and non-misleading labeling, advertising and promotional materials. Class II devices are subject to the FDA’s General Controls, and special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, post-market surveillance, patient registries and FDA guidance documents.

While most Class I devices are exempt from the 510(k) premarket notification requirement, manufacturers of most Class II devices are required to submit to the FDA a premarket notification under Section 510(k) of the FDCA requesting permission to commercially distribute the device. The FDA’s permission to commercially distribute a device subject to a 510(k) premarket notification is generally known as 510(k) clearance. Devices deemed by the FDA to pose the greatest risks, such as life sustaining, life supporting or some implantable devices, or devices that have a new intended use, or use advanced technology that is not substantially equivalent to that of a legally marketed device, are placed in Class III, requiring approval of a PMA. Some pre-amendment devices are unclassified, but are subject to the FDA’s premarket notification and clearance process in order to be commercially distributed.

510(k) Clearance Marketing Pathway

We expect the Nanox.ARC will be a Class II device subject to premarket notification and clearance under section 510(k) of the FDCA. To obtain 510(k) clearance, we must submit to the FDA a premarket notification submission demonstrating that the proposed device is “substantially equivalent” to a predicate device already on the market. A predicate device is a legally marketed device that is not subject to premarket approval, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device), and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was found substantially equivalent through the 510(k) process. The FDA’s 510(k) clearance process usually takes from three to twelve months, but often takes longer. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence. In addition, the FDA collects user fees for certain medical device submissions and annual fees and for medical device establishments. For fiscal year 2020, the standard user fee for a 510(k) premarket notification application is \$11,594.

If the FDA agrees that the device is substantially equivalent to a predicate device currently on the market, it will grant 510(k) clearance to commercially market the device. If the FDA determines that the device is “not substantially equivalent” to a previously cleared device, the device is automatically designated as a Class III device. The device sponsor must then fulfill more rigorous PMA requirements, or can request a risk-based classification determination for the device in accordance with the “*de novo*” process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device.

After a device receives 510(k) marketing clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change or modification in its intended use, will require a new 510(k) clearance or, depending on the modification, PMA approval or *de novo* reclassification. The FDA requires each manufacturer to determine whether the proposed change requires submission of a 510(k), a *de novo* request or a PMA in the first instance, but the FDA can review any such decision and disagree with a manufacturer’s determination. If the FDA disagrees with a manufacturer’s determination, the FDA can require the manufacturer to cease marketing and/or request the recall of the modified device until 510(k) marketing clearance or until PMA approval is obtained or a *de novo* request is granted. Also, in these circumstances, the manufacturer may be subject to significant regulatory fines or penalties.

Over the last several years, the FDA has proposed reforms to its 510(k) clearance process, and such proposals could include increased requirements for clinical data and a longer review period, or could make it more difficult for manufacturers to utilize the 510(k) clearance process for their products. For example, in November 2018, the FDA officials announced forthcoming steps that the FDA intends to take to modernize the premarket notification pathway under Section 510(k) of the FDCA. Among other things, the FDA announced that it planned to develop proposals to drive manufacturers utilizing the 510(k) pathway toward the use of newer predicates. These proposals included plans to potentially sunset certain older devices that were used as predicates under the 510(k) clearance pathway, and to potentially publish a list of devices that have been cleared on the basis of demonstrated substantial equivalence to predicate devices that are more than 10 years old. In May 2019, the FDA solicited public feedback on these proposals. The FDA requested public feedback on whether it should consider certain actions that might require new authority, such as whether to sunset certain older devices that were used as predicates under the 510(k) clearance pathway. These proposals have not yet been finalized or adopted, and the FDA may work with Congress to implement such proposals through legislation.

More recently, in September 2019, the FDA finalized guidance describing an optional “safety and performance based” premarket review pathway for manufacturers of “certain, well-understood device types” to demonstrate substantial equivalence under the 510(k) clearance pathway by showing that such device meets objective safety and performance criteria established by the FDA, thereby obviating the need, in the case of applicable products, for manufacturers to compare the safety and performance of their medical devices to specific predicate devices in the clearance process. The FDA maintains a list of device types appropriate for the “safety and performance based” pathway and will continue to develop product-specific guidance documents that identify the performance criteria for each such device type, as well as the testing methods recommended in the guidance documents, where feasible.

PMA Approval Pathway

Class III devices require PMA approval before they can be marketed, although some pre-amendment Class III devices for which the FDA has not yet required a PMA are cleared through the 510(k) process. The PMA process is more demanding than the 510(k) premarket notification process. In a PMA, the manufacturer must demonstrate that the device is safe and effective, and the PMA must be supported by extensive data, including data from preclinical studies and human clinical trials. The PMA must also contain a full description of the device and its components, a full description of the methods, facilities and controls used for manufacturing and proposed labeling. Following receipt of a PMA, the FDA determines whether the application is sufficiently complete to permit a substantive review. If the FDA accepts the application for review, it has 180 days under the FDCA to complete its review of a PMA, although in practice, the FDA’s review often takes significantly longer, and can take up to several years. An advisory panel of experts from outside the FDA may be convened to review and evaluate the application and provide recommendations to the FDA as to the approvability of the device. The FDA may or may not accept the panel’s recommendation. In addition, the FDA will generally conduct a pre-approval inspection of the applicant or its third-party manufacturers’ or suppliers’ manufacturing facility or facilities to ensure compliance with the QSR. PMA devices are also subject to the payment of user fees, which for fiscal year 2020 includes a standard application fee of \$340,995 and an annual establishment registration fee of \$5,236.

The FDA will approve the new device for commercial distribution if it determines that the data and information in the PMA constitute valid scientific evidence and that there is reasonable assurance that the device is safe and effective for its intended use(s). The FDA may approve a PMA with post-approval conditions intended to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution and collection of long-term follow-up data from patients in the clinical study that supported PMA approval or requirements to conduct additional clinical studies post-approval. The FDA may condition PMA approval on some form of post-market surveillance when deemed necessary to protect the public health or to provide additional safety and efficacy data for the device in a larger population or for a longer period of use. In such cases, the manufacturer might be required to follow certain patient groups for a number of years and to make periodic reports to the FDA on the clinical status of those patients. Failure to comply with the conditions of approval can result in material adverse enforcement action, including withdrawal of the approval.

Certain changes to an approved device, such as changes in manufacturing facilities, methods or quality control procedures, or changes in the design performance specifications, which affect the safety or effectiveness of the device, require submission of a PMA supplement. PMA supplements often require submission of the same type of information as a PMA, except that the supplement is limited to information needed to support any changes from the device covered by the original PMA and may not require as extensive clinical data or the convening of an advisory panel. Certain other changes to an approved device require the submission of a new PMA, such as when the design change causes a different intended use, mode of operation, and technical basis of operation, or when the design change is so significant that a new generation of the device will be developed, and the data that were submitted with the original PMA are not applicable for the change in demonstrating a reasonable assurance of safety and effectiveness. We do not expect any of our products to be marketed pursuant to a PMA.

Clinical Trials

Clinical trials are almost always required to support a PMA and are sometimes required to support a 510(k) submission. All clinical investigations of devices to determine safety and effectiveness must be conducted in accordance with the FDA's investigational device exemption ("IDE") regulations which govern investigational device labeling, prohibit promotion of the investigational device and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. If the device presents a "significant risk" to human health, as defined by the FDA, the FDA requires the device sponsor to submit an IDE application to the FDA, which must become effective prior to commencing human clinical trials. If the device under evaluation does not present a significant risk to human health, then the device sponsor is not required to submit an IDE application to the FDA before initiating human clinical trials, but must still comply with abbreviated IDE requirements when conducting such trials. A significant risk device is one that presents a potential for serious risk to the health, safety or welfare of a patient and either is implanted, used in supporting or sustaining human life, substantially important in diagnosing, curing, mitigating or treating disease or otherwise preventing impairment of human health, or otherwise presents a potential for serious risk to a subject. An IDE application must be supported by appropriate data, such as animal and laboratory test results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. The IDE will automatically become effective 30 days after receipt by the FDA unless the FDA notifies the company that the investigation may not begin. If the FDA determines that there are deficiencies or other concerns with an IDE for which it requires modification, the FDA may permit a clinical trial to proceed under a conditional approval.

Regardless of the degree of risk presented by the medical device, clinical studies must be approved by, and conducted under the oversight of, an Institutional Review Board ("IRB") for each clinical site. The IRB is responsible for the initial and continuing review of the IDE, and may pose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent and labeling and record-keeping requirements. Acceptance of an IDE application for review does not guarantee that the FDA will allow the IDE to become effective and, if it does become effective, the FDA may or may not determine that the data derived from the trials support the safety and effectiveness of the device or warrant the continuation of clinical trials. An IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan or the rights, safety or welfare of human subjects.

During a study, the sponsor is required to comply with the applicable FDA requirements, including, for example, trial monitoring, selecting clinical investigators and providing them with the investigational plan, ensuring IRB review, adverse event reporting, record keeping and prohibitions on the promotion of investigational devices or on making safety or effectiveness claims for them. The clinical investigators in the clinical study are also subject to FDA regulations and must obtain patient informed consent, rigorously follow the investigational plan and study protocol, control the disposition of the investigational device and comply with all reporting and recordkeeping requirements. Additionally, after a trial begins, we, the FDA or the IRB could suspend or terminate a clinical trial at any time for various reasons, including a belief that the risks to study subjects outweigh the anticipated benefits.

Post-market Regulation

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;

- labeling regulations and FDA prohibitions against the promotion of investigational products, or the promotion of “off-label” uses of cleared or approved products;
- requirements related to promotional activities;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices, or approval of certain modifications to PMA-approved devices;
- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;
- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- the FDA’s recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and
- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Our manufacturing processes are required to comply with the applicable portions of the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, device history file and complaint files. As a manufacturer, we will be subject to periodic scheduled or unscheduled inspections by the FDA. Our failure to maintain compliance with the QSR requirements could result in the shut-down of, or restrictions on, our manufacturing operations and the recall or seizure of our products, which would have a material adverse effect on our business. The discovery of previously unknown problems with any of our products, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that we failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, which may result in any of the following sanctions:

- warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;
- recalls, withdrawals or administrative detention or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) marketing clearance or PMA approvals of new products or modified products;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export approvals for our products; or
- criminal prosecution.

We and our products will also be regulated by the FDA under the Electronic Product Radiation Control provisions of the FDCA because the Nanox.ARC contains radiation emitting components, and because we assemble these components during manufacturing and service activities. The Electronic Product Radiation Control provisions require radiation-producing products to comply with certain regulations and applicable performance standards. Manufacturers are required to certify in product labeling and reports to the FDA that their products comply with all necessary standards as well as maintain manufacturing, testing and sales records for their products. The Electronic Product Radiation Control provisions also require manufacturers to report product defects and affix appropriate labeling to covered products. Failure to comply with these requirements could result in enforcement action by the FDA, which can include any of the sanctions described above.

Healthcare Regulatory Laws

Within the United States, our products and our customers will be subject to extensive regulation by a wide range of federal and state agencies that govern business practices in the medical device industry. These laws include federal and state anti-kickback, fraud and abuse, false claims, transparency and anti-corruption statutes and regulations. Internationally, other governments also impose regulations in connection with their healthcare reimbursement programs and the delivery of healthcare items and services.

U.S. federal healthcare fraud and abuse laws will generally apply to our activities, among other reasons because we expect that our products will be covered under federal healthcare programs such as Medicare and Medicaid. The Anti-Kickback Statute is particularly relevant because of its broad applicability. Specifically, the Anti-Kickback Statute prohibits persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for, or to induce, either the referral of an individual, or the furnishing, arranging for or recommending a good or service for which payment may be made in whole or part under federal healthcare programs, such as the Medicare and Medicaid programs. Almost any financial interaction with a healthcare provider, patient or customer will implicate the Anti-Kickback Statute. Statutory exceptions and regulatory safe harbors protect certain interactions if specific requirements are met. However, only those interactions that represent fair market value exchanges generally are protected by a safe harbor or exception. The government can exercise enforcement discretion in taking action against unprotected activities. Further, a person or entity does not need to have actual knowledge of the Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act or federal civil money penalties statute. Penalties for Anti-Kickback Statute violations may include both criminal penalties such as imprisonment and civil sanctions such as fines, imprisonment and possible exclusion from Medicare, Medicaid and other federal healthcare programs. Exclusion would mean that diagnostic tests using our products would no longer be eligible for reimbursement under federal healthcare programs.

Many states have adopted laws similar to the Anti-Kickback Statute. Some of these state prohibitions apply to referral of patients for healthcare items or services reimbursed by any payor, not only federal healthcare programs. Insurance companies may also bring a private cause of action for treble damages against a manufacturer for a pattern of causing false claims to be filed under the federal Racketeer Influenced and Corrupt Organizations Act.

Another development affecting the healthcare industry is the increased use of the federal Civil False Claims Act and, in particular, actions brought pursuant to the False Claims Act's "whistleblower" or "qui tam" provisions. The False Claims Act imposes liability on any person or entity that, among other things, knowingly presents, or causes to be presented, a false or fraudulent claim for payment by a federal healthcare program. The qui tam provisions of the False Claims Act allow a private individual to bring actions on behalf of the federal government alleging that the defendant has submitted a false claim to the federal government, and to share in any monetary recovery. In recent years, the number of suits brought against healthcare providers by private individuals has increased dramatically. In addition, various states have enacted false claim laws analogous to the Civil False Claims Act, although many of these state laws apply where a claim is submitted to any third-party payor and not merely a federal healthcare program.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, among other things, created two new federal crimes: healthcare fraud and false statements relating to healthcare matters. The HIPAA healthcare fraud statute prohibits, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private payors. A violation of this statute is a felony and may result in fines, imprisonment and/or exclusion from government-sponsored programs. The HIPAA false statements statute prohibits, among other things, knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement or representation in connection with the delivery of or payment for healthcare benefits, items or services. A violation of this statute is a felony and may result in fines and/or imprisonment. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statutes or specific intent to violate them in order to have committed a violation.

Laws and regulations have also been enacted by the federal government and various states to regulate the sales and marketing practices of medical device and pharmaceutical manufacturers. The laws and regulations generally limit financial interactions between manufacturers and healthcare providers, require pharmaceutical and medical device companies to comply with voluntary compliance standards issued by industry associations and the relevant compliance guidance promulgated by the U.S. federal government and/or require disclosure to the government and/or public of financial interactions (so-called "sunshine laws"). Many of these laws and regulations contain ambiguous requirements or require administrative guidance for implementation. Manufacturers must adopt reasonable interpretations of requirements if there is ambiguity and those interpretations could be challenged. Given the lack of clarity in laws and their implementation, our activities could be subject to the penalty provisions of the pertinent federal and state laws and regulations.

Coverage and Reimbursement

Over the past few years, the growth rate of advanced imaging volumes has slowed in part due to additional patient-related cost-sharing programs and an increasing trend of third-party payors intensifying their utilization management efforts, for example, through benefit managers who require prior authorizations to control the growth rate of imaging services generally. We expect that these trends will continue.

By way of example, in the United States, the Protecting Access to Medicare Act of 2014 required CMS, in conjunction with medical specialty societies, to adopt AUC for certain advanced diagnostic imaging services, including MRI, CT, nuclear medicine (including positron emission tomography). Beginning in 2022, payment will be made to the furnishing professional for an applicable advanced diagnostic imaging service only if the claim indicates that the ordering professional consulted a qualified clinical decision support mechanism, as identified by HHS, as to whether the ordered service adheres to the applicable AUC. Applicable settings include physician offices, hospital outpatient departments, including emergency departments, ambulatory surgical centers and independent diagnostic testing facilities. Advanced imaging services ordered by certain physicians identified as having outlier-ordering partners will be subject to prior authorization for applicable imaging services provided to Medicare beneficiaries. The outlier methodology used by CMS will be subject to future notice and comment rulemaking before the prior authorization component is implemented. We cannot predict the full impact of this project.

Third-party payors may impose limits on coverage or reimbursement for diagnostic imaging services, including denying reimbursement for tests that do not follow recommended diagnostic procedures or can only be billed using an unlisted or miscellaneous code. To the extent our customers will depend on third-party payors, unfavorable coding, coverage and reimbursement policies may constrict the profit margins of our provider customers, which may force us to lower our fees to attract and retain customers. If we are required to request new billing codes that more precisely identify and describe our imaging services, coverage is limited or reimbursement rates are inadequate, a healthcare provider might find it financially unattractive to own our diagnostic imaging systems. It is possible that third-party payor coding, coverage and reimbursement policies will affect the need or prices for our products in the future, which could significantly affect our financial performance and our ability to conduct our business.

In the United States and certain foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system. In March 2010, the ACA was signed into law and substantially changed the way healthcare is financed by both governmental and private insurers in the United States. The ACA contains a number of provisions, including those governing enrollment in federal healthcare programs, reimbursement adjustments and fraud and abuse changes. Additionally, the ACA imposed, among other things, a new federal excise tax on the sale of certain medical devices, which, through a series of legislative amendments, was suspended, effective January 1, 2016, and subsequently repealed altogether on December 20, 2019, provided incentives to programs that increase the federal government's comparative effectiveness research and implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. By way of example, in 2017, Congress enacted the TCJA, which eliminated the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a Texas U.S. District Court Judge ruled that the individual mandate is a critical and inseparable feature of the ACA, and therefore, because it was repealed as part of the TCJA, the remaining provisions of the ACA are invalid as well. On December 18, 2019, the U.S. Court of Appeals for the 5th Circuit ruled that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court is currently reviewing the case. A decision is expected during the current Supreme Court term in 2021, and the ACA remains in effect while judicial review of the decision is pending. It is unclear how these decisions, future decisions, subsequent appeals, and other efforts to repeal and replace the ACA will impact the ACA.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted, including aggregate reductions of Medicare payments to providers of 2% per fiscal year, which has been temporarily suspended from May 1, 2020 through March 31, 2021, and reduced payments to several types of Medicare providers. We believe the overall escalating cost of medical products and services being paid for by the government and private health insurance has led to, and will continue to lead to, increased pressures on the healthcare and medical device industry to reduce the costs of products and services.

Data Privacy and Security

Medical device companies may be subject to U.S. federal and state and foreign health information privacy, security and data breach notification laws, which may govern the collection, use, disclosure and protection of health-related and other personal information. In the United States, HIPAA imposes privacy, security and breach reporting obligations with respect to individually identifiable health information upon "covered entities" (health plans, health care clearinghouses and certain health care providers), and their respective business associates, individuals or entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity. HIPAA and its respective implementing regulations, including the final omnibus rule published on January 25, 2013, imposes specified requirements relating to the privacy, security and transmission of individually identifiable health information. HIPAA mandates the reporting of certain breaches of health information to HHS, affected individuals and if the breach is large enough, the media. Entities that are found to be in violation of HIPAA as the result of a breach of unsecured protected health information ("PHI"), a complaint about privacy practices or an audit by HHS, may be subject to significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. The Health Information Technology For Economic and Clinical Health Act also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions.

Even when HIPAA does not apply, according to the Federal Trade Commission or the FTC, failing to take appropriate steps to keep consumers' personal information secure constitutes unfair acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, 15 U.S.C § 45(a). The FTC expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits stronger safeguards. The FTC's guidance for appropriately securing consumers' personal information is similar to what is required by the HIPAA Security Rule.

In addition, certain state and non-U.S. laws, such as the GDPR, govern the privacy and security of health information in certain circumstances, some of which are more stringent or broader in scope than HIPAA and many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts. Further, “business associates,” defined as independent contractors or agents of covered entities that create, receive, maintain or transmit protected health information in connection with providing a service for or on behalf of a covered entity, are also subject to certain HIPAA privacy and security standards. Failure to comply with these laws, where applicable, can result in the imposition of significant civil and/or criminal penalties and private litigation. For example, California enacted the CCPA, which went into effect January 1, 2020. The CCPA, among other things, creates new data privacy obligations for covered companies and provides new privacy rights to California residents, including the right to opt out of certain disclosures of their information. The CCPA also creates a private right of action with statutory damages for certain data breaches, thereby potentially increasing risks associated with a data breach. Although the law includes limited exceptions, including for PHI maintained by a covered entity or business associate, it may regulate or impact our expected processing of personal information depending on the context. Further, the California Privacy Rights Act (CPRA), recently passed in California. The CPRA will impose additional data protection obligations on covered businesses, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. The majority of the provisions will go into effect on January 1, 2023, and additional compliance investment and potential business process changes may be required. In Europe, the GDPR went into effect in May 2018 and introduces strict requirements for processing the personal data of individuals within the EEA. Companies that must comply with the GDPR face increased compliance obligations and risk, including more robust regulatory enforcement of data protection requirements and potential fines for noncompliance of up to €20 million or 4% of the annual global revenues of the noncompliant company, whichever is greater. Relatedly, following the United Kingdom’s withdrawal from the European Economic Area and the European Union, and the expiry of the transition period, companies have to comply with both the GDPR and the GDPR as incorporated into United Kingdom national law, the latter regime having the ability to separately fine up to the greater of £17.5 million or 4% of global turnover. The relationship between the United Kingdom and the European Union in relation to certain aspects of data protection law remains unclear, for example around how data can lawfully be transferred between each jurisdiction, which exposes us to further compliance risk. The State of Israel has also implemented data protection laws and regulations, including the Israeli Protection of Privacy Law of 1981.

Foreign Regulation

As we plan to market and deploy our Nanox System broadly across the globe, we will be subject to regulations applicable to medical and radiation-emitting devices in the jurisdictions in which we operate, which regulations vary among countries. While some countries’ regulations may not impose barriers to marketing and selling our products or only require certain notification, others may require that we obtain the clearance, registration or approval of a specified regulatory body. Process for obtaining such clearance, registration or approvals may involve additional testing and time. Furthermore, complying with foreign regulatory requirements can be expensive and time-consuming, and we will need to seek for regulatory clearances or approvals in each country in which we plan to market our products.

In addition, depending on the country, if we modify our products, we may need to apply for additional regulatory clearances or approvals before we are permitted to sell the modified product. Also, for maintaining our authorizations in a particular country, we will need to continue meeting quality and safety standards required in such country.

Finally, while regulatory clearance or approval by the FDA does not ensure registration, clearance or approval by regulatory authorities in other countries, registration or regulatory clearance or approval in one country, or denial thereof, may have effects on the regulatory process in others.

Legal Proceedings

In September 2020, two securities class action complaints were filed, which were subsequently consolidated and captioned as *White v. Nano-X Imaging Ltd. et al*, Case No. 1:20-cv-04355, filed in the United States District Court for the Eastern District of New York against us and certain current officers and a director alleging violations of securities laws and seeking unspecified damages. On December 7, 2020, proposed lead plaintiffs submissions were fully briefed. We believe this lawsuit is without merit and intend to defend the case vigorously.

We are unable to estimate a range of loss, if any, that could result were there to be an adverse final decision in this case. If an unfavorable outcome were to occur, it is possible that the impact could be material to our results of operations in the period in which any such outcome becomes probable and estimable.

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business.

C. Organizational Structure

NANO-X IMAGING LTD, an Israeli Company (“Nanox IL”), was incorporated on December 20, 2018 and commenced its operations on September 3, 2019.

On September 19, 2019, Nanox IL established Nanox Imaging Inc., a wholly owned subsidiary in Japan.

On September 25, 2020, Nanox IL established Nano-X Korean Inc., a wholly owned subsidiary in Korea.

D. Property, Plants and Equipment

Our principal executive offices are located in a leased facility in Neve Ilan, Israel. We lease approximately 550 square meters (approximately 5,920 square feet) of office space and warehouses. The lease expires in December 2021, and we have the option to extend our lease for an additional 24 months so long as we meet the terms of the original lease agreement.

We also lease approximately 620 square meters (approximately 6,670 square feet) of office space in Neve Ilan, Israel, that may be used for offices and technical development. The lease expires in June 2023. In November 2020, we leased an additional approximately 370 square meters (approximately 3,980 square feet) of office space in Neve Ilan, Israel. This lease also expires in June 2023.

Nanox Japan (predecessor) leases additional facilities of approximately 740 square feet of lab space and approximately 190 square feet of space in a clean room at the premises of the University of Tokyo for research and development activities. The lease automatically renews on a semi-annual basis.

We lease approximately 390 square meters of space for a temporary factory and approximately 200 square meters of space for a research and development center in Korea. The lease for the temporary factory expires in January 2022 and the lease for the research and development center expires in November 2021. In December 2020, we purchased approximately 11,889 square meters of land in Yongin, Geonggi province, on which we intend to build a manufacturing facility for approximately \$6.2 million.

We believe this space will be sufficient to meet our needs for the next 12-18 months and that suitable additional space will be available as and when needed.

(a) Unresolved Staff Comments

Not applicable.

Item 5. Operating and Financial Review and Prospects

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our audited consolidated financial statements and the related notes included elsewhere in this annual report on Form 20-F. This discussion contains forward-looking statements based upon current expectations that involve risks and uncertainties. Our actual results may differ materially from those anticipated in these forward-looking statements as a result of various factors, including those discussed in the section titled “Item 3. Key Information—D. Risk Factors” and in other parts of this annual report on Form 20-F. Our consolidated financial statements have been prepared in accordance with U.S. GAAP. The functional currency of NANO-X IMAGING LTD is the U.S. dollar.

A. Operating Results

Overview

Early detection saves lives—and we at Nanox are focused on applying our proprietary medical imaging technology to make diagnostic medicine more accessible and affordable across the globe. Our vision is to increase early detection of medical conditions that are discoverable by X-ray, which we believe is key to increasing early treatment, improving health outcomes and, ultimately, saving lives.

To further our vision, we have developed a working prototype of the Nanox.ARC, a medical imaging system incorporating our novel X-ray source, and we have developed a prototype of the Nanox.CLOUD, a companion cloud software. If cleared, we plan to market and deploy the Nanox System broadly across the globe at a substantially lower cost compared to currently available medical imaging systems, such as CT. We believe that, if cleared, our technology’s relatively low cost will enable us to increase accessibility and affordability of early-detection medical imaging systems globally.

Since our inception, we have devoted substantially all of our financial resources to acquiring the base technology for our X-ray source and related know-how, conducting research and development activities, organizing and staffing our company, developing our business plan, securing related intellectual property rights and raising capital. We do not have any product approved for sale and have not generated any revenue from product sales. We have funded our operations to date primarily with proceeds from the sale of our ordinary shares and warrants (after September 3, 2019) and those of our predecessor company (prior to September 3, 2019). During the years ended December 31, 2020, 2019 and 2018, we received net cash proceeds of \$240.4 million, \$14.0 million and \$3.7 million, respectively, from the sales of our and our predecessor’s ordinary shares.

We have incurred significant operating losses since our inception. Our ability to achieve profitability depends on the successful development and commercialization of our technology and our products. We incurred net losses of \$43.8 million, \$22.6 million and \$1.9 million for the years ended December 31, 2020, 2019 and 2018, respectively. As of December 31, 2020 and 2019, we had an accumulated deficit of \$84.4 million and \$40.6 million, respectively. We expect to continue to incur significant expenses for at least the next several years as we advance the Nanox System through further development and regulatory approval. If we obtain marketing approval for the Nanox.ARC, we expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. In addition, we incur additional costs associated with operating as a public company, including significant legal, accounting, investor relations and other expenses that we did not incur as a private company.

We plan to jumpstart the MSaaS-based medical imaging market by producing and deploying an initial wave of approximately 15,000 Nanox.ARC units by the end of 2024. We estimate that effectively stimulating market interest in our Nanox System will require deploying at least 5,000 to 10,000 Nanox.ARC units. In addition, we believe that a minimum installed base of at least 1,000 Nanox.ARC units will be required to support our business during the initial wave of deployment, assuming we enter into at least one licensing agreement on commercially reasonable terms. We expect to incur significant expenses for the manufacture, installation, deployment and maintenance of the Nanox System. As a result, we need substantial funding to support our continuing operations and pursue our business strategy before we can generate significant revenues. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financings or other capital sources, including collaborations, strategic partnerships or marketing, distribution or licensing arrangements with third parties. We may be unable to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we may have to significantly delay, scale back or discontinue the development and commercialization of one or more of our products or delay our pursuit of potential in-licenses or acquisitions.

As of December 31, 2020, we had cash and cash equivalents of \$213.5 million. We believe that our cash on hand and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements for at least the next twelve months from the date of issuance of the financial statements. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our capital resources sooner than we expect. See “Item 5. Operating and Financial Review and Prospects—B. Liquidity and Capital Resources.”

Asset Purchase

We were formed on December 20, 2018. Pursuant to the Asset Purchase Agreement, as amended on December 3, 2019 and December 31, 2019, substantially all of the assets of Nanox Gibraltar, including all patents, patent applications and all other intellectual property rights, but not including the shares of Nanox Japan (predecessor), were sold to us for an aggregate consideration of \$13.3 million, reflecting the fair market value of the transferred assets, which was estimated to be \$6.1 million (excluding cash) based on an independent valuation report, plus the cash balance less \$200,000, which cash amount totaled \$7.2 million as of the date of the Asset Purchase Agreement.

Under the terms of the Asset Purchase Agreement, the consideration for the transferred assets will be paid only on the occurrence of one of the following events: (a) the closing of a transaction involving the sale of all or substantially all of our assets; (b) the acquisition of us by, or the merger of us with, another entity, consolidation, reorganization, recapitalization, sale, assignment or disposal by us of all or substantially all of our issued and outstanding shares; (c) the transfer, sale, lease, grant or other disposition of or the grant of an exclusive license over all or substantially all of our assets, including, but not limited to, intellectual property, with the same economic effect to that of a sale and/or cessation of its business; (d) any other transaction, except for a financing round, following which our shareholders prior to the closing of such transaction own, directly or indirectly, less than 50% of the voting power of the surviving entity; (e) the closing of our first underwritten public offering pursuant to a registration statement under the Securities Act or the Securities Law (or under equivalent securities law of another jurisdiction) or any other securities laws world-wide with the same effects and results; and (f) an equity financing by us at a minimum pre-money valuation of \$100.0 million, with proceeds to us of at least \$30.0 million. In the events of (e) or (f) above, we will have the option to pay the consideration in cash or by the issuance to Nanox Gibraltar of our securities of the same series to be issued upon such event, in an amount reflecting a 25% discount on the price per share to be determined in connection with (e) and (f) above. If we elect to pay such consideration in cash, Nanox Gibraltar will have the right, at its sole discretion and in good faith, to reject such payment in cash, and require that we pay such consideration in the form of our securities in such amount and with such discount described above. In connection with this, we recorded a related party liability in an amount of \$17.8 million in its financial statements as of and for the year ended December 31, 2019.

In January 2020, our board of directors and the board of directors and shareholders of Nanox Gibraltar approved the issuance of shares in accordance with the terms of the Asset Purchase Agreement described above. As a result, 1,109,245 of our ordinary shares were issued to Nanox Gibraltar, representing an aggregate consideration of approximately \$17.8 million, and we have no further obligations to Nanox Gibraltar under the Asset Purchase Agreement.

Components of Our Results of Operations

Revenue

As of the date of this annual report on Form 20-F, we have not generated any revenue from product sales or otherwise.

Operating Expenses

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with the research and development of our products. These expenses include:

- expenses incurred in connection with the development of our products, including payments made pursuant to agreements with third parties, such as outside consultants related to process development and manufacturing activities, as well as patent registrations;
- costs of components and materials, including payments made pursuant to agreements with third parties;
- costs of laboratory supplies incurred for each program;
- facilities, depreciation and other expenses, including direct or allocated expenses for rent and maintenance of facilities, as well as insurance costs;
- costs related to compliance with regulatory requirements; and
- employee-related expenses, including salaries, related benefits and share-based compensation expenses for employees engaged in research and development activities.

We recognize external development costs based on an evaluation of the progress to completion of specific tasks using information provided to us by our suppliers and service providers. Upfront payments, milestone payments (other than those deemed contingent consideration in a business combination) and annual maintenance fees under license agreements are expensed in the period in which they are incurred.

Research and development activities are central to our business. We expect that our research and development expenses will increase substantially over the next several years as we continue development of the Nanox System. We expect to continue to devote a substantial portion of our resources to the Nanox.ARC hardware, the Nanox.CLOUD software and our underlying technology for the foreseeable future.

The successful development and commercialization of our products are highly uncertain. At this time, we cannot reasonably estimate or know the nature, timing and costs of the efforts that will be necessary to complete the development of any of our products. This uncertainty is due to the numerous risks and uncertainties associated with product development and commercialization, including the uncertainty of:

- the timing and progress of development activities;
- our ability to maintain our current research and development programs and to establish new ones;
- the receipt of regulatory approvals from applicable regulatory authorities without the need for independent clinical trials or validation;
- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities;
- our ability to establish new licensing or collaboration arrangements;
- the performance of our future collaborators, if any;
- establishing commercial manufacturing capabilities or making arrangements with third-party manufacturers;
- obtaining, maintaining, defending and enforcing patent claims and other intellectual property rights;
- launching commercial sales of our products, including the Nanox.ARC hardware and Nanox.CLOUD software, whether alone or in collaboration with others; and
- maintaining a continued acceptable safety profile of the products following approval.

Any changes in the outcome of any of these variables with respect to the development of our products could result in a significant change in the costs and timing associated with the development of these products. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials or other testing beyond what we currently expect, we could be required to expend significant additional financial resources and time to complete development of our products. We may never obtain regulatory approval for any of our products and third parties may never obtain regulatory approvals for any products containing our technology.

Marketing, General and Administrative Expenses

Marketing expenses consist of public relations and general marketing expenses. General and administrative expenses consist primarily of salaries, related benefits and share-based compensation expense for personnel in executive, finance and administrative functions. General and administrative expenses also include facilities, depreciation and other expenses, which include direct or allocated expenses for rent and maintenance of facilities and insurance, as well as professional fees for legal, patent, consulting, investor and public relations, accounting and audit services.

We anticipate that our marketing, general and administrative expenses will increase as we increase our headcount to support our continued research activities and development of our products. We also incur accounting, audit, legal, regulatory, compliance, director and officer insurance and investor and public relations costs associated with being a public company.

Results of Operations

Comparison of the year ended December 31, 2020 and 2019

The table below summarizes the results of operations for the years ended December 31, 2020 and 2019, respectively, together with the changes in those items in dollars:

	Year Ended December 31,		Change
	2020	2019	
	(\$ in thousands)		
Operating expenses			
Research and development	\$ 9,210	\$ 2,717	\$ 6,493
Marketing	12,445	1,556	10,889
General and administrative	22,268	18,298	3,970
Operating loss	(43,923)	(22,571)	(21,352)
Financial (income) expenses, net	(108)	(8)	(100)
Net loss	\$ (43,815)	\$ (22,563)	\$ (21,252)

Research and Development Expenses

The table below summarizes our research and development expenses incurred during the periods presented:

	Year Ended December 31,	
	2020	2019
	(\$ in thousands)	
Research and Development Expenses:		
R&D - salaries and wages	\$ 2,091	\$ 437
Share-based compensation	3,384	661
R&D - professional services	3,647	1,450
Other	88	169
Total	\$ 9,210	\$ 2,717

Research and development expenses increased by \$6.5 million to \$9.2 million for the year ended December 31, 2020 from \$2.7 million for the year ended December 31, 2019. The increase in research and development expenses was primarily attributable to increases in salaries and wages, share-based compensation and professional services as we continue to expand our research and development activities relating to the Nanox System.

Marketing, General and Administrative Expenses

The table below summarizes our marketing expenses incurred during the periods presented:

	Year Ended December 31,	
	2020	2019
	(\$ in thousands)	
Marketing Expenses:		
Marketing – salaries and wages	\$ 733	\$ 200
Marketing and business development	2,460	739
Share-based compensation	9,252	617
Total	\$ 12,445	\$ 1,556

Marketing expenses increased by \$10.89 million to \$12.45 million for the year ended December 31, 2020 from \$1.6 million for the year ended December 31, 2019. The increase in marketing expenses was primarily attributable to increases in salaries and wages, share-based compensation (of which \$6.1 million related to the amendment to a certain business development agreement with two of our finders, as discussed in “Item 4. Information on the Company—B. Business Overview—Commercial Agreements—MSaaS Agreements”), and professional services as we continue to expand our business and to build management infrastructure to move toward the commercial stage of our business.

The table below summarizes our general and administrative expenses incurred during the periods presented:

	Year Ended December 31,	
	2020	2019
	(\$ in thousands)	
General and Administrative Expenses:		
G&A – salaries and wages	\$ 3,847	\$ 461
Share-based compensation	12,145	14,967
Executives and officers’ insurance	1,812	---
Management fee	171	534
G&A – professional services	2,449	1,470
Legal fees	671	417
Rent and Maintenance	620	143
Depreciation and Amortization	208	32
Other	345	274
Total	\$ 22,268	\$ 18,298

General and administrative expenses increased by \$4.0 million to \$22.3 million for the year ended December 31, 2020 from \$18.3 million for the year ended December 31, 2019. The increase in general and administrative expenses was primarily attributable to increases in salaries and wages, executives' insurance and professional services as we continue to expand our business and to build management infrastructure to move toward the commercial stage of our business.

Comparison of the years ended December 31, 2019 and 2018

The table below summarizes the results of operations for the years ended December 31, 2019 and 2018, respectively, together with the changes in those items in dollars:

	Year Ended December 31,		Change
	2019	2018	
	(\$ in thousands)		
Operating expenses			
Research and development	\$ 2,717	\$ 672	\$ 2,045
Marketing	1,556	209	1,347
General and administrative	18,298	1,023	17,275
Operating loss	(22,571)	(1,904)	(20,667)
Financial (income) expenses, net	(8)	5	(13)
Net loss	\$ (22,563)	\$ (1,909)	\$ (20,654)

Research and Development Expenses

The table below summarizes our research and development expenses incurred during the periods presented:

	Year Ended December 31,	
	2019	2018
	(\$ in thousands)	
Research and Development Expenses:		
R&D - salaries and wages	\$ 437	\$ 131
Share-based compensation	661	—
R&D - professional services	1,450	519
Other	169	22
Total	\$ 2,717	\$ 672

Research and development expenses increased by \$2 million to \$2.7 million for the year ended December 31, 2019 from \$0.7 million for the year ended December 31, 2018. The increase in research and development expenses was primarily attributable to increases in salaries and wages, share-based compensation and professional services as we continue to expand our research and development activities relating to the Nanox System.

Marketing, General and Administrative Expenses

The table below summarizes our marketing expenses incurred during the periods presented:

	Year Ended December 31,	
	2019	2018
	(\$ in thousands)	
Marketing Expenses:		
Marketing – salaries and wages	\$ 200	\$ —
Marketing and business development	739	209
Share-based compensation	617	—
Total	\$ 1,556	\$ 209

Marketing expenses increased by increased by \$1.35 million to \$1.56 million for the year ended December 31, 2019 from \$0.21 million for the year ended December 31, 2018. The increase in marketing expenses was primarily attributable to increases in share-based compensation and professional services as we continue to expand our business and to build management infrastructure to move toward the commercial stage of our business.

The table below summarizes our general and administrative expenses incurred during the periods presented:

	Year Ended December 31,	
	2019	2018
	(\$ in thousands)	
General and Administrative Expenses:		
G&A – salaries and wages	\$ 461	\$ 88
Share-based compensation	14,967	115
Management fee	534	429
G&A – professional services	1,470	84
Legal fees	417	165
Other	449	142
Total	\$ 18,298	\$ 1,023

General and administrative expenses increased by increased by \$17.3 million to \$18.3 million for the year ended December 31, 2019 from \$1.0 million for the year ended December 31, 2018. The increase in general and administrative expenses was primarily attributable to increases in share-based compensation and professional services as we continue to expand our business and to build management infrastructure to move toward the commercial stage of our business.

Critical Accounting Policies and Significant Judgments and Estimates

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States. The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are 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. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 2 to our audited consolidated financial statements appearing elsewhere in this annual report on Form 20-F, we believe that the following accounting policies are those most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Use of Estimates in the Preparation of Financial Statements

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results may differ from those estimates and such differences may have a material impact on our consolidated financial statements. As applicable to the consolidated financial statements, the most significant estimates relate to fair value of share-based payments.

Functional Currency

The U.S. dollar is the currency of the primary economic environment in which our operations is conducted. A substantial portion of the operational costs are denominated in U.S. dollars. Accordingly, our functional currency is the U.S. dollar (“primary currency”).

Foreign currency assets and liabilities are translated into the primary currency using the exchange rates in effect on the consolidated balance sheet date. Equity accounts are translated at historical rates, except for the change in accumulated deficit during the year, which is the result of the income statement translation process. Expense accounts are translated using the weighted average exchange rate during the period. Currency transaction gains and losses are presented in financial income and expenses.

Property and Equipment, Net

Property and equipment are stated at cost, net of accumulated depreciation. Depreciation is calculated on a straight-line basis over the following estimated useful lives:

	%
Computers and electronic equipment	10–33
Office furniture and lab equipment	6-20
Machines	10-20
Leasehold Improvement	10
Land	0
Construction in progress	0

Impairment of Long-Lived Assets

Our long-lived assets are reviewed for impairment in accordance with ASC No. 360, “Property, Plant and Equipment,” whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. The recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to the future undiscounted cash flows expected to be generated by such assets. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. During the years ended December 31, 2020 and 2019, no impairment triggering events were identified.

Legal and Other Contingencies

We are involved in claims and other legal proceedings that arise from time to time in the ordinary course of business. We record accruals for these types of contingencies to the extent that we conclude their occurrence is probable and that the related liabilities are estimable. When accruing these costs, we will recognize an accrual in the amount within a range of loss that is the best estimate within the range. When no amount within the range is a better estimate than any other amount, we accrue for the minimum amount within the range. We record anticipated recoveries under existing insurance contracts that are virtually certain of occurring at the gross amount that is expected to be collected.

We review the adequacy of the accruals on a periodic basis and may determine to alter our reserves at any time in the future if we believe it would be appropriate to do so. As such accruals are based on management's judgment as to the probability of losses and, where applicable, actuarially determined estimates, accruals may materially differ from actual verdicts, settlements or other agreements made with regards to such contingencies.

Research and Development Expenses

Research and development expenses are charged to the statement of operations as incurred and consist primarily of personnel, materials and supplies for research and development activities.

Marketing and Sales Expenses

Marketing expenses consist primarily of marketing campaigns and business development expenses. Marketing expenses are charged to the statement of operations, as incurred. Marketing expenses for the years ended December 31, 2020 and 2019, amounted to \$12.45 million and \$1.6 million, respectively.

Income Tax

We account for income taxes in accordance with ASC 740, "Income Taxes" ("ASC 740"). ASC 740 prescribes the use of the liability method whereby deferred tax asset and liability account balances are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. We provide a valuation allowance, if necessary, to reduce deferred tax assets to the assets' estimated realizable value if it is more likely than not that a portion or all of the deferred tax assets will not be realized, based on the weight of available positive and negative evidence. Deferred tax liabilities and assets are classified as non-current in accordance with ASU 2015-17.

Taxes that would apply in the event of disposal of investments in our foreign subsidiary have not been taken into account in computing the deferred income taxes, as it is our intent and ability to hold these investments.

We account for uncertain tax positions in accordance with ASC 740-10. ASC 740-10 contains a two-step approach to recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position taken or expected to be taken in a tax return by determining if the weight of available evidence indicates that it is more likely than not that, on an evaluation of the technical merits, the tax position will be sustained on audit, including resolution of any related appeals or litigation processes. The second step is to measure the tax benefit as the largest amount that is more than 50% (cumulative probability) likely to be realized upon ultimate settlement. We accrue interest and penalties related to unrecognized tax benefits under taxes on income (tax benefit).

Share-Based Compensation

We measure and recognize share-based compensation expense in our consolidated financial statements based on the grant date fair value for all share-based payment awards made to non-employees, employees, officers and directors. We recognize the grant date fair value of the award as an expense based on the straight-line method over the requisite service periods in our consolidated statements of operations.

We estimated the grant date fair value of share options for the years ended December 31, 2020 and 2019 using the Black-Scholes option-pricing model. Our use of the Black-Scholes option-pricing model requires the input of highly subjective assumptions, including estimated fair value of our ordinary share price, expected share price volatility and expected term.

- **Estimated Fair Value of Share Price.** Because our shares were not publicly traded prior to our initial public offering, we estimated the fair value of options granted to non-employees, employees, officers and directors at the date of grant using a number of objective and subjective factors consistent with the methodologies outlined in the American Institute of Certified Public Accountants Practice Aid, Valuation of Privately-Held-Companies Equity Securities Issued as Compensation, and based on independent third-party valuations that we obtained on a periodic basis. Following our initial public offering, our ordinary shares are publicly traded, and therefore we currently base the value of our ordinary shares on their market price.
- **Risk-Free Interest Rate.** We base the risk-free interest rate on the implied yield on currently available U.S. treasury bonds with a remaining term equal to the expected life of our options.
- **Dividend Yield.** We base dividend yield on our historical experience and expectation of no future dividend payouts. We have historically not paid cash dividends and have no foreseeable plans to pay cash dividends in the future.
- **Expected Volatility.** We base expected share price volatility on the historical volatility of the ordinary shares of comparable companies that are publicly traded.
- **Expected Term.** The expected term of options granted represents the period of time that options granted are expected to be outstanding. As we do not have sufficient historical exercise data to provide a reasonable basis upon which to estimate expected term, the expected term was determined using the simplified method, which takes into consideration the option's contractual life and the vesting periods.

Any changes in these highly subjective assumptions would significantly impact our share-based compensation expense.

Loss per Share

Basic earnings per share are computed by dividing net income (loss) attributable to our ordinary shareholders by the weighted average number of ordinary shares outstanding for each reporting period.

In computing our diluted earnings per share, the denominator for diluted earnings per share is a computation of the weighted-average number of ordinary shares and the potential dilutive ordinary shares outstanding during the period. Potential dilutive ordinary shares outstanding include the dilutive effect of in-the-money options using the treasury stock method.

We did not take into account any dilutive instruments, such as share-based payments, since their effect, on a fully diluted basis, is anti-dilutive.

Fair Value Measurement

Fair value is based on the price that would be received from the sale of an asset or that would be paid to transfer a liability in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability in fair value measurements, the guidance establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described as follows:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable prices that are based on inputs not quoted on active markets, but corroborated by market data.

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, we utilize valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible and considers counterparty credit risk in its assessment of fair value.

Deferred offering costs directly relating to our initial public offering are capitalized. As of December 31, 2020 we did not capitalize any deferred offering costs on the consolidated balance sheet, comparing to \$1.2 million as of December 31, 2019.

JOBS Act

The JOBS Act permits an “emerging growth company” such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected to “opt out” of such extended transition period and, as a result, we will comply with new or revised accounting standards as required when they are adopted for public companies.

Recently Issued Accounting Pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in Note 2 to our audited consolidated financial statements, included elsewhere in this annual report on Form 20-F.

B. Liquidity and Capital Resources

Since our inception, we have not generated any revenue from product sales or otherwise, and have incurred significant operating losses and negative cash flows from our operations. We have not yet commercialized any products or technologies, and we do not expect to generate revenue from sales of any products in the near term, if at all. We have funded our operations to date primarily with proceeds from the sale of our and our predecessor company’s ordinary shares.

Cash Flows

The following table provides information regarding our cash flows for the periods presented:

	Year Ended December 31,		
	2020	2019	2018
	(\$ in thousands)		
Net cash used in operating activities	(\$ 21,487)	(\$ 5,524)	(\$ 3,671)
Net cash used in investing activities	(13,937)	(125)	(73)
Net cash provided by financing activities	240,991	13,861	3,684
Net change in cash and cash equivalents and restricted cash	\$ 205,567	\$ 8,212	\$ (60)

Net Cash used in Operating Activities

During the years ended December 31, 2020, 2019 and 2018, net cash used in operating activities was \$21.5 million, \$5.5 million and \$3.7 million, respectively, resulting from our net loss of \$43.8 million, \$22.6 million and \$1.9 million, respectively, adjusted for stock-based compensation changes of \$24.8 million, non-cash charges of \$0.2 million and changes in components of working capital of (\$2.7) million for the year ended December 31, 2020, \$16.25 million, \$0.1 million and \$0.75 million for the year ended December 31, 2019 and \$0.1 million, \$0.1 million and (\$1.9) million for the year ended December 31, 2018, respectively. The increase in cash used in operating activities was primarily due to activities related to our business expansion.

Net Cash used in Investing Activities

During the years ended December 31, 2020, 2019 and 2018, net cash used in investment activities was \$13.9 million, \$0.1 million and \$0.1 million, respectively. The increase in cash used in investing activities during the year ended December 31, 2020 was primarily due to purchases of land and equipment in Korea, as part of the preparation for the commencement of full manufacturing activity.

Net Cash provided by Financing Activities

During the years ended December 31, 2020, 2019 and 2018, net cash provided by financing activities was \$241 million, \$13.9 million and \$3.7 million, respectively, primarily due to proceeds from the issuance of ordinary shares and warrants, net of issuance costs.

Funding Requirements

We expect our expenses to increase in connection with our ongoing activities, particularly as we continue the research and development of the Nanox System and seek marketing approval for this product. In addition, we incur additional costs associated with operating as a public company. Our expenses will also increase if, and as, we:

- seek regulatory approvals for any additional products;
- seek to discover and develop additional products;
- establish a manufacturing, sales, marketing, medical affairs and distribution infrastructure to commercialize the Nanox System for which we may obtain marketing approval and intend to commercialize on our own or jointly;
- hire additional quality control and scientific personnel;
- expand our operational, financial and management systems and increase personnel, including personnel to support our clinical development, manufacturing and commercialization efforts and our operations as a public company;
- construct a manufacturing facility in South Korea for the purpose of manufacturing MEMs X-ray chips;
- maintain, expand and protect our intellectual property portfolio; and
- acquire or in-license other products and technologies.

We believe that our cash on hand and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements for at least the next twelve months from the date of issuance of the financial statements. We have based this estimate on assumptions that may prove to be wrong, and we could exhaust our available capital resources sooner than we expect.

Because of the numerous risks and uncertainties associated with manufacture, research, development and commercialization of products, we are unable to estimate the exact amount of our working capital requirements. Our future funding requirements will depend on, and could increase significantly as a result of, many factors, including:

- the scope, progress, results and costs of researching and developing the Nanox System;
- the costs, timing and outcome of regulatory review of the Nanox.ARC;
- the costs of future activities, including product sales, medical affairs, marketing, manufacturing and distribution, for the Nanox System for which we receive marketing approval;
- commercial manufacturing, shipping, installation and deployment of the Nanox System and sufficient inventory to support commercial launch;
- the revenue, if any, received from commercial sale of the Nanox System, should the Nanox.ARC receive marketing approval;
- the cost and timing of hiring new employees to support our continued growth;

- the costs of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending intellectual property-related claims;
- the ability to establish and maintain collaborations on favorable terms, if at all;
- the costs incurred with respect to and the outcome of the securities class-action litigation we are currently subject to and any similar or other claims and litigation we may be subject to in the future; and
- the timing, receipt and amount of sales of the Nanox System, if any.

A change in any of these or other variables with respect to the development of any of our products could significantly change the costs and timing associated with the development of that product. Further, our operating plans may change in the future, and we may need additional funds to meet operational needs and capital requirements associated with such operating plans.

Until such time, if ever, as we can generate substantial product revenue, we expect to finance our cash needs through a combination of public or private equity offerings, debt financings, collaborations, strategic partnerships or marketing, distribution or licensing arrangements with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest may be materially diluted, and the terms of such securities could include liquidation or other preferences that adversely affect your rights as an ordinary shareholder. Debt financing and preferred equity financing, if available, may involve agreements that include restrictive covenants that limit our ability to take specified actions, such as incurring additional debt, making capital expenditures or declaring dividends. In addition, debt financing would result in increased fixed payment obligations.

If we raise funds through collaborations, strategic partnerships or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or products or grant licenses on terms that may not be favorable to us.

If we are unable to raise additional funds when needed, we may be required to delay, reduce or eliminate our product development or future commercialization efforts, or grant rights to develop and market products that we would otherwise prefer to develop and market ourselves.

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

Research and Development Expenses

Research and development expenses are charged to the statement of operations as incurred and consist primarily of personnel, materials and supplies for research and development activities. See “Item 5. Operating and Financial Review and Prospects—A. Operating Results—Critical Accounting Policies and Significant Judgments and Estimates—Research and Development Expenses.”

Intellectual Property

As of February 28, 2021, we had four issued patents in the United States and six provisional or pending U.S. patent applications. We also had three patents issued in Israel, two patents pending in Israel, five pending patent applications in the European Patent Office and two pending Patent Cooperation Treaty patent applications, which are the counterparts of our U.S. patent applications. As of January 3, 2021, we had three patents issued in each of Japan and China, two patents pending in each of Japan and China and five pending patent applications in Korea. Our issued patents expire between the years 2032 and 2034, and are directed to various features and combinations of features of the Nanox.ARC. We also have three trademarks granted and three trademarks pending in Israel.

We intend to continue filing for patents on new technologies as they are developed and to actively pursue any infringement upon our patents. We believe that our know-how and trade secrets represent de facto barriers to potential competition.

D. Trend Information

We are a development-stage company and cannot predict with any degree of accuracy the outcome of our research and development efforts. As such, we cannot predict with any degree of accuracy any significant trends, uncertainties or events that are reasonably likely to have a material effect on our net loss, liquidity or capital resources, or cause financial information to not be indicative of future operating results or financial condition. However, to the extent possible, certain trends, uncertainties, demands, commitments and events are described in this “Item 5. Operating and Financial Review and Prospects.”

E. Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

F. Contractual Obligations and Commitments

The following table summarizes our contractual obligations as of December 31, 2020 and the effects that such obligations are expected to have on our liquidity and cash flows in future periods:

Contractual Obligations	Payment due by period				
	(\$ in thousands)				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Capital (Finance) Lease Obligations	—	—	—	—	—
Operating Lease Obligations	\$ 1,558	\$ 588	\$ 970	—	—
Purchase Obligations	—	—	—	—	—
Total	\$ 1,558	\$ 588	\$ 970	—	—

We have entered into contracts in the normal course of business with third parties. These contracts do not contain any minimum purchase commitments and are cancelable by us upon prior notice and, as a result, are not included in the table of contractual obligations and commitments above. Payments due upon cancellation consist only of payments for services provided and expenses incurred, including non-cancelable obligations of our service providers, up to the date of cancellation.

G. Safe Harbor

This annual report on Form 20-F contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act and as defined in the Private Securities Litigation Reform Act of 1995. See section titled “Forward-Looking Statements.”

Item 6. Directors, Senior Management and Employees

A. Directors and Senior Management

The following table sets forth information concerning our executive officers and directors, including their ages, as of March 20, 2021:

Name	Age	Position
Executive Officers		
Ran Poliakine	53	Founder, Chief Executive Officer and Chairman of the Board
Itzhak Maayan	55	Chief Financial Officer
James Dara	51	Chief Operating Officer
Tal Shank	43	Vice President Corporate Development
Ofir Koren	51	Chief Technology Officer
Tamar Aharon Cohen	44	Chief Marketing Officer
Anat Kaphan	51	Vice President Product Marketing
Shirly Kaufman-Kirshenbaum	46	Vice President Human Resources
Non-Employee Directors		
Onn Fenig	46	Director
Floyd Katske	69	Director
Jung Ho Park	57	Director
Erez Meltzer	63	Director
Richard Stone	78	Director
Noga Kainan	66	Director
Dan Suesskind	77	Director

Executive Officers

Ran Poliakine, our founder, has served as a member of our board of directors since our inception and has served as the Chairman of the Board of Directors since the closing of our initial public offering. Mr. Poliakine has served as our Chief Executive Officer since September 2019, and served as Chief Executive Officer of Nanox Gibraltar since August 2018. Prior to that, he served as Chief Strategy Officer in Nanox Gibraltar from June 2015 to August 2018. Mr. Poliakine is a serial entrepreneur and has founded numerous companies over the past two decades, including SixAI Ltd. (“SixAI”) and its controlled subsidiary (51%) 634 Ai Ltd. (previously known as Musashi Ai Ltd.) (“634 Ai”), Powermat Technologies Ltd., Wellsense, Inc., Wellsense Technologies Ltd., Tap Systems, Inc. and Illumigyn Ltd. (“Illumigyn”). Mr. Poliakine is a member of the board of directors of SixAI, Powermat Technologies Ltd., 634 Ai, and CLKIM Ltd. In addition, Mr. Poliakine currently serves as a member of senior management of Illumigyn.

Itzhak Maayan has served as our Chief Financial Officer since November 2019. Prior to joining us, Mr. Maayan served in different finance leadership roles in Perrigo Company from 2007 to 2019, including Vice President, Financial Services and European Investor Relations, Vice President, International Finance, and Vice President and Chief Financial Officer, Perrigo Israel. Prior to Perrigo Company, Mr. Maayan held various finance leadership roles at Cisco Systems Israel from 2003 to 2007, Xtivia, Inc. from 1999 to 2003, Kulick & Soffa from 1995 to 1999 and Elscint Ltd. from 1993 to 1995. Mr. Maayan received his bachelor’s degree in economics and accounting from Haifa University, and is a Certified Public Accountant in Israel.

James Dara has served as our Chief Operating Officer since January 2021. Prior to joining us, Mr. Dara served as President of myCharge from 2012 to 2020. Prior to myCharge, Mr. Dara served as Vice President of Business Development for Powermat Technologies Ltd. from 2009 to 2014 and as Interim CEO and Vice President of Business Development of Wellsense Technologies Ltd. from 2009 to 2015. From 2003 to 2009, Mr. Dara served as Chief Sales Officer, Senior Vice President and General Manager of North America for Braintech Inc. In addition, from 1998 to 2002, Mr. Dara served as a Sales Manager and Sales Engineer for ITW Shakeproof Group. Mr. Dara received his bachelor of science in Mechanical Engineering from Michigan State University, and his master’s degree in Finance from Walsh University.

Tal Shank has served as our Vice President of Corporate Development since September 2019. Mr. Shank has served as Head of Corporate Development at Illumigyn from 2017 to date. Mr. Shank currently serves on the board of directors of Nanox Gibraltar. From 2016 to 2017, Mr. Shank was responsible for the corporate and governance aspects of Head Start, a company supplier of services to technology portfolio companies related to Ran Poliakine. Prior to that, Mr. Shank served as Deputy CEO & Legal Counsel of Speech Modules Holdings Ltd. from 2014 to 2015. From 2009 to 2014, Mr. Shank worked at Guy, Bachar & Co. Law Firm, where he started as an associate and became partner in 2011. Mr. Shank has practiced corporate and securities law in Israel since 2003, and he holds an M.B.A. and a LL.M. from Tel Aviv University.

Ofir Koren has served as our Chief Technology Officer since January 2021. Prior to joining us, Mr. Koren served as General Manager Israel and Vice President of Research & Development and Regulatory at ReWalk Robotics from 2013 to 2021. From 2012 to 2013, Mr. Koren served as Research & Development Manager for ReWalk Robotics. Prior to ReWalk Robotics, Mr. Koren served as General Manager at RuggedCOM from 2009 to 2012. From 2007 to 2009, Mr. Koren served as Vice President of Research & Development at Alvarion. Mr. Koren served as Research & Development Director at Alvarion from 2004 to 2007. Mr. Koren received his bachelor of science in Electrical Engineering from Tel Aviv University, and he holds an M.B.A. from Heriot-Watt University.

Tamar Aharon Cohen has served as our Chief Marketing Officer since January 2021. Prior to joining us, Ms. Aharon Cohen served as the Chief Executive Officer of Tempo Beverages Cyprus Ltd from 2017 to 2021. Ms. Aharon Cohen served as a Marketing Manager and a Division Manager at Tempo Beverages Ltd from 2010 to 2017. From 2006 to 2010, Ms. Aharon Cohen served as a Marketing Manager, for L'Oréal Israel. Ms. Aharon Cohen holds a bachelor of Law, a bachelor's in Management and an executive M.B.A. from Tel Aviv University.

Anat Kaphan has served as our Vice President of Product Marketing since September 2019. Prior to joining us, Ms. Kaphan served as Vice President of Product and Marketing at Mazor Robotics Ltd. from 2015 to 2018, and General Manager at Essence Group from 2014 to 2015. She also served as Marketing Director at Phillips from 2011 to 2014. Prior to that, Ms. Kaphan served as Business Development Director at Lumenis from 2001 to 2011 and Product Manager at Elscint Ltd. from 1991 to 2001. Ms. Kaphan holds an M.B.A. in International marketing from Tel Aviv University and received her bachelor's degree in Economics and Accounting from Haifa University.

Shirly Kaufman-Kirshenbaum has served as our Vice President Human Resources since April 2020. Prior to joining us, Ms. Kaufman-Kirshenbaum served as Human Resources Director of Israeli-American Council (IAC) from December 2017 to April 2020, and as Regional Human Resources Director and HRBP of EMEA and Canada at ZIM Integrated Shipping Services Ltd. from September 2010 to August 2016. Ms. Kaufman-Kirshenbaum has her bachelor's degree in Human Resources from Haifa University.

Directors

Onn Fenig has served as a member of our board of directors since November 2019. Mr. Fenig has served as the chairman of the board of directors of "Beit Meitar" Waldorf Education Association since 2018. Mr. Fenig is a member of the board of directors of SixAI and manages the operations of 634 Ai. Mr. Fenig has served as Chief Executive Officer and a member of the board of directors of Rioglass Solar systems Ltd. since 2014, and as Chief Executive Officer of Rioglass Solar Receivers BU from 2016 to 2018. Prior to that, Mr. Fenig co-founded and served as a member of the board of directors of DUTYFREEBEE LTD from 2013 to 2015. From 2011 to 2014, Mr. Fenig served as Commercial Director, Project Acquisition Finance at Siemens, where he managed finance and commercial matters relating to engineering procurement and construction projects. Prior to joining Siemens, Mr. Fenig served as Finance Manager, Inside Sales European Markets at Cisco Systems from 2008 to 2010, Service Fulfilment Delivery Manager at Amdocs UK from 2006 to 2008, and Systems Analyst, Cyber Security Department at Israeli Ministry of the Prime Minister from 2001 to 2005. Mr. Fenig received his bachelor's degree in Computer Science from the Interdisciplinary Center Herzliya in Herzliya, Israel, and holds an M.B.A. from the University of Chicago Booth School of Business in Chicago, Illinois.

Floyd Katske has served as a member of our board of directors since February 2020. Dr. Katske serves on the board of directors of Floyd A. Katske, M.D., a professional corporation, and Triurol Inc. Since 1983, Dr. Katske has served as President of Floyd A. Katske, M.D. and since 1999, he has served as President of Triurol, Inc. From 2009 to 2011, Dr. Katske served as the President of the Santa Clarita Valley Medical Society and from 1997 to 1999, Dr. Katske served as the President of the California Urologic Association. Dr. Katske is a member of the Medical Board of California and has worked as a professor and as Chief of Staff, Chief of Surgery and Chief of Urology in various hospitals. Dr. Katske received his bachelor's degree from Rutgers University, and received his medical degree from The George Washington University.

Jung Ho Park has served as a member of our board of directors since August 2020. Mr. Park has served as CEO of SK Telecom since March 2017 and Co-CEO of SK hynix since March 2021. In his role he also oversees SK ICT Family companies, which include SK broadband, 11street, ADT Caps and T map Mobility Co. He serves on the board of directors for SK Telecom and is the Chairman of SK Group's ICT Committee. He previously served as the Vice Chairman of SK Hynix. Prior to that, Mr. Park served as CEO of SK Holdings from 2015 to 2016, Executive Vice President of Corporate Development Division of SK C&C from 2013 to 2014, Executive Vice President of Corporate Development Division of SK Telecom from 2009 to 2014, Managing Director of Business Development of SK Communication from 2007 to 2008, Head of Tokyo office for SK Telecom beginning in 2006, Director of Corporate Relations for the SK Group from 2004 to 2006 and President of the New York Branch Office of SK Telecom from 1995 to 1999. Mr. Park received his bachelor's degree in Business Administration from Korea University, and received a master's degree in Business Administration from George Washington University.

Erez Meltzer has served as a member of our board of directors since December 2019. Mr. Meltzer served as the Executive Chairman of the board of directors of Hadassah Medical and University Center from 2014 to 2020. Since 2008, Mr. Meltzer has served as a teaching professor at the Tel Aviv Faculty of Medicine in the area of crisis management. Meltzer served as Executive Vice Chairman and Chief Executive Officer of Gadot Chemicals & Shipping Group from 2008 to 2013. Prior to that, he served as Chief Executive Officer of Africa-Israel Ltd from 2006 to 2008 and President and Chief Executive Officer of Netafim Ltd from 2001 to 2006. Mr. Meltzer also served as Chief Executive Officer of Creo Scitex from 1996 to 2001.

Richard Stone has served as a member of our board of directors since November 2019. Professor Stone has taught at Columbia University Law School since 1974, and became Professor Emeritus in 2018. Professor Stone has taught courses in several fields of business law, specializing in federal income taxation. From 1969 to 1973, Professor Stone served in the United States Justice Department as Assistant to the Solicitor General of the United States. Beginning in 1981, Professor Stone began providing consulting to private and public technology start-ups, primarily in the biotechnology field. Professor Stone co-founded several biotechnology companies, including Lev Pharmaceuticals, Siga Technologies and OptMed. In 2007, Professor Stone began working primarily with Israeli technology companies, mostly in the medical space. He is a member of the board of directors of OptMed, Inc., Espro Information Technologies, Quality In Flow, LabStyle Innovations and Illumigyn. Professor Stone received his bachelor's degree, Magna Cum Laude, from Harvard College, and his Juris Doctor degree, Magna Cum Laude, from Harvard Law School.

Noga Kainan has served as a member of our board of directors since February 2021. Ms. Kainan established in 2008 the forum for owners, chairpersons and CEOs of the leading companies in the Israeli economy. Ms. Kainan also serves as chairperson of the CFO Forum, which brings together the CFOs of the leading companies in the economy, since she established it in 1997. Her public activities include membership in committees in the Israeli Prime Minister's Office, member in the Board of Trustees of Bar Ilan University, the College of Management in Israel, and the council of NGO for IDF soldiers' welfare. Ms. Kainan heads an association that she founded to promote the integration of autistic students in academia. Ms. Kainan served as a director of the following companies traded on the Tel Aviv Stock Exchange: Bizportal Ltd., Poalim I.B.I – Managing & Underwriting Ltd. and Analyst Provident Funds Ltd. She also served as director at Oil Refineries Ltd. before the company was listed on the Tel Aviv Stock Exchange. She served as a representative at the International Association of Financial Executives Institutes (IAFEI) and as Chair of the Founding Committee of the Organization of Foreign Companies traded in the U.S. Ms. Kainan, co-authored "Israel - Success Story," translated to English under the name: "Israel - Island of Success." Ms. Kainan has a bachelor's degree in art and literature from Haifa University and an M.B.A. from Tel Aviv University.

Dan Suesskind has served as a member of our board of directors since February 2021. Mr. Suesskind served as the Chief Financial Officer of Teva Pharmaceutical Industries Ltd. (“Teva”) from 1977 to 2008 and as a director of Teva for several periods of time, until 2018. Mr. Suesskind also served as a director of the following companies: Redhill Biopharma Ltd., Syneron Medical Ltd., Migdal Ltd., Ness Technologies Inc., The First International Bank of Israel, First International Selective Investment – Portfolio Management Company LTD, Lanoptics Ltd., ESC Medical Systems and the Hadassah Medical Center in Jerusalem. Mr. Suesskind is currently a director of Nexfar Limited - China, Israel Corporation Ltd. and The Jerusalem Foundation. His public activities include membership in the Investment Committee of the Israeli Academy of Sciences and Humanities, member in the Board of Trustees of The Hebrew University and the Board of Trustees of the Ben Gurion University. Mr. Suesskind has a bachelor’s degree in economics and political science from the Hebrew University of Jerusalem, an M.B.A. from the University of Massachusetts, and a Certificate in Business Administration from the Hebrew University of Jerusalem.

B. Compensation

Compensation of Executive Officers and Directors

For so long as we qualify as a foreign private issuer, we are not required to comply with the proxy rules applicable to U.S. domestic companies, including the requirement applicable to emerging growth companies to disclose the compensation of our chief executive officer and other two most highly compensated executive officers on an individual, rather than an aggregate, basis. The aggregate compensation, including bonuses described in more detail below and share-based compensation, paid and by us to our executive officers and directors for the year ended December 31, 2020 was approximately \$6.5 million. In addition, approximately \$274,000 in the aggregate was set aside or accrued to provide pension, severance, retirement or similar benefits or expenses. The figure does not include business travel, relocation, professional and business association dues, meals and expenses reimbursed to officers, and other benefits commonly reimbursed or paid by companies in Israel, on the same basis for all full-time employees generally. The aggregate compensation to our executive officers and directors includes payments from Nanox Gibraltar, including through Six-Eye Interactive Ltd.

During 2020, certain of our executive officers received bonuses in the following gross amounts: \$700,000 to Mr. Poliakine in recognition of his efforts in connection with our initial public offering and certain private placement investments; \$100,000 to Mr. Maayan in recognition of his efforts in connection with our initial public offering; \$40,911 to Mr. Yron in connection with his hiring as our Chief Business Officer; \$139,000 to Mr. Shank in recognition of his efforts in connection with our initial public offering and his contribution to our business; and \$34,232 to Ms. Kaphan in recognition of her efforts in connection with our initial public offering. The gross amounts were paid, less applicable taxes and social security payments and withholdings to the extent applicable.

We pay each of our non-employee directors who serves on a board committee an annual retainer of \$36,000, with additional annual payment for service on board committees as follows: \$7,500 (or \$15,000 for the chairperson) per membership of any committee. In addition, our external directors receive a cash fee of \$36,000 per year plus additional compensation for service on a committee, as discussed above, and options to purchase our ordinary shares with an economic value at the date of grant of \$580,723, vesting quarterly over a period of four years, with full acceleration upon consummation of an M&A Transaction (as defined in our 2019 Equity Incentive Plan). Effective as of October 1, 2020, we paid Dr. Floyd Katske a cash amount of \$200 per hour (not exceeding 100 hours per month) and a grant of Restricted Share Units (“RSUs”) in each calendar quarter, in the amount calculated by dividing (a) two times the cash compensation paid during such quarter by (b) the fair market value of our ordinary shares on the last trading day of such quarter for services provided to us not related to his duty as director. Effective as of January 2, 2021, we appointed Erez Melzer as a “Designated Director” (as defined below) pursuant to the compensation policy and will pay him additional compensation in such capacity, consisting of cash compensation of \$80,000 per year, and \$200,000 in equity-based compensation in the form of RSUs to be granted in quarterly installments, calculated according to the fair market value of our ordinary shares on the last trading day of such quarter.

Directorship Agreements

We have entered into directorship agreements with each of our directors, pursuant to which such directors will serve on our board of directors. Pursuant to these agreements, each director was granted options under our 2019 Equity Incentive Plan in the number and terms set out under “—Equity Incentive Plan” below.

Employment Agreements

We have entered into written employment agreements with certain of our executive officers. These agreements provide for notice periods of varying duration for termination of the agreement by us or by the relevant executive officer, during which time the executive officer will continue to receive base salary and benefits. These agreements also contain customary provisions regarding non-competition, confidentiality of information and assignment of inventions. However, the enforceability of the non-competition provisions may be limited under applicable law. See “Item 3. Key Information—D. Risk Factors—Risks Related to Employee Matters—Under applicable employment laws, we may not be able to enforce covenants not to compete and therefore may be unable to prevent our competitors from benefitting from the expertise of some of our former employees” for a further description of the enforceability of non-competition clauses.

We have entered into an employment agreement with Ran Poliakine, our founder, director and Chief Executive Officer. Pursuant to the agreement, if the Company terminates Ran Poliakine’s employment and waives his obligation to perform services during the notice period of 180 days, Ran Poliakine will be entitled to receive payments of his base salary and social benefits in lieu of notice for the waived period, up to the full notice period for an immediate termination. The agreement provides Ran Poliakine with a gross monthly base salary equal to \$40,000 which was increased to \$60,000 upon the consummation of our initial public offering.

Equity Incentive Plan

On September 3, 2019, we adopted the 2019 Equity Incentive Plan and its U.S. sub-Plan (the “2019 Equity Incentive Plan” or “Plan”). The 2019 Equity Incentive Plan is intended to afford an incentive to any of our and our affiliates’ employees, directors, officers, consultants, advisors and any other person or entity who provides services to us, to continue as service providers, to increase their efforts on our and our affiliates’ behalf and to promote our success, by providing such persons with opportunities to acquire a proprietary interest in us. The U.S. sub-Plan applies to our and any of our affiliates’ employees, directors, officers, consultants, advisors and any other person or entity who provides services to us who are subject to United States federal income tax.

We may issue under the 2019 Equity Incentive Plan and its U.S. sub-Plan up to 8,041,936 of our ordinary shares, subject to adjustment if particular capital changes affect our share capital or such other number as our board of directors may determine from time to time. Ordinary shares subject to outstanding awards under the 2019 Equity Incentive Plan and its U.S. sub-Plan that subsequently expire, or are cancelled, forfeited or terminated for any reason before being exercised will be automatically, and without any further action, returned to the share reserve under the Plan and will again be available for grant.

The following table sets forth, as of December 31, 2020, the total number of ordinary shares issuable upon exercise of the options granted to each of our executive officers and our non-employee directors, the exercise price of such options, the grant date and the expiration date.

Name	Number of Options	Exercise Price	Date of Grant	Expiration Date
Ran Poliakine	1,206,290	\$ 2.21	November 25, 2019	November 25, 2029
Onn Fenig	40,234	\$ 2.21	November 25, 2019	November 25, 2029
Floyd Katske	40,234	\$ 16.00	April 20, 2020	April 20, 2030
Erez Meltzer	40,234	\$ 2.21	February 11, 2020	February 11, 2030
Jung Ho Park	100,000	\$ 16.00	June 4, 2020	June 4, 2030
Richard Stone	100,584	\$ 2.21	November 25, 2019	November 25, 2029
Itzhak Maayan	161,107	\$ 2.21	November 25, 2019	November 25, 2029
Gilad Yron ⁽¹⁾	100,000	\$ 26.56	October 22, 2020	October 22, 2030
James Dara	0	N/A	N/A	N/A
Anat Kaphan	112,754	\$ 2.21	November 25, 2019	November 25, 2029
Ofir Koren	0	N/A	N/A	N/A
Yoel Raab ⁽²⁾	152,754	\$ 2.21	November 25, 2019	November 25, 2029
Tamar Aharon Cohen	0	N/A	N/A	N/A
Tal Shank	74,362	\$ 2.21	November 25, 2019	November 25, 2029
Shirly Kaufman-Kirshenbaum	50,000	\$ 16.00	April 20, 2020	April 20, 2030

(1) Mr. Yron ceased serving as an executive officer on February 28, 2021. As of February 28, 2021, Mr. Yron had 8,333 options that expire on May 31, 2021.

(2) Mr. Raab ceased serving as an executive officer on January 17, 2021.

In January 2021, we approved the grant of options to each of Ofir Koren, James Dara and Tamar Aharon Cohen in respect of 100,000, 100,000 and 33,000 ordinary shares, respectively. In March 2021, our Compensation Committee and board of directors ratified and confirmed the above grants as required by the Israeli Companies Law. All grants of options will be issued pursuant to the 2019 Equity Incentive Plan. All options held by our directors, our Chief Executive Officer and our Chief Financial Officer will be fully accelerated upon a “Deemed Liquidation” as defined in the 2019 Equity Incentive Plan and 50% of unvested options held by our other executive officers will be fully accelerated upon a “Deemed Liquidation.”

For a description of our compensation policy, see “Item 6. Directors, Senior Management and Employees—C. Board Practices—Compensation Committee.”

C. Board Practices

Board of Directors

Our board of directors currently consists of eight directors. Our two external directors, as well as three additional directors, are qualified as independent directors under the corporate governance standards of the Nasdaq corporate governance rules and the independence requirements of Rule 10A-3 of the Exchange Act.

Under our amended and restated articles of association, the number of directors on our board of directors will be no less than five and no more than ten. Pursuant to the Companies Law, the board of directors must include at least two external directors who must be nominated within three months of the closing of the initial public offering. We exceeded the three-month period. However, our shareholders approved the appointment of two external directors at the shareholder meeting in February 2021, and as a result we are now in compliance with the Companies Law. The minimum and maximum number of directors may be changed, at any time and from time to time, by vote of our shareholders.

Other than external directors, for whom special election requirements apply under the Companies Law, as detailed below, our directors are divided into three classes with staggered three-year terms. Each class of directors consists, as nearly as possible, of one-third of the total number of directors constituting the entire board of directors (other than the external directors). At each annual general meeting of our shareholders, the election or re-election of directors following the expiration of the term of office of the directors of that class of directors will be for a term of office that expires on the third annual general meeting following such election or re-election, such that from 2021 and after, at each annual general meeting, the term of office of only one class of directors will expire. Each director holds office until the third annual general meeting of our shareholders and until his or her successor is duly appointed, unless the tenure of such director expires earlier pursuant to the Companies Law or unless removed from office as described below, except that our external directors have a term of office of three years under Israeli law (see “—External Directors—Election and Dismissal of External Directors”).

Our directors, other than external directors, are divided among three classes as follows: the Class I directors, consisting of Erez Meltzer and Richard Stone, will hold office until our annual general meeting of shareholders to be held in 2021; the Class II directors, consisting of Onn Fenig and Floyd Katske, will hold office until our annual general meeting of shareholders to be held in 2022; and the Class III directors, consisting of Ran Poliakine and Jung Ho Park, will hold office until our annual general meeting of shareholders to be held in 2023. Our external directors, Noga Kainan and Dan Suesskind, will hold office until our annual general meeting of shareholders in 2024.

Under our amended and restated articles of association, our board of directors may appoint directors to fill vacancies on our board of directors, including if the number of directors is below the maximum number of directors who may serve as provided in our amended and restated articles, for a term of office equal to the remaining period of the term of office of the director(s) whose office(s) has been vacated. External directors are elected for an initial term of three years and may be elected for up to two additional three-year terms under the circumstances described below. External directors may be removed from office only under the limited circumstances set forth in the Companies Law. See “—External Directors.”

Under Israeli law, the chief executive officer or a relative of the chief executive officer of a public company may not serve as the chairman of the board of directors of the company and the chairman or a relative of the chairman may not be vested with the authority of the chief executive officer, in each case, unless approved by a special majority of our shareholders as required under the Companies Law. The shareholders’ approval can be provided for a period of five years following an initial public offering, and subsequently, for additional periods of up to three years. In addition, a person who is subordinated, directly or indirectly, to the chief executive officer may not serve as the chairman of the board of directors; the chairman of the board of directors may not be vested with authorities that are granted to persons who are subordinated to the chief executive officer; and the chairman of the board of directors may not serve in any other position in the company or in a controlled subsidiary, but he or she may serve as a director or chairman of a controlled subsidiary. Prior to our initial public offering, we obtained our shareholders’ approval that Mr. Ran Poliakine may serve as both our chairman of the board of directors and chief executive officer for a period of up to five years from the closing of our initial public offering.

In addition, under the Companies Law, our board of directors must determine the minimum number of directors who are required to have financial and accounting expertise. Under applicable regulations, a director with financial and accounting expertise is a director who, by reason of his or her education, professional experience and skill, has a high level of proficiency in and understanding of business accounting matters and financial statements. See “—External Directors—Qualifications of External Directors.” He or she must be able to thoroughly comprehend the financial statements of the company and initiate debate regarding the manner in which financial information is presented. In determining the number of directors required to have such expertise, the board of directors must consider, among other things, the type and size of the company and the scope and complexity of its operations. Our board of directors has determined that we require at least one director with the requisite financial and accounting expertise and that Erez Meltzer has such expertise.

There are no family relationships among any of our office holders (including directors).

External Directors

Qualifications of External Directors

Under the Companies Law, companies incorporated under the laws of the State of Israel, whose shares are publicly traded, including companies with shares listed on the Nasdaq, are required to appoint at least two external directors. Our shareholders approved the appointment of Noga Kainan and Dan Suesskind as external directors in February 2021.

A person may not be appointed as an external director if the person is a relative of a controlling shareholder or if on the date of the person’s appointment or within the preceding two years the person or his or her relatives, partners, employers or anyone to whom that person is subordinate, whether directly or indirectly, or entities under the person’s control have or had any affiliation with any of (each an “Affiliated Party”): (1) us; (2) any person or entity controlling us on the date of such appointment; (3) any relative of a controlling shareholder; or (4) any entity controlled, on the date of such appointment or within the preceding two years, by us or by a controlling shareholder. If there is no controlling shareholder or any shareholder holding 25% or more of voting rights in the company, a person may not be appointed as an external director if the person has any affiliation to the chairman of the board of directors, the general manager (chief executive officer), any shareholder holding 5% or more of the company’s shares or voting rights or the senior financial officer as of the date of the person’s appointment.

The term affiliation includes:

- an employment relationship;
- a business or professional relationship maintained on a regular basis;
- control; and
- service as an office holder, excluding service as a director in a private company prior to the first offering of its shares to the public if such director was appointed as a director of the private company in order to serve as an external director following the initial public offering.

The term “relative” is defined as a spouse, sibling, parent, grandparent, descendant, spouse’s descendant, sibling and parent and the spouse of each of the foregoing.

A person may not serve as an external director if that person or that person’s relative, partner, employer, a person to whom such person is subordinate (directly or indirectly) or any entity under the person’s control has a business or professional relationship with any entity that has an affiliation or other prohibited relationship with any Affiliated Party, even if such relationship is intermittent (excluding insignificant relationships). Additionally, any person who has received compensation intermittently (excluding insignificant relationships) other than compensation permitted under the Companies Law may not continue to serve as an external director.

No person can serve as an external director if the person’s position or other affairs create, or may create, a conflict of interest with the person’s responsibilities as a director or may otherwise interfere with the person’s ability to serve as an external director or if such a person is an employee of the Israel Securities Authority or of an Israeli stock exchange. If at the time an external director is appointed all current members of the board of directors, who are not controlling shareholders or relatives of controlling shareholders, are of the same gender, then the external director to be appointed must be of the other gender. In addition, a person who is a director of a company may not be elected as an external director of another company if, at that time, a director of the other company is acting as an external director of the first company.

The Companies Law provides that an external director must meet certain “professional qualifications” or have “financial and accounting expertise” and that at least one external director must have “financial and accounting expertise.” However, if at least one of our other directors (1) meets the independence requirements of the Exchange Act, (2) meets the standards of the Nasdaq corporate governance rules for membership on the audit committee and (3) has “financial and accounting expertise” as defined in the Companies Law and applicable regulations, then none of our external directors is required to possess financial and accounting expertise as long as they possess other requisite professional qualifications. The determination of whether a director possesses “financial and accounting expertise” is made by the board of directors.

The regulations promulgated under the Companies Law define an external director with requisite professional qualifications as a director who satisfies one of the following requirements: (1) the director holds an academic degree in either economics, business administration, accounting, law or public administration, (2) the director either holds an academic degree in any other field or has completed another form of higher education in the company’s primary field of business or in an area which is relevant to his or her office as an external director in the company, or (3) the director has at least five years of experience serving in any one of the following, or at least five years of cumulative experience serving in two or more of the following capacities: (a) a senior business management position in a company with a substantial scope of business, (b) a senior position in the company’s primary field of business or (c) a senior position in public administration. The determination of whether a director possesses the requisite “professional qualifications” is made by the board of directors.

Until the lapse of a two-year period from the date that an external director of a company ceases to act in such capacity, the company in which such external director served, and its controlling shareholder (as defined below) or any entity under control of such controlling shareholder, may not, directly or indirectly, grant such former external director, or his or her spouse or child, any benefit, including via (i) the appointment of such former director or his or her spouse or his child as an officer in the company or in an entity controlled by the company's controlling shareholder, (ii) the employment of such person, and (iii) the engagement, directly or indirectly, of such person as a provider of professional services for compensation, directly or indirectly, including via an entity under his or her control. With respect to a relative who is not a spouse or a child, such limitations shall only apply for one year from the date such external director ceased to be engaged in such capacity.

The term "controlling shareholder" means a shareholder with the ability to direct the activities of the company, other than by virtue of being an office holder. A shareholder is presumed to have "control" of the company and thus to be a controlling shareholder of the company if the shareholder holds 50% or more of the "means of control" of the company. "Means of control" is defined as (1) the right to vote at a general meeting of a company or a corresponding body of another corporation; or (2) the right to appoint directors of the corporation or its general manager. For the purpose of approving certain related-party transactions, the term also includes any shareholder that holds 25% or more of the voting rights of the company if the company has no shareholder that owns more than 50% of its voting rights. For the purpose of determining the holding percentage stated above, two or more shareholders who have a personal interest in a transaction that is brought for the company's approval are deemed as joint holders. The term "office holder" is defined as a chief executive officer (referred to in the Companies Law as a general manager), chief business manager, deputy general manager, vice general manager, director or manager directly subordinate to the general manager or any other person assuming the responsibilities of any of the foregoing positions, without regard to such person's title.

Audit Committee

Companies Law Requirements

Under the Companies Law, the board of directors of a public company must also appoint an audit committee comprised of at least three directors, including all of the external directors. The audit committee may not include:

- the chairman of the board of directors;
- a controlling shareholder or a relative of a controlling shareholder;
- any director employed by the company or by one of its controlling shareholders or by an entity controlled by one of its controlling shareholders (other than as a member of the board of directors);
- any director who regularly provides services to the company, to one of its controlling shareholders or to an entity controlled by one of its controlling shareholders; or
- a director who derives most of his or her income from a controlling shareholder.

According to the Companies Law, the majority of the members of the audit committee, as well as the majority of members present at audit committee meetings, will be required to be "independent" (as defined below) and the chairman of the audit committee will be required to be an external director. Any persons not qualified from serving as a member of the audit committee may not be present at the audit committee meetings, unless the chairman of the audit committee has determined that such person is required to be present at the meeting or if such person qualifies under one of the exemptions of the Companies Law.

The term "independent director" is defined under the Companies Law as an external director or a director who meets the following conditions and who is appointed or classified as such according to the Companies Law: (1) he or she meets the qualifications for being appointed as an external director, except for (i) the requirement that the director be an Israeli resident (which does not apply to companies such as ours whose securities have been offered outside of Israel or are listed outside of Israel); and (ii) the requirement for "financial and accounting expertise" or professional qualifications, and the audit committee approves the director having met such conditions and (2) he or she has not served as a director of the company for over nine consecutive years with any interruption of up to two years of his or her service not being deemed a disruption to the continuity of his or her service.

Nasdaq Listing Requirements

Under the Nasdaq corporate governance rules, we are required to maintain an audit committee consisting of at least three independent directors, all of whom are financially literate and one of whom has accounting or related financial management expertise.

In accordance with U.S. law and Nasdaq requirements, our audit committee is also responsible for the appointment, compensation and oversight of the work of our independent auditors and for assisting our board of directors in monitoring our financial statements, the effectiveness of our internal controls and our compliance with legal and regulatory requirements.

Our audit committee consists of Erez Meltzer, Noga Kainan and Dan Suesskind. In accordance with the Companies Law, Noga Kainan serves as chairperson of the audit committee. Our board of directors has determined, in its business judgment, that Noga Kainan is an audit committee financial expert as defined by the SEC rules and has the requisite financial experience as defined by the Nasdaq corporate governance rules.

Each of the members of the audit committee is required to be “independent” as such term is defined in Rule 10A-3(b)(1) under the Exchange Act.

Approval of Transactions with Related Parties

The approval of the audit committee is required to effect specified actions and transactions with office holders and controlling shareholders and their relatives, or in which they have a personal interest. The audit committee may not approve an action or a transaction with a controlling shareholder or with an office holder unless, among other things, at the time of approval the audit committee meets the composition requirements under the Companies Law.

Audit Committee Role

Our board of directors has adopted an audit committee charter setting forth the responsibilities of the audit committee consistent with the rules of the SEC and the Nasdaq corporate governance rules, as well as the requirements for such committee under the Companies Law, which include:

- recommending the retention and termination of our independent registered public accounting firm to the board of directors in accordance with Israeli law;
- recommending to the board of directors in accordance with Israeli law the appointment, compensation, retention and oversight of any accounting firm engaged for the purpose of preparing or issuing an audit report or performing other audit services;
- recommending the terms of audit and non-audit services to be provided by the independent registered public accounting firm for pre-approval by our board of directors;
- recommending the engagement or termination of the person filling the office of our internal auditor;
- reviewing with management and our independent directors our financial statements prior to their submission to the SEC; and
- approval of certain transactions with office holders and controlling shareholders, as described below, and other related party transactions.

Additionally, under the Companies Law, the role of the audit committee includes the identification of irregularities in our business management, among other things, by consulting with the internal auditor or our independent auditors and suggesting an appropriate course of action to the board of directors. The audit committee is also required to adopt procedures with respect to processing of employees' complaints in connection with deficiencies in the management of the company, and the appropriate means of protection afforded to such employees. In addition, the audit committee or the board of directors, as set forth in the articles of association of the company, is required to approve the yearly or periodic work plan proposed by the internal auditor, and where the board of directors approves such work plan, to examine such work plan before its submission to the board of directors and propose amendments thereto. The audit committee is required to assess the company's internal audit system and the performance of its internal auditor. The Companies Law also requires that the audit committee assess the scope of the work and compensation of the company's external auditor. In addition, the audit committee is required to determine whether certain related party actions and transactions are "material" or "extraordinary" for the purpose of the requisite approval procedures under the Companies Law and whether certain transactions with a controlling shareholder will be subject to a competitive procedure.

The audit committee charter shall state that in fulfilling its role the committee is empowered to conduct or authorize investigations into any matters within its scope of responsibilities.

Compensation Committee

Under the Companies Law, public companies are required to appoint a compensation committee in accordance with the guidelines set forth thereunder.

Under the Companies Law, our compensation committee must consist of at least three members. All of the external directors must serve on the committee and constitute a majority of its members. The chairman of the compensation committee must be an external director. The remaining members are not required to be external directors, but must be directors who would qualify to serve as members of the audit committee (as described above).

The compensation committee consists of Onn Fenig, Noga Kainan and Dan Suesskind, and assists the board of directors in determining compensation for our directors and officers. In accordance with the Companies Law, Dan Suesskind serves as chairperson of the compensation committee. In addition, Onn Fenig replaced Erez Meltzer on the compensation committee following the approval of Mr. Meltzer as a "Designated Director" at the shareholder meeting in February 2021, since Mr. Meltzer's compensation disqualifies him from serving on the compensation committee under the Companies Law. Under our compensation policy, a "Designated Director" is a member of the board of directors who due to his particular stature or added value to us was designated as such by the compensation committee, board of directors and/or our shareholders, as applicable. In accordance with our compensation policy, members of the board of directors who are determined as Designated Directors are eligible to receive additional compensation from us.

In accordance with the Companies Law, the roles of the compensation committee are, among others, as follows:

1. to recommend to the board of directors the compensation policy for directors and officers, and, once every three years, or five years from a company's initial public offering, to recommend to the board of directors, whether the compensation policy that had been approved should be extended for a longer period of time;
2. to recommend to the board of directors updates to the compensation policy, from time to time, and examine its implementation;
3. to decide whether to approve the terms of office and employment of directors and officers that require approval of the compensation committee; and
4. to decide whether the compensation terms of the chief executive officer, which were determined pursuant to the compensation policy, will be exempted from approval by the shareholders because such approval would harm the ability to engage the chief executive officer.

In addition to the roles mentioned above, our compensation committee may also make recommendations to our board of directors regarding the awarding of employee equity grants.

In general, under the Companies Law, a public company must have a compensation policy approved by the board of directors after receiving and considering the recommendations of the compensation committee. In addition, the compensation policy requires the approval of the general meeting of the shareholders. In public companies such as our company, shareholder approval by a majority vote of the ordinary shares present and voting at a meeting of shareholders called for such purpose is required, provided that either: (i) such majority includes the majority of the votes of those shareholders who are non-controlling shareholders and do not have a personal interest in the approval of the compensation policy, who voted at the meeting (excluding abstentions) or (ii) the total number of votes against the proposal among the shareholders mentioned in clause (i) does exceed 2% of the voting rights in the company. Under special circumstances, the board of directors may approve the compensation policy despite the objection of the shareholders on the condition that the compensation committee and then the board of directors decide, on the basis of detailed arguments and after discussing again the compensation policy, that approval of the compensation policy, despite the objection of the meeting of shareholders, is in the best interests of the company.

However, if a company initially offering its securities to the public, adopts a compensation policy in advance of its initial public offering, and describes the compensation policy in the prospectus relating to the offering, or adopts a compensation policy within nine months from the date the company becomes a public company, then the compensation policy is deemed a validly adopted policy in accordance with the Companies Law requirements described above and will be valid for a term of five years from the date such company becomes a public company.

The compensation policy must be based on certain considerations, include certain provisions and needs to reference certain matters as set forth in the Companies Law.

The compensation policy must serve as the basis for decisions concerning the financial terms of employment or engagement of office holders, including exculpation, insurance, indemnification or any monetary payment or obligation of payment in respect of employment or engagement. The compensation policy must relate to certain factors, including advancement of the company's objectives, business plan and long-term strategy, and creation of appropriate incentives for office holders. It must also consider, among other things, the company's risk management, size and the nature of its operations. The compensation policy must furthermore consider the following additional factors:

- the education, skills, experience, expertise and accomplishments of the relevant office holder;
- the office holder's position, responsibilities and prior compensation agreements with him or her;
- the ratio between the cost of the terms of employment of an office holder and the cost of the employment of other employees of the company, including employees employed through contractors who provide services to the company, in particular the ratio between such cost, the average and median salary of the employees of the company, as well as the impact of such disparities on the work relationships in the company;
- if the terms of employment include variable components — the possibility of reducing variable components at the discretion of the board of directors and the possibility of setting a limit on the exercise value of non-cash variable equity-based components; and
- if the terms of employment include severance compensation — the term of employment or office of the office holder, the terms of his or her compensation during such period, the company's performance during the such period, his or her individual contribution to the achievement of the company goals and the maximization of its profits and the circumstances under which the office holder is leaving the company.

The compensation policy must also include, among others:

- with regard to variable components:
- with the exception of office holders who are subordinate to the chief executive officer, determining the variable components on long-term performance basis and on measurable criteria; however, the company may determine that an immaterial part of the variable components of the compensation package of an office holder shall be awarded based on non-measurable criteria, if such amount is not higher than three monthly salaries per annum while taking into account the office holder's contribution to the company;

- the ratio between variable and fixed components, as well as the limit of the values of variable components at the time of their grant.
- a condition under which the office holder will return to the company, according to conditions to be set forth in the compensation policy, any amounts paid as part of his or her terms of employment, if such amounts were paid based on information later to be discovered to be wrong, and such information was than re-presented in the company's financial statements;
- the minimum holding or vesting period of variable equity-based components, while taking into consideration long-term incentives; and
- a limit to retirement grants.

Our compensation policy was approved by the board of directors and the shareholders on February 9, 2021, and will be in effect for a period of five years from the date of approval. Our compensation policy is designed to promote retention and motivation of directors and executive officers, incentivize superior individual excellence, align the interests of our directors and executive officers with our long-term performance and provide a risk management tool. To that end, a portion of an executive officer's compensation package is targeted to reflect our short and long-term goals, as well as the executive officer's individual performance. On the other hand, our compensation policy includes measures designed to reduce the executive officer's incentives to take excessive risks that may harm us in the long-term, such as limits on the value of cash bonuses and equity-based compensation, limitations on the ratio between the variable and the total compensation of an executive officer and minimum vesting periods for equity-based compensation.

Our compensation policy also addresses our executive officers' individual characteristics (such as his or her respective position, education, scope of responsibilities and contribution to the attainment of our goals) as the basis for compensation variation among our executive officers, and considers the internal ratios between compensation of our executive officers and directors and other employees. Pursuant to our compensation policy, the compensation that may be granted to an executive officer may include: base salary, annual bonuses and other cash bonuses (such as relocation, signing and special bonuses) as well as change of control related bonuses, equity-based compensation, benefits and retirement and termination of employment arrangements. All cash bonuses are limited to a maximum amount linked to the executive officer's base salary (or to the total annual compensation in the case of the special bonus for special achievements).

An annual cash bonus may be awarded to executive officers upon the attainment of pre-set periodic objectives and individual targets. The annual cash bonus that may be granted to our executive officers, other than our chief executive officer, will be based on performance objectives and a discretionary evaluation of the executive officer's overall performance by our chief executive officer, subject to minimum thresholds. Furthermore, the performance objectives will be recommended by our chief executive officer and approved by our compensation committee (and, if required by law, by our board of directors).

The performance measurable objectives of our chief executive officer, which will be determined annually by our compensation committee and board of directors, will include the weight to be assigned to each achievement in the overall evaluation. A less significant portion of the chief executive officer's annual cash bonus may be based on a discretionary evaluation of the chief executive officer's overall performance by the compensation committee and the board of directors based on quantitative and qualitative criteria.

The equity-based compensation under our compensation policy for our executive officers is designed in a manner consistent with the underlying objectives in determining the base salary and the annual cash bonus, with its main objectives being to enhance the alignment between the executive officers' interests with our long-term interests and those of our shareholders and to strengthen the retention and the motivation of executive officers in the long term. Our compensation policy entitles our executive officers to compensation in the form of share options or other equity-based awards, such as restricted share units, in accordance with our share incentive plan then in place (subject to the compensation committee's approval or the approval of the board of directors). All equity-based incentives granted to executive officers shall be subject to vesting periods in order to promote long-term retention of the awarded executive officers. The equity-based compensation may be granted from time to time and will be individually determined and awarded according to the performance, educational background, prior business experience, qualifications, role and the personal responsibilities of the executive officer.

In addition, our compensation policy contains compensation recovery provisions which allows us under certain conditions to recover bonuses paid in excess, enables our chief executive officer to approve an immaterial change in the terms of employment of an executive officer (provided that the changes of the terms of employment are in accordance with our compensation policy) and allows us to exculpate, indemnify and insure our executive officers and directors, subject to certain limitations set forth thereto.

Our compensation policy also governs the compensation of the members of our board of directors and determines that the compensation of the directors shall be in accordance with the Companies Regulations (Rules Regarding the Compensation and Expenses of an External Director), 5760-2000, as amended by the Companies Regulations (Relief for Public Companies Traded in Stock Exchange Outside of Israel), 5760-2000, or the compensation of directors regulations, as such regulations may be amended from time to time, provided, however, that under special circumstances such as in the case of a professional director, an expert director or a director who has particular stature or added value and makes a unique contribution to the Company, such director's compensation may be different than the compensation of all other directors. Our directors may also be entitled to receive equity-based compensation in the form of restricted shares, restricted share units or share options subject to an annual maximum and to a vesting period in order to promote long-term retention of the awarded director, subject to the approval of our shareholders, as required under the Companies Law. Furthermore, the chairman of our board of directors may be entitled to a higher base compensation or equity-based compensation.

D. Employees

As of December 31, 2020, we had 40 employees based in Israel, six employees based in Japan and four employees based in Korea. We have never experienced any employment-related work stoppages and believe our relationship with our employees is good. The following table sets out our total number of employees by function for the last three years.

Area of Activity	As of December 31, 2018	As of December 31, 2019	As of December 31, 2020
General and Administrative	—	10	22
Research, Development and Quality Assurance	6	9	24
Sales and Marketing	—	1	4
Total	6(1)	20	50

(1) Total does not include subcontractors.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase shareholder value and the success of our company by motivating such individuals to perform to the best of their abilities and achieve our objectives.

E. Share Ownership

For information regarding the share ownership of our directors and executive officers, see “Item 7. Major Shareholders and Related Party Transactions—A. Major Shareholders.” For information regarding equity-based grants to our directors, executive officers and other employees, see “Item 6. Directors, Senior Management and Employees—B. Compensation—Compensation of Executive Officers and Directors” and “Item 6. Directors, Senior Management and Employees—B. Compensation—Equity Incentive Plan.”

Item 7. Major Shareholders and Related Party Transactions

A. Major Shareholders

The following table sets forth information with respect to the beneficial ownership of our ordinary shares as of March 20, 2021 by:

- each person or entity known by us to own beneficially more than 5% of our outstanding ordinary shares;
- each of our directors and executive officers;
- all of our directors and executive officers as a group; and
- each selling shareholder.

The beneficial ownership of our ordinary shares is determined in accordance with the rules of the SEC. Under these rules, a person is deemed to be a beneficial owner of a security if that person has or shares voting power, which includes the power to vote or to direct the voting of the security, or investment power, which includes the power to dispose of or to direct the disposition of the security. In determining beneficial ownership percentages, we deem ordinary shares that a shareholder has the right to acquire, including the ordinary shares issuable pursuant to options or warrants that are currently exercisable or exercisable within 60 days of March 20, 2021, if any, to be outstanding and to be beneficially owned by the person with such right to acquire additional ordinary shares for the purposes of computing the percentage ownership of that person, but we do not treat them as outstanding for the purpose of computing the percentage ownership of any other person. The percentage of ordinary shares beneficially owned prior to or after the offering is based on 47,378,183 ordinary shares outstanding as of March 20, 2021.

Except where otherwise indicated, we believe, based on information furnished to us by such owners, that the beneficial owners of the ordinary shares listed below have sole investment and voting power with respect to such shares.

None of our shareholders have different voting rights from other shareholders. To the best of our knowledge, we are not owned or controlled, directly or indirectly, by another corporation or by any foreign government. We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company.

Unless otherwise noted below, the address for each beneficial owner is c/o Communications Center, Neve Ilan, Israel 9085000.

Name of Beneficial Owner	Shares Beneficially Owned After the Offering	
	Number	Percentage
5% or greater shareholders		
Ran Poliakine(1)	4,131,513	8.66%
Moshe Moalem(2)	3,948,670	8.33%
SK Telecom Co., Ltd and SK Telecom TMT Investment Corp.(3)	4,869,909	10.28%
Yozma Group Korea(4)	2,512,000	5.30%
Directors and executive officers		
Ran Poliakine(1)	4,131,513	8.66%
Omn Fenig(5)	2,515	*
Floyd Katske(6)	12,573	*
Erez Meltzer(7)	15,088	*
Jung Ho Park(8)	18,750	*
Richard Stone(9)	554,761	1.17%
Noga Kainan(10)	794	*
Dan Suesskind	—	—
Itzhak Maayan(11)	40,554	*
James Dara	—	—
Ofir Koren	—	—
Tamar Aharon Cohen	—	—
Anat Kaphan(12)	22,184	*
Tal Shank(13)	23,025	*
Shirly Kaufman-Kirshenbaum(14)	9,099	*
All directors and executive officers as a group (15 persons)	4,830,856	10.09%

* Amount represents less than 1% of outstanding ordinary shares.

- (1) Represents (a) 3,958,570 ordinary shares of the Company held by Ran Poliakine as of March 20, 2021, (b) 118,750 ordinary shares of the Company held in trust by Shay Zuckerman & Co. Law Firm (“Shay Zuckerman”), pursuant to an Escrow Agreement, dated February 3, 2020, between Ran Poliakine, Moshe Moalem and Shay Zuckerman, as trustee, (c) options to purchase 304,193 ordinary shares exercisable within 60 days of March 20, 2021, which have not yet been exercised and (d) a sale of 250,000 ordinary shares that is in the reporting process and not reflected in the records of Continental Stock Transfer & Trust Co. as of March 20, 2021. The ordinary shares held by Shay Zuckerman are held in trust for the benefit of Ran Poliakine. Ran Poliakine has voting power of all the ordinary shares held in trust by Shay Zuckerman. Pursuant to a mediation agreement signed between the parties in October 2020, during 2021, the parties will take a number of actions, upon which the dispositive power over these ordinary shares will pass to Ran Poliakine.
- (2) Represents 3,948,670 ordinary shares held by Moshe Moalem, based solely on the Schedule 13G filed by Moshe Moalem on February 18, 2021.
- (3) Based solely on the Schedule 13G filed by SK Telecom Co., Ltd and SK Telecom TMT Investment Corp. on February 11, 2021, consisting of (a) 2,607,466 ordinary shares and (b) warrants to purchase 2,262,443 ordinary shares held by SK Telecom TMT Investment Corp., a wholly owned subsidiary of SK Telecom Co., Ltd.
- (4) Based solely on the Schedule 13G filed by YOZMA GROUP KOREA Co., Ltd. on March 5, 2021, consisting of (a) 887,000 ordinary shares held by Yozma Global AI Fund No.2 (“Yozma Fund No.2”) and (b) 1,625,000 ordinary shares held by Yozma Global AI Fund No.3 (“Yozma Fund No.3”). Yozma Group Korea is the general partner of each of Yozma Fund No.2 and Yozma Fund No.3. Wonjae Lee is the Chief Executive Officer and controlling shareholder of Yozma Group Korea and is deemed to have voting and dispositive power over the shares held by Yozma Fund No.2 and Yozma Fund No.3.
- (5) Represents options to purchase 15,088 ordinary shares exercisable within 60 days of March 20, 2021, of which 12,573 have been exercised and sold.
- (6) Represents options to purchase 12,573 ordinary shares exercisable within 60 days of March 20, 2021, and have not yet been exercised.
- (7) Represents options to purchase 15,088 ordinary shares exercisable within 60 days of March 20, 2021, and have not yet been exercised.
- (8) Represents options to purchase 18,750 ordinary shares exercisable within 60 days of March 20, 2021, and have not yet been exercised.
- (9) Represents (a) 426,400 ordinary shares held by Richard Stone as of March 20, 2021 based solely on the records of Continental Stock Transfer & Trust Co., (b) options to purchase 37,719 ordinary shares exercisable within 60 days of March 20, 2021, (c) warrants to purchase 192,927 ordinary shares held by Richard Stone, (d) 66,215 ordinary shares held by Frostop Securities (“Frostop”) as of March 20, 2021, and (e) a sale of 168,500 ordinary shares that is in the reporting process and not reflected in the records of Continental Stock Transfer & Trust Co. as of March 20, 2021. Richard Stone is a minority holder of Frostop and is deemed to have sole current voting and dispositive power over the 66,215 ordinary shares held by Frostop, and Frostop has agreed to transfer such shares to Richard Stone.
- (10) Represents 794 ordinary shares held by I.B.L BUSINESS CONSULTING LTD. (“I.B.L.”). Noga Kainan is the controlling shareholder of I.B.L. and is deemed to have voting and dispositive power of the shares held by I.B.L.
- (11) Represents options to purchase 40,554 ordinary shares exercisable within 60 days of March 20, 2021, and have not yet been exercised, which include the acceleration of 50% of Mr. Maayan’s unvested options approved in January 2021.
- (12) Represents options to purchase 22,184 ordinary shares exercisable within 60 days of March 20, 2021, and have not yet been exercised.
- (13) Represents options to purchase 23,025 ordinary shares exercisable within 60 days of March 20, 2021, and have not yet been exercised.
- (14) Represents options to purchase 9,099 ordinary shares exercisable within 60 days of March 20, 2021, and have not yet been exercised.

As of March 20, 2021, according to the records of Continental Stock Transfer & Trust Co., approximately 4,853,369 of our outstanding ordinary shares are held by 31 record holders in the United States.

We are not aware of any arrangement that may, at a subsequent date, result in a change of control of our company.

B. Related Party Transactions

Our policy is to enter into transactions with related parties on terms that, on the whole, are no more favorable, or no less favorable, than those available from unaffiliated third parties. Based on our experience in the business sectors in which we operate and the terms of our transactions with unaffiliated third parties, we believe that all of the transactions described below met this policy standard at the time they occurred. The following is a description of material transactions, or series of related material transactions, since January 1, 2020, to which we were or will be a party and in which the other parties included or will include our directors, executive officers, holders of more than 5% of our voting securities or any member of the immediate family of any of the foregoing persons.

Asset Purchase by the Company From Nanox Gibraltar

Pursuant to the Asset Purchase Agreement, dated as of September 3, 2019, as amended on December 3, 2019 and December 31, 2019, substantially all of the assets of Nanox Gibraltar, including all patents, patent applications and all other intellectual property rights, but not including the shares of Nanox Japan (predecessor), were sold to the Company for an aggregate consideration of \$13.3 million, reflecting the fair market value of the transferred assets, which was estimated to be \$6.1 million (excluding cash) based on an independent valuation report, plus the cash balance less \$200,000, which totaled \$7.2 million as of the date of the Asset Purchase Agreement. Following the Asset Purchase, substantially all the employees of Nanox Japan (predecessor) dedicated to the Company's business have become employees of Nanox Imaging, Inc., our wholly owned Japanese subsidiary incorporated on September 19, 2019, in December 2019.

Under the terms of the Asset Purchase Agreement, the consideration for the transferred assets will be paid only on the occurrence of one of the following events: (a) the closing of a transaction involving the sale of all or substantially all of the Company's assets; (b) the acquisition of the Company by, or the merger of the Company with, another entity, consolidation, reorganization, recapitalization, sale, assignment or disposal by the Company of all or substantially all of the issued and outstanding shares of the Company; (c) the transfer, sale, lease, grant or other disposition of or the grant of an exclusive license over all or substantially all of Company's assets, including, but not limited to, intellectual property, with the same economic effect to that of a sale and/or cessation of its business; (d) any other transaction, except for a financing round, following which the shareholders of the Company prior to the closing of such transaction own, directly or indirectly, less than 50% of the voting power of the surviving entity; (e) the closing of the first underwritten public offering of the Company pursuant to a registration statement under the Securities Act or the Securities Law (or under equivalent securities law of another jurisdiction) or any other securities laws world-wide with the same effects and results; (f) an equity financing of the Company at a minimum pre-money valuation of \$100.0 million, with proceeds to the Company of at least \$30.0 million. In the events of (e) or (f) above, the Company will have the option to pay the consideration in cash or by the issuance to Nanox Gibraltar of the Company's securities of the same series to be issued upon such event, in an amount reflecting a 25% discount on the price per share to be determined in connection with (e) and (f) above. If the Company elects to pay such consideration in cash, Nanox Gibraltar will have the right, at its sole discretion and in good faith, to reject such payment in cash, and require that the Company pay such consideration in the form of the Company's securities in such amount and with such discount described above.

In January 2020, the board of directors of the Company and the board of directors and shareholders of Nanox Gibraltar approved the issuance of shares in accordance with the terms of the Asset Purchase Agreement described above. As a result, 1,109,245 of the Company's ordinary shares were issued to Nanox Gibraltar, representing an aggregate consideration of approximately \$17.8 million at the date of issuance, and the Company has no further obligations to Nanox Gibraltar under the Asset Purchase Agreement.

Relationship With SKT

On June 17, 2019, Nanox Gibraltar entered into a Strategic Share Purchase Agreement with SKT, Pureun Partners Asset Management Co., Ltd. and EBEST-PPAM Fund No. 9 (collectively, the "SKT Entities"), pursuant to which Nanox Gibraltar sold 2,262,443 ordinary shares to the SKT Entities for an aggregate purchase price of approximately \$5.0 million. In connection with such transaction, Nanox Gibraltar also issued a warrant to SKT to acquire 2,262,443 ordinary shares at an exercise price of \$20.87 per share (the "Warrant").

In connection with the transactions described above, Nanox Gibraltar also entered into an investor rights agreement with the SKT Entities (the “Investor Rights Agreement”). The agreement provides for the rights to nominate a member of our board of directors, as well as certain registration rights. The rights under the Investor Rights Agreement terminated upon the closing of our initial public offering. The SKT Entities became parties to the Registration Rights Agreement prior to the closing of our initial public offering. See “Item 10. Additional Information—C. Material Contracts—Registration Rights Agreements” for detailed description of the registration rights.

On June 4, 2020, we entered into a Share Purchase Agreement with SKT, pursuant to which we sold 1,250,000 ordinary shares to SKT for an aggregate purchase price of \$20.0 million. In connection with such agreement, we amended the Warrant to extend the exercise period to the earlier of June 17, 2025 or an exit event, which event does not include an initial public offering, and we amended the Investor Rights Agreement which grants SKT the right to appoint Mr. Jung Ho Park (or another person designated by SKT) as a director for a term of three years. In addition, we granted Mr. Park options to purchase 100,000 of our ordinary shares, vesting in equal quarterly installments over a period of four years, at an exercise price of \$16.00 per ordinary share. In the event that SKT nominates any replacement director, any such director may receive options with the same terms, but the aggregate number of options granted to all such directors together shall not exceed 100,000.

Furthermore, on June 4, 2020, we entered into a collaboration agreement with SK Telecom, pursuant to which we and SK Telecom continue to explore and engage in good faith to develop a definitive agreement for the deployment of 2,500 Nanox Systems in South Korea and Vietnam, and we have established a wholly-owned subsidiary in South Korea with the support of SK Telecom for the purpose of manufacturing MEMs X-ray chips for the Nanox.ARC. The collaboration agreement will be in effect until the earlier of December 31, 2021 or the execution of a definitive agreement, and may be extended upon the mutual agreement of the parties. The agreement may be terminated by mutual notice or by notice of the non-breaching party in case of a material breach of a party’s material obligations.

In addition, we signed an agreement with Dr. Ilung Kim, dated December 16, 2019, for the provision of consulting services to us. Under the agreement, we granted Dr. Kim options to purchase 1,206,290 of our ordinary shares at an exercise price of \$2.21 per ordinary share. 301,572 of the options vested as of the grant date and the remaining 904,718 options will vest in equal monthly installments over a period of three years from the vesting commencement date (September 1, 2019). All unvested options will be fully accelerated immediately prior to the closing of Deemed Liquidation (as defined in the Equity Incentive Plan). The vested options are exercisable until the earlier of (a) the second anniversary of termination of the engagement between us and Dr. Kim or (b) the tenth anniversary from the date of grant.

Agreements With Directors and Officers

The following is a summary of each material contract, other than material contracts entered into in the ordinary course of business, to which we are or have been a party, for the two years immediately preceding the date of this Annual Report.

Relationship With Illumigyn Ltd.

Since December 1, 2019, Illumigyn has sub-leased approximately 165 square meters of private office space, including access to shared public spaces, from us in Neve Ilan, Israel. Illumigyn pays approximately \$12,000 per month and during the year ended December 31, 2020, the total payment received from Illumigyn was approximately \$163,000. Mr. Poliakine currently serves as a member of senior management of Illumigyn through a service provider agreement and is a significant shareholder primarily through indirect holdings, and he served as a member of the board of directors of Illumigyn until August 2019. In addition, Mr. Richard Stone is a significant shareholder in, and serves as a member of the board of directors of Illumigyn, Anat Kaphan, our Vice President of Product Marketing, also serves as a consultant to Illumigyn and Tal Shank, our Vice President of Corporate Development, is also Head of Corporate Development of Illumigyn.

Relationship with SixAI Ltd.

On April 16, 2020, we entered into a service agreement (the “Service Agreement”) with SixAI, pursuant to which SixAI shall provide Nanox with certain software development and mechanical engineering services. The Service Agreement is effective as of March 1, 2020 and has been extended by mutual agreement of the parties to March 31, 2021. In consideration for the services provided, we will pay SixAI a monthly fee of \$40,000 plus VAT. As of December 31, 2020, we have paid \$415,350 to SixAI. Mr. Poliakine and Mr. Fenig currently serve as members of the board of directors of SixAI and Mr. Poliakine is a controlling shareholder of SixAI. In addition, Mr. Poliakine is a director of 634 Ai which is a controlled subsidiary (51%) of SixAI and Mr. Fenig manages 634 Ai operations.

Relationship with Wellsense Technologies, Ltd.

Since February 2020, Wellsense Technologies, Ltd. has sub-leased approximately 165 square meters of private office space, including access to shared public spaces, from us in Neve Ilan, Israel. Wellsense Technologies, Ltd. pays approximately \$7,000 per month and, during the year ended December 31, 2020, the total payment received from Wellsense Technologies, Ltd. was approximately \$59,000. Each of Ran Poliakine and Richard Stone is a shareholder of the parent company of Wellsense Technologies, Ltd.

Service Agreement

In February 2021, the shareholders approved the entry into an agreement with Floyd Katske, effective as of October 1, 2020, whereby Floyd Katske will assist the Chief Executive Officer and us with various tasks given his medical knowledge, expertise and experience, as may be requested from time-to-time by our Chief Executive Officer. These tasks are in addition and unrelated to his role as a director. We have agreed to pay Floyd Katske with respect to such services \$200 per hour, (plus applicable VAT) against an invoice. The services will be limited to 100 hours in any calendar month, according to hours approved by the Chairman. In addition, we agreed to pay Floyd Katske cash compensation consisting of RSUs granted in each calendar quarter, in the amount calculated by dividing (i) two times the cash compensation paid during such quarter as aforesaid by (ii) the fair market value of our ordinary shares on the last trading day of such quarter. All tax consequences shall be borne by Floyd Katske. The agreement may be terminated by 14 days’ written notice by either party.

Designated Director

Under our compensation policy, we have designated Erez Meltzer as a “Designated Director,” effective as of January 1, 2021, due to his stature, added value and extraordinary contribution to us, including throughout our initial public offering process and thereafter. As a Designated Director, Erez Meltzer shall receive additional cash compensation (in addition to the annual base compensation and annual equity compensation paid to him for service as a director) of \$80,000 per year, and of \$200,000 in equity-based compensation in the form of RSUs to be granted in quarterly installments, calculated according to the fair market value of our ordinary shares on the last trading day of such quarter.

Directorship Agreements

We have entered into directorship agreements with each of our directors, pursuant to which such directors will serve on our board of directors. Pursuant to these agreements, each director was granted options under our 2019 Equity Incentive Plan in the number and terms set out under “Item 6. Directors, Senior Management and Employees—B. Compensation—Equity Incentive Plan.”

Equity Incentive Plans

For a description of our equity incentive plans with members of our board of directors and executive officers, see “Item 6. Directors, Senior Management and Employees—B. Compensation—Equity Incentive Plan.”

Directors and Officers Insurance Policy and Indemnification Agreements

Our amended and restated articles of association permit us to exculpate, indemnify and insure each of our directors and officers to the fullest extent permitted by the Companies Law. We have obtained directors and officers insurance for each of our executive officers and directors.

We have entered into agreements with each of our current directors and officers exculpating them from a breach of their duty of care to us to the fullest extent permitted by law, and undertaking to indemnify them to the fullest extent permitted by law including, with respect to liabilities resulting from our initial public offering, to the extent that these liabilities are not covered by insurance, all subject to limited exceptions. This indemnification is limited, with respect to any monetary liability imposed in favor of a third party, to events determined as foreseeable by the board of directors based on our current or expected activities. The maximum aggregate amount of indemnification that we may pay to our directors and officers based on such indemnification agreement shall not exceed the greater of (i) in relation to indemnity in connection with an offering to the public of our securities, the aggregate amount of proceeds from the sale by us and/or any of our shareholders in connection with such public offering, (ii) 25% of our total shareholders' equity pursuant to our most recent financial statements as of the time of the actual payment of indemnification, and (iii) \$50 million (in each case as may be increased from time to time by shareholders' approval). Such indemnification amounts are in addition to any insurance amounts.

However, in the opinion of the SEC, indemnification of office holders for liabilities arising under the Securities Act is against public policy and therefore unenforceable.

Registration Rights Agreements

We have entered into a registration rights agreement (the "Registration Rights Agreement") that entitles holders of approximately 14,231,839 of our ordinary shares and other securities convertible into or exchangeable for ordinary shares, including SKT and Yozma, to certain piggyback registration rights. See "Item 10. Additional Information—C. Material Contracts—Registration Rights Agreements."

C. Interests of Experts and Counsel

Not applicable.

Item 8. Financial Information

A. Consolidated Financial Statements and Other Financial Information

See "Item 18. Financial Statements."

Legal Proceedings

See "Item 4. Information on the Company—B. Business Overview—Legal Proceedings."

Dividend Policy

We have never declared or paid any cash dividends on our ordinary shares and we anticipate that, for the foreseeable future, we will retain any future earnings to support operations and to finance the growth and development of our business. Therefore, we do not expect to pay cash dividends for at least the next several years.

The distribution of dividends may also be limited by the Companies Law, which permits the distribution of dividends only out of retained earnings or earnings derived over the two most recent fiscal years, whichever is higher, provided that there is no reasonable concern that payment of a dividend will prevent a company from satisfying its existing and foreseeable obligations as they become due. Our amended and restated articles of association provide that dividends will be paid at the discretion of, and upon resolution by, our board of directors, subject to the provision of the Companies Law.

B. Significant Changes

Except as disclosed elsewhere in this annual report on Form 20-F, we have not experienced any significant changes since the date of our audited consolidated financial statements included in this annual report on Form 20-F.

Item 9. Offer and Listing

A. Offer and Listing Details

Our ordinary shares have been listed on the NASDAQ Global Market since August 20, 2020 under the symbol “NNOX.”

B. Plan of Distribution

Not applicable.

C. Markets

Our ordinary shares have been listed on the NASDAQ Global Market since August 20, 2020 under the symbol “NNOX.”

D. Selling Shareholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

Item 10. Additional Information

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

A copy of our amended and restated articles of association is attached as Exhibit 1.1 to this Annual Report. Our registration number with the Israeli Registrar of Companies is 515942076. Our registration number may be changed by the Israeli Registrar of Companies to indicate that we are a public company. The following are summaries of material provisions of our current amended and restated articles of association that became effective immediately prior to the completion of our initial public offering in August 2020, insofar as they relate to the material terms of our ordinary shares.

Objects of Our Company

Our purpose as set forth in our amended and restated articles of association is to engage in any lawful activity.

Board of Directors

See “Item 6. Directors, Senior Management and Employees—C. Board Practices.”

Ordinary Shares

As of December 31, 2020, we had 46,100,173 ordinary shares outstanding.

Dividends

We have never declared or paid any cash dividends on our ordinary shares.

We may declare a dividend to be paid to the holders of our ordinary shares in proportion to their respective shareholdings. See “Item 8. Financial Information—A. Consolidated Statements and Other Financial Information—Dividend Policy” for more information with respect to the requirements under Israeli law for the declaration and payment of dividends to our shareholders. Under the Companies Law, dividend distributions are determined by the board of directors and do not require the approval of the shareholders of a company unless the company’s articles of association provide otherwise. Our amended and restated articles of association do not require shareholder approval of a dividend distribution and provide that dividend distributions may be determined by our board of directors.

Voting Rights

All of our ordinary shares have identical voting and other rights in all respects.

Holders of our ordinary shares have one vote for each ordinary share held on all matters submitted to a vote before the shareholders at a general meeting. In any meeting of shareholders, we will follow the quorum requirements for general meetings as set forth in our amended and restated articles of association, instead of one-third of the issued share capital as required under the Nasdaq Marketplace Rules. Pursuant to our amended and restated articles of association, the quorum required for our general meetings of shareholders will consist of at least two shareholders present in person or by proxy (including by voting deed) and holding shares conferring in the aggregate at least 25% of the voting power of the Company. A meeting adjourned for lack of a quorum will generally be adjourned to the same day of the following week at the same time and place, or to such other day, time or place as indicated by our board of directors if so specified in the notice of the meeting. At the reconvened meeting, subject to a limited exception, any number of shareholders present in person or by proxy shall constitute a lawful quorum.

An ordinary resolution to be passed at a meeting by the shareholders requires the affirmative vote of a simple majority of the votes attaching to the ordinary shares cast at a meeting, while a special resolution requires the affirmative vote of no less than two-thirds of the votes attaching to the ordinary shares cast at a meeting. Both ordinary resolutions and special resolutions may also be passed by a unanimous written resolution signed by all the shareholders of our company, as permitted by the Companies Law and our amended and restated memorandum and articles of association. A special resolution will be required for important matters such as a change of name or making changes to our amended and restated memorandum and articles of association. Holders of the ordinary shares may, among other things, divide or combine their shares by ordinary resolution.

Transfer of Ordinary Shares

Our fully paid ordinary shares are issued in registered form and may be freely transferred under our amended and restated articles of association, unless the transfer is restricted or prohibited by another instrument, applicable law or the rules of a stock exchange on which the shares are listed for trade. The ownership or voting of our ordinary shares by non-residents of Israel is not restricted in any way by our amended and restated articles of association or the laws of the State of Israel, except for ownership by nationals of some countries that are, or have been, in a state of war with Israel.

Liquidation

In the event of our liquidation, after satisfaction of liabilities to creditors and other payments due as per applicable law, our assets will be distributed to the holders of our ordinary shares in proportion to their shareholdings. This right, as well as the right to receive dividends, may be affected by the grant of preferential dividend or distribution rights to the holders of a class of shares with preferential rights that may be authorized in the future.

Calls on Shares and Forfeiture of Shares

Our board of directors may from time to time make calls upon shareholders for any amounts unpaid on their shares in a notice served to such shareholders at least 14 calendar days prior to the specified time or times of payment. The shares that have been called upon and remain unpaid are subject to forfeiture. Any amount unpaid in respect of a call shall bear interest from the date on which it is payable until actual payment thereof, at such rate (not exceeding the then prevailing debitory rate charged by leading commercial banks in Israel), and at such time(s) as the Board of Directors may prescribe. Upon the allotment of shares, the Board of Directors may provide for differences among the allottees of such shares as to the amount of calls and/or the times of payment thereof.

Redemption, Repurchase and Surrender of Ordinary Shares

We may, subject to applicable law, issue redeemable shares and redeem the same or issue conditional securities with such conditions so as such securities may be cancelled or revoked or may be considered to have been cancelled or revoked upon the fulfillment of such conditions.

Modifications of Rights of Shares

Under the Companies Law and our amended and restated articles of association, the rights attached to any class of share, such as voting, liquidation and dividend rights, may be amended by adoption of a resolution by the holders of a majority of the shares of that class present at a separate class meeting, or otherwise in accordance with the rights attached to such class of shares, as set forth in our amended and restated articles of association, in addition to the ordinary majority vote of all classes of voting shares voting together as a single class.

Issuance of Additional Shares

We may, upon a resolution of the shareholders at a General Meeting, from time to time, increase our share capital by the creation of new shares. Any such increase shall be in such amount and shall be divided into shares of such nominal amounts or without nominal amounts, and such shares shall confer such rights and preferences, and shall be subject to such restrictions, as the resolution approving the creation of such shares shall provide. Except to the extent otherwise provided in the resolution creating such new shares, such new shares shall be subject to all the provisions applicable to the shares of the original capital. Without prejudice to any special rights previously conferred upon the holders of existing shares in the Company, the Company may, from time to time, provide for shares with such preferred or deferred rights or rights of redemption or other special rights and/or such restrictions, whether in regard to dividends, voting, repayment of share capital or otherwise, as may be stipulated in the resolution pursuant to which such shares are created.

Access to Corporate Records

Under the Companies Law, shareholders generally have the right to review minutes of our general meetings, our shareholders register and material shareholders register, our amended and restated articles of association, our annual audited financial statements and any document that we are required by law to file publicly with the Israeli Registrar of Companies or the Israel Securities Authority. In addition, any shareholder who specifies the purpose of their request may request to be provided with any document related to an action or transaction requiring shareholder approval under the related party transaction provisions of the Companies Law. We may deny this request if we believe it has not been made in good faith or if such denial is necessary to protect our interests or protect a trade secret or patent.

Anti-Takeover Provisions

A person wishing to acquire shares of an Israeli public company and who would as a result hold over 90% of the target company's voting rights or issued and outstanding share capital is required by the Companies Law to make a tender offer to all of the company's shareholders for the purchase of all of the issued and outstanding shares of the company. A person wishing to acquire shares of a public Israeli company and who would as a result hold over 90% of the voting rights or issued and outstanding share capital of a certain class of shares is required to make a tender offer to all of the shareholders who hold shares of the relevant class for the purchase of all of the issued and outstanding shares of that class. If the shareholders who do not accept the offer hold less than 5% of the issued and outstanding share capital of the company or of the applicable class, and more than half of the shareholders who do not have a personal interest in the offer accept the offer, all of the shares that the acquirer offered to purchase will be transferred to the acquirer by operation of law. However, a tender offer will also be accepted if the shareholders who do not accept the offer hold less than 2% of the issued and outstanding share capital of the company or of the applicable class of shares.

Upon a successful completion of such a full tender offer, any shareholder that was an offeree in such tender offer, whether such shareholder accepted the tender offer or not, may, within six months from the date of acceptance of the tender offer, petition an Israeli court to determine whether the tender offer was for less than fair value and that the fair value should be paid as determined by the court. However, under certain conditions, the offeror may include in the terms of the tender offer that an offeree who accepted the offer will not be entitled to petition the Israeli court as described above.

If the full tender offer was not accepted in accordance with the above alternatives, the acquirer may not acquire shares of the company that will increase its holdings to more than 90% of the company's issued and outstanding share capital or of the applicable class from shareholders who accepted the tender offer.

General Meetings of Shareholders and Shareholder Proposals

Under Israeli law, we are required to hold an annual general meeting of our shareholders once every calendar year that must be held no later than 15 months after the date of the previous annual general meeting. All general meetings other than the annual meeting of shareholders are referred to in our amended and restated articles of association as special meetings. Our board of directors may call special meetings whenever it sees fit, at such time and place, within or outside of Israel, as it may determine. In addition, the Companies Law provides that our board of directors is required to convene a special general meeting upon the written request of (i) any two or more of our directors or one-quarter or more of the members of our board of directors or (ii) one or more shareholders holding, in the aggregate, either (a) 5% or more of our outstanding issued shares and 1% or more of our outstanding voting power or (b) 5% or more of our outstanding voting power.

Under Israeli law, one or more shareholders holding at least 1% of the voting rights at the general meeting may request that the board of directors include a matter in the agenda of a general meeting to be convened in the future, provided that it is appropriate to discuss such a matter at the general meeting. Our amended and restated articles of association contain procedural guidelines and disclosure items with respect to the submission of shareholder proposals for shareholder meetings.

C. Material Contracts

FoxSemicon Integrated Technology, Inc. Manufacturing Agreement

On May 26, 2020, we entered into a Contract Manufacturing Agreement with FITI. Under the terms of the agreement, FITI agrees to manufacture, package, distribute and ship, and we agree to purchase, certain products and procurement and assembly services, including a minimum of 1,000 Nanox Systems per year. We agree to provide FITI with a rolling forecast of our estimated monthly purchases, which FITI will use to prepare its supply chain to cover the material and manufacturing needs. Subsequently, we will send purchase orders to FITI for certain products and services. Prices for the products will be agreed by the parties at least 90 days prior to the first expected delivery date. FITI will be entitled to order materials in accordance with an approved supplier list and on the terms that the parties agree upon on a quarterly basis, and FITI must obtain our prior written consent if it procures materials from other suppliers. FITI may also purchase materials from us to support orders pursuant to our requests. The parties also agree to enter into a quality agreement, which will set forth the manufacturing standards applicable to FITI. The agreement will be in effect for three years from the date of the agreement and is renewable for successive terms of one year unless or until either party notifies the other in writing of its intention not to renew with 90 days' prior notice. The agreement may be terminated by notice of the non-breaching party in case of a material breach of a party's material obligations, or by either party in case of the bankruptcy or insolvency of the other party.

Asset Purchase Agreement

We entered into an Asset Purchase Agreement with Nanox Gibraltar on September 3, 2019. See “Item 4. Information on the Company—A. History and Development of the Company” for a description of the agreement.

Warrant Agreements

As of March 20, 2021, there were 13 outstanding warrants to purchase a total of 2,838,496 ordinary shares with exercise prices ranging from \$0.01 per share to \$20.87 per share. These warrants are exercisable immediately and expire on various dates.

The warrants were issued to certain persons in connection with certain corporate, financing and consulting transactions. Eleven of these warrants were issued on September 2, 2019, in the framework of the Asset Purchase Agreement. The remaining two are a warrant issued to A-Labs upon the consummation of our initial public offering to purchase 50,000 ordinary shares with exercise price of \$18, as described above under “Item 4. Information on the Company—B. Business Overview—Letter Agreement with A-Labs” and the Warrant issued to SKT to purchase 2,262,443 ordinary shares with exercise price of \$20.87, as described above under “Item 7. Major Shareholders and Related Party Transactions—B. Related Party Transactions—Relationship With SKT.”

Registration Rights Agreements

We have entered into the Registration Rights Agreement with shareholders who held 14,533,835 of our ordinary shares and other securities convertible into or exchangeable for ordinary shares; however, some of these shares may have been sold on the market, in which case the registration rights would no longer be applicable. This amount includes the exercised warrants, as of March 20, 2021, which were entitled to piggyback registration rights (as described below) but exclude the shares that were sold in our secondary offering in February 2021.

Under the terms of the Registration Rights Agreement, and subject to the limitations specified therein, if we register our ordinary shares under the Securities Act for sale to the public, either for our own account or for the account of other security holders or both, the holders of registrable securities are entitled to notice of the intended registration and to include any or all of their registrable securities in the registration. The right of holders of registrable securities to include shares in an underwritten offering is subject to the right of the underwriters to limit the number of shares included in such offering. Holders of registrable securities are generally required to pay all expenses of registration, including the fees and disbursements of its counsel and all underwriting discounts and commissions.

In addition, as of March 20, 2021, holders of warrants to purchase an aggregate of 2,282,443 ordinary shares are entitled to piggyback registration rights under the terms of such warrants substantially similar to the registration rights described in the preceding paragraph.

D. Exchange Controls

There are currently no Israeli currency control restrictions on remittances of dividends on our ordinary shares, proceeds from the sale of the shares or interest or other payments to non-residents of Israel, except for shareholders who are subjects of certain countries that have been, or are considered to be, in a state of war with Israel.

E. Taxation

Israeli Tax Considerations and Government Programs

General Corporate Tax Structure in Israel

Israeli resident companies are generally subject to corporate tax, currently at the rate of 23% of a company’s taxable income. However, the effective tax rate payable by a company that derives income from a Benefited Enterprise, a Preferred Enterprise, or a Preferred Technological Enterprise (as discussed below) may be considerably less. Capital gains derived by an Israeli resident company are subject to tax at the regular corporate tax rate.

Under Israeli tax legislation, a corporation will be considered as an “Israeli resident company” if it meets one of the following: (i) it was incorporated in Israel; or (ii) the control and management of its business are exercised in Israel.

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

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

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

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

- Amortization over an eight-year period of the cost of purchased know-how and patents and rights to use a patent and know-how which are used for the development or advancement of the Industrial Enterprise, commencing from the tax year where the Industrial Enterprise began to use them.
- Under limited conditions, an election to file consolidated tax returns with related Israeli Industrial Companies; and
- Expenses related to a public offering are deductible in equal amounts from income attributed to the Industrial Enterprise over three years commencing in the year of the offering.

Although, as of the date of this annual report on Form 20-F, we do not have industrial production activities, we may qualify as an Industrial Company in the future and may be eligible for the benefits described above. However, we cannot assure that we will qualify as an Industrial Company or that the benefits described above will be available to us, or that even if available, we shall opt to use them.

Tax Benefits and Grants for Research and Development

Israeli tax law allows, under certain conditions, a tax deduction for expenditures related to scientific research and development projects, including capital expenditures, for the year in which they are incurred. Expenditures are deemed related to scientific research and development projects, if:

- The expenditures are approved by the relevant Israeli government ministry, determined by the field of research; or
- The research and development is for the promotion of the company and is carried out by or on behalf of the company seeking such tax deduction.

The amount of such deductible expenses is reduced by the sum of any funds received through government grants for the financing of such scientific research and development projects. No deduction under these research and development deduction rules is allowed if such deduction is related to an expense invested in an asset depreciable under the general depreciation rules of the Ordinance. Expenditures not so approved are deductible in equal amounts over three years.

From time to time, we may apply to the Israeli Innovation Authority (the “IIA”), for approval to allow a tax deduction for research and development expenses during the year incurred. There can be no assurance that such application will be accepted.

Law for the Encouragement of Capital Investments, 5719-1959

The Law for the Encouragement of Capital Investments, 5719-1959 (the “Investment Law”), provides certain incentives for capital investments in production facilities (or other eligible assets) by “Industrial Enterprises” (as defined under the Investment Law). The benefits available under the Investment Law are subject to the fulfillment of conditions stipulated therein. If a company does not meet these conditions, it may be required to refund the amount of tax benefits, as adjusted by the Israeli consumer price index, and interest, or other monetary penalties.

Tax Benefits Subsequent to the 2005 Amendment

An amendment to the Investment Law, which became effective as of April 1, 2005, or the 2005 Amendment, changed certain provisions of the Investment Law. An eligible investment program under the 2005 Amendment qualifies for benefits as a “Benefited Enterprise.” Prior to the 2005 Amendment, investment programs under the Investment Law were called “Approved Enterprises.” The extent of the tax benefits available under the 2005 Amendment to qualifying income of a Benefited Enterprise depend on, among other things, the geographic location of the Benefited Enterprise in Israel. 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 Benefited Enterprise in Israel, and a reduced corporate tax rate of between 10% and the applicable corporate tax rate for the remainder of the benefits period, depending on the level of foreign investment in the company in each year during the benefits period.

We are not entitled to tax benefits under the 2005 Amendment.

Tax Benefits Under the 2011 Amendment

The Investment Law was significantly amended as of January 1, 2011, or the 2011 Amendment. 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.

The 2011 Amendment introduced new tax benefits for income generated by a “Preferred Company” through its “Preferred Enterprise,” in accordance with the definition of such terms in the Investment Law. The definition of a Preferred Company, includes, inter alia, a company incorporated in Israel that (1) is not wholly owned by a government entity, (2) owns a Preferred Enterprise and (3) is controlled and managed from Israel and is subject to further conditions set forth in the Investment Law. Moreover, a Preferred Company needs to meet certain conditions stipulated in the Investment Law such as being an industrial company (including a minimum threshold of 25% export).

A Preferred Company is entitled to a reduced corporate tax rate of 16% with respect to the income attributed to its Preferred Enterprise, unless the Preferred Enterprise is located in development area “A,” in which case the rate will be 7.5%. Our operations are currently not located in development area “A.”

Dividends distributed from income which is attributed to a “Preferred Enterprise” will be subject to withholding tax at the following rates: (i) Israeli resident individuals—20% and (ii) non-Israeli residents—20%, subject to a reduced tax rate under the provisions of an applicable double tax treaty and subject to the receipt in advance of valid certificate from the Israeli Tax Authority, or the ITA. If such dividends are paid to an Israeli company, no tax is required to be withheld. However, if such dividends are subsequently distributed by such Israeli company to individuals or a non-Israeli company, withholding tax at a rate of 20% or such lower rate as may be provided in an applicable tax treaty will apply.

The provisions of the 2011 Amendment do not apply to existing “Benefited Enterprises” or “Approved Enterprises,” which will continue to be entitled to the tax benefits under the Investment Law, as in effect prior to the 2011 Amendment, unless the company owning such enterprises had made an election to apply the provisions of the 2011 Amendment (such election cannot be later rescinded), which is to be filed with the ITA, not later than the date prescribed for the filing of the company’s annual Israeli tax return for the respective year.

We are currently not entitled to tax benefits under the 2011 Amendment.

Tax Benefits Under the 2017 Amendment

Additional amendments to the Investment Law became effective in January 2017, or the 2017 Amendment. The 2017 Amendment provides new tax benefits for two types of “Technological Enterprises,” as described below, and is in addition to the other existing tax benefit programs under the Investment Law.

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

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

Dividends distributed by a Preferred Technological Enterprise or a Special Preferred Technological Enterprise, paid out of Preferred Technological Income or income attributed to production are generally subject to withholding tax at the rate of 20% or such lower rate, as may be provided in an applicable tax treaty (subject to the receipt in advance of a valid certificate from the ITA allowing for a reduced tax rate). However, if such dividends are paid to an Israeli company, no tax is required to be withheld. However, if such dividends are subsequently distributed by such Israeli company to individuals or a non-Israeli company, withholding tax at a rate of 20% or such lower rate as may be provided in an applicable tax treaty will apply. If dividends paid out of Preferred Technological Income are distributed to a foreign company and other conditions are met, the withholding tax rate will be 4% (or a lower rate under a tax treaty, if applicable, subject to the receipt in advance of a valid certificate from the ITA allowing for a reduced tax rate).

We are currently not entitled to tax benefits under the 2017 Amendment.

Taxation of Our Shareholders

Capital Gains

Capital gain tax is imposed on the disposition of capital assets by an Israeli resident for tax purposes, and on the disposition of such assets by a non-Israeli resident for tax purposes if those assets are (i) located in Israel; (ii) are shares or a right to a share in an Israeli resident corporation, or (iii) represent, directly or indirectly, rights to assets located in Israel. The Ordinance distinguishes between “Real Capital Gain” and the “Inflationary Surplus.” Real Capital Gain is the excess of the total capital gain over Inflationary Surplus computed generally on the basis of the increase in the Israeli consumer price index or, in certain circumstances, a foreign currency exchange rate, between the date of purchase and the date of disposition. Inflationary Surplus is not currently subject to tax in Israel.

Real Capital Gain accrued by individuals on the sale of our ordinary shares will be taxed at the rate of 25%. However, if the individual shareholder is a “Controlling Shareholder” (i.e., a person who holds, directly or indirectly, alone or together with another, 10% or more of one of the Israeli resident company’s “means of control,” which includes, among other things, the right to receive profits of the company, voting rights, the rights to receive proceeds upon the company’s liquidation and the right to appoint a director) at the time of sale or at any time during the preceding 12-month period, such capital gain will be taxed at the rate of 30%. Furthermore, where an individual claimed real interest expenses and linkage differentials on securities, the capital gain on the sale of the securities will be taxed at a rate of 30% (exclusive of excess tax described below).

Real Capital Gain derived by corporations will be generally subject to the corporate tax rate (23% in 2018 and thereafter).

Individual and corporate shareholder dealing in securities in Israel are taxed at the tax rates applicable to business income—23% for corporations in 2018 and thereafter and a marginal tax rate of up to 47% in 2019 for individuals, not including excess tax (described below). Notwithstanding the foregoing, Real Capital Gain derived from the sale of our ordinary shares by a non-Israeli shareholder may be exempt under the Ordinance from Israeli taxation provided that the following cumulative conditions are met: (i) the shares were purchased upon or after the registration of the shares on the stock exchange, (ii) the seller does not have a permanent establishment in Israel to which the derived capital gain is attributable, (iii) if the seller is a corporation, no more than 25% of its means of control are held, directly and indirectly, by Israeli residents, and (iv) if the seller is a corporation, there is no Israeli resident that is entitled to 25% or more of the revenues or profits of the corporation, directly or indirectly. In addition, such exemption would not be available to a person whose capital gains from selling or otherwise disposing of the securities are deemed to be business income.

In addition, the sale of shares may be exempt from Israeli capital gain tax under the provisions of an applicable tax treaty. For example, the Convention between the Government of the United States and the Government of the State of Israel with respect to Taxes of Income, as amended, or the U.S.-Israel Double Tax Treaty, exempts U.S. residents for the purposes of the treaty from Israeli capital gain tax in connection with such sale, provided (i) the U.S. resident owned, directly or indirectly, less than 10% of the Israeli resident company's voting power at any time within the 12-month period preceding such sale; (ii) the seller, being an individual, is present in Israel for a period or periods of less than 183 days during the taxable year; and (iii) the capital gain from the sale was not derived through a permanent establishment of the U.S. resident in Israel.

Shareholders may be liable for Israeli tax on the sale of their ordinary shares and the payment of the consideration may be subject to withholding of Israeli tax. Shareholders may be required to demonstrate that they are exempt from tax on their capital gains in order to avoid withholding at the time of sale. For example, in transactions involving a sale of all of the shares of an Israeli resident company, in the form of a merger or otherwise, the ITA may require from shareholders who are not liable for Israeli tax to sign declarations in forms specified by this authority or obtain a specific exemption from the ITA to confirm their status as a non-Israeli resident, and, in the absence of such declarations or exemptions, may require the purchaser of the shares to withhold taxes.

The purchaser, the Israeli stockbrokers or financial institutions through which the shares are held is obligated, subject to the above mentioned exemptions, to withhold tax on the amount of consideration paid upon the sale of the shares (or on the Real Capital Gain on the sale, if known) at the rate of 25% in respect of an individual and 23% in respect of a corporation.

Upon the sale of securities traded on a stock exchange, a detailed return, including a computation of the tax due, must be filed and an advanced payment must be paid on January 31 and July 31 of every calendar year in respect of sales of securities made within the previous six months. However, if all tax due was withheld according to applicable provisions of the Ordinance and regulations promulgated thereunder the aforementioned return need not be filed and no advance payment must be paid. Capital gain is also reportable on the annual income tax return.

Dividends

We have never paid cash dividends. A distribution of dividend by our company from income attributed to a Preferred Enterprise to Israeli residents will generally be subject to withholding tax in Israel at the following tax rates: Israeli resident individuals—20%; Israeli resident companies—0% (although, if such dividends are subsequently distributed to individuals or a non-Israeli company, withholding tax at a rate of 20% or such lower rate as may be provided if an applicable tax treaty will apply (subject to the receipt in advance of a valid tax certificate from the ITA allowing for a reduced tax rate)). A distribution of dividends from income, which is not attributed to a Preferred Enterprise to an Israeli resident individual, will generally be subject to withholding tax at a rate of 25% or 30% if the dividend recipient is a "Controlling Shareholder" (as defined above) at the time of distribution or at any time during the preceding 12-month period. If the recipient of the dividend is an Israeli resident corporation, such dividend will be exempt from income tax provided the income from which such dividend is distributed was derived or accrued within Israel (although, if such dividends are subsequently distributed to individuals or a non-Israeli company, withholding tax at a rate of 25% or such lower rate as may be provided if an applicable tax treaty will apply (subject to the receipt in advance of a valid tax certificate from the ITA allowing for a reduced tax rate)).

A non-Israeli resident (either individual or corporation) is generally subject to Israeli withholding tax on the receipt of dividends at the rate of 25% (30% if the dividends recipient is a “Controlling Shareholder” (as defined above), at the time of distribution or at any time during the preceding 12-month period); those rates are subject to a reduced tax rate under the provisions of an applicable double tax treaty (subject to the receipt in advance of a valid certificate from the ITA allowing for a reduced tax rate). Under the U.S.-Israel Double Tax Treaty, the following withholding rates will apply in respect of dividends distributed by an Israeli resident company to a U.S. resident: (i) if the U.S. resident is a corporation which holds during that portion of the taxable year which precedes the date of payment of the dividend and during the whole of its prior taxable year (if any), at least 10% of the outstanding voting shares of the Israeli resident paying corporation and not more than 25% of the gross income of the Israeli resident paying corporation for such prior taxable year (if any) consists of certain type of interest or dividends—the tax rate is 12.5%, (ii) if both the conditions mentioned in (i) above are met and the dividend is paid from an Israeli resident company’s income which was entitled to a reduced tax rate applicable to an Approved Enterprise, Benefited Enterprise or Preferred Enterprise—the tax rate is 15% if a certificate for a reduced withholding tax rate would be provided in advance from the ITA and (iii) in all other cases, the tax rate is 25%. The aforementioned rates under the U.S.-Israel Double Tax Treaty will not apply if the dividend income was derived through a permanent establishment of the U.S. resident in Israel.

A non-Israeli resident who receives dividends from which tax was withheld is generally exempt from the obligation to file tax returns in Israel with respect to such income, provided that (i) such income was not generated from business conducted in Israel by the taxpayer and (ii) the taxpayer has no other taxable sources of income in Israel with respect to which a tax return is required to be filed.

Excess Tax

Individuals who are subject to tax in Israel (whether such individual is an Israeli resident or non-Israeli resident) are also subject to an additional tax on annual income exceeding a certain threshold (NIS 651,600, for 2020), which amount is linked to the Israeli consumer price index, at a rate of 3%, including, but not limited to, income derived from dividends, interest and capital gains.

Foreign Exchange Regulations

Non-residents of Israel who hold our ordinary shares are able to receive any dividends, and any amounts payable upon the dissolution, liquidation and winding up of our affairs, repayable in non-Israeli currency at the rate of exchange prevailing at the time of conversion. However, Israeli income tax is generally required to have been paid or withheld on these amounts. In addition, the statutory framework for the potential imposition of currency exchange control has not been eliminated, and may be restored at any time by administrative action.

Estate and Gift Tax

Israeli law presently does not impose estate tax or in general gift taxes.

U.S. Federal Income Tax Considerations

The following discussion is a summary of U.S. federal income tax considerations generally applicable to the ownership and disposition of our ordinary shares. This summary applies only to investors that are U.S. Holders (as defined below) that hold our ordinary shares as “capital assets” (generally, property held for investment) under the U.S. Internal Revenue Code of 1986, as amended (the “Code”). This discussion is based upon U.S. federal tax law as in effect on the date of this annual report on Form 20-F and on U.S. Treasury regulations in effect or, in some cases, proposed, as of the date of this annual report on Form 20-F, as well as judicial and administrative interpretations thereof available on or before such date. All of the foregoing authorities are subject to differing interpretations or change, which change could apply retroactively and could affect the tax considerations described below. No ruling has been sought from the Internal Revenue Service, or the IRS, with respect to any U.S. federal income tax considerations described below, and there can be no assurance that the IRS or a court will not take a contrary position. This discussion, moreover, does not address the U.S. federal estate, gift, alternative minimum tax considerations, the Medicare tax on certain net investment income, any withholding or information reporting requirements, or any state, local and non-U.S. tax considerations relating to the ownership or disposition of our ordinary shares. The following summary does not address all aspects of U.S. federal income taxation that may be important to particular investors in light of their individual circumstances or to persons in special tax situations such as:

- banks and other financial institutions;
- insurance companies;

- pension plans;
- cooperatives;
- regulated investment companies;
- real estate investment trusts;
- broker-dealers;
- traders that elect to use a mark-to-market method of accounting;
- certain former U.S. citizens or long-term residents;
- tax-exempt entities (including private foundations);
- holders who acquire our ordinary shares pursuant to any employee share option or otherwise as compensation;
- investors that will hold our ordinary shares as part of a straddle, hedge, conversion, constructive sale or other integrated transaction for U.S. federal income tax purposes;
- persons holding our ordinary shares in connection with a trade or business outside the United States;
- persons that actually or constructively own 10% or more of our stock (by vote or value);
- investors that have a functional currency other than the U.S. dollar;
- partnerships or other entities classified as partnerships for U.S. federal income tax purposes, or persons holding our ordinary shares through such entities, all of whom may be subject to tax rules that differ significantly from those discussed below.

Investors are urged to consult their tax advisors about the application of the U.S. federal tax rules to their particular circumstances as well as the state, local, non-U.S. and other tax consequences to them of the ownership and disposition of our ordinary shares.

General

For purposes of this discussion, a “U.S. Holder” is a beneficial owner of our ordinary shares that is, for U.S. federal income tax purposes:

- an individual who is a citizen or resident of the United States;
- a corporation (or other entity treated as a corporation for U.S. federal income tax purposes) created in, or organized under the law of, the United States or any state thereof or the District of Columbia;
- an estate the income of which is includible in gross income for U.S. federal income tax purposes regardless of its source; or
- a trust (A) the administration of which is subject to the primary supervision of a U.S. court and which has one or more U.S. persons who have the authority to control all substantial decisions of the trust or (B) that has otherwise validly elected to be treated as a U.S. person under the Code.

If a partnership (or other entity treated as a partnership for U.S. federal income tax purposes) is a beneficial owner of our ordinary shares, the tax treatment of a partner in the partnership will generally depend upon the status of the partner and the activities of the partnership. Partnerships holding our ordinary shares and their partners are urged to consult their tax advisors regarding the ownership and disposition of our ordinary shares.

Dividends

Subject to the discussion below under “—Passive Foreign Investment Company Considerations,” any cash distributions (including the amount of any Israeli tax withheld) paid on our ordinary shares out of our current or accumulated earnings and profits, as determined under U.S. federal income tax principles, will generally be includible in the gross income of a U.S. Holder as dividend income on the day actually or constructively received by the U.S. Holder. Because we do not intend to determine our earnings and profits on the basis of U.S. federal income tax principles, any distribution we pay will generally be treated as a “dividend” for U.S. federal income tax purposes. Dividends received on our ordinary shares will not be eligible for the dividends received deduction allowed to corporations in respect of dividends received from U.S. corporations.

Individuals and other non-corporate U.S. Holders may be subject to tax at the lower capital gains tax rate applicable to “qualified dividend income,” provided that certain conditions are satisfied, including that (1) the ordinary shares on which the dividends are paid are readily tradable on an established securities market in the United States, or we are eligible for the benefit of the U.S.-Israel Double Tax Treaty, (2) we are neither classified as a PFIC nor treated as such with respect to a U.S. Holder (as discussed below) for the taxable year in which the dividend is paid or the preceding taxable year, and (3) certain holding period and other requirements are met. Our ordinary shares are listed and traded on the Nasdaq Global Market. Thus, we believe that our ordinary shares will generally be considered to be readily tradable on an established securities market in the United States. There can be no assurance that the ordinary shares will continue to be considered readily tradable on an established securities market in later years. U.S. Holders are urged to consult their tax advisors regarding the availability of the lower rate for dividends paid with respect to our ordinary shares.

For U.S. foreign tax credit purposes, dividends paid on our ordinary shares generally will be treated as income from foreign sources and generally will constitute passive category income. A U.S. Holder may be subject to Israeli withholding taxes on dividends paid on our ordinary shares. See “—Israeli Tax Considerations and Government Programs—Taxation of Our Shareholders—Dividends.” Depending on the U.S. Holder’s particular facts and circumstances and subject to a number of complex conditions and limitations, Israeli withholding taxes on dividends not in excess of any applicable rate under the U.S.-Israel Double Tax Treaty may be treated as foreign taxes eligible for credit against a U.S. Holder’s U.S. federal income tax liability. A U.S. Holder who does not elect to claim a foreign tax credit for foreign tax withheld may instead claim a deduction for U.S. federal income tax purposes in respect of such withholding, but only for a year in which such holder elects to do so for all creditable foreign income taxes. The rules governing the foreign tax credit are complex and each U.S. Holder is urged to consult its tax advisor regarding the availability of the foreign tax credit under its particular circumstances.

Sale or Other Disposition

A U.S. Holder will generally recognize gain or loss upon the sale or other disposition of our ordinary shares in an amount equal to the difference between the amount realized upon the disposition and the U.S. Holder’s adjusted tax basis in such ordinary shares. Subject to the discussion below under “—Passive Foreign Investment Company Considerations,” the gain or loss will generally be capital gain or loss and individuals and other non-corporate U.S. Holders who have held the ordinary shares for more than one year will generally be eligible for reduced tax rates. The deductibility of a capital loss may be subject to limitations. Any such gain or loss that the U.S. Holder recognizes will generally be treated as U.S. source income or loss for foreign tax credit limitation purposes, such that the U.S. Holder may not be able to use the foreign tax credit arising from any Israeli tax imposed on the disposition of our ordinary shares unless such credit can be applied (subject to applicable limitations) against U.S. federal income tax due on other income derived from foreign sources in the same income category (generally, the passive category). Each U.S. Holder is urged to consult its tax advisor regarding the tax consequences if a foreign tax is imposed on a disposition of our ordinary shares, including the availability of the foreign tax credit under its particular circumstances.

Passive Foreign Investment Company Considerations

A non-U.S. corporation, such as our company, will be classified as a PFIC for U.S. federal income tax purposes for any taxable year, if either (i) 75% or more of its gross income for such year consists of certain types of passive income or (ii) 50% or more of the value of its assets (generally determined on the basis of a quarterly average) during such year is attributable to assets that produce or are held for the production of passive income. For this purpose, cash and assets readily convertible into cash are generally classified as passive assets and goodwill and other unbooked intangibles associated with active business activities may generally be classified as non-passive assets. Passive income generally includes, among other things, dividends, interest, royalties and rents (other than certain royalties and rents derived in the active conduct of a trade or business and not derived from a related person), and gains from the disposition of passive assets. We will be treated as owning a proportionate share of the assets and earning a proportionate share of the income of any other corporation in which we own, directly or indirectly, at least 25% (by value) of the stock.

Whether we are, or will be, classified as a PFIC is a factual determination made annually that will depend, in part, upon the composition of our income and assets.

Prior to the commercialization of our medical imaging technology, passive income could constitute more than 75% of gross income for any taxable year. Consequently, we believe that we will technically be classified as a PFIC for the taxable year ended December 31, 2020. Depending upon the composition of our income and assets and the market price of our ordinary shares during 2021 and subsequent taxable years and whether we start generating a substantial amount of active revenue, we could continue to be classified as a PFIC for 2021 and subsequent taxable years if we are classified as a PFIC for 2020. Accordingly, U.S. Holders of our ordinary shares should be willing to assume the risks of investing in a PFIC.

Furthermore, because there are uncertainties in the application of the relevant rules, it is possible that the IRS may challenge our classification of certain income or assets as non-passive, or our valuation of our goodwill and other unbooked intangibles, each of which may increase the likelihood of us becoming classified as a PFIC for the current or subsequent taxable years.

If we are classified as a PFIC for any taxable year during which a U.S. Holder holds our ordinary shares, unless the U.S. Holder makes a mark-to-market election (as described below), the U.S. Holder will generally be subject to special tax rules on (i) any excess distribution that we make to the U.S. Holder (which generally means any distribution paid during a taxable year to a U.S. Holder that is greater than 125% of the average annual distributions paid in the three preceding taxable years or, if shorter, the U.S. Holder's holding period for the ordinary shares), and (ii) any gain realized on the sale or other disposition of our ordinary shares. In addition, dividends paid in respect of our ordinary shares would not be eligible for the lower tax rate described under "—Dividends" above.

Under the PFIC rules:

- the excess distribution or gain will be allocated ratably over the U.S. Holder's holding period for the ordinary shares;
- the amount allocated to the taxable year of the excess distribution, sale or other disposition and to any taxable years in the U.S. Holder's holding period prior to the first taxable year in which we are classified as a PFIC (each, a "pre-PFIC year"), will be taxable as ordinary income;
- the amount allocated to each prior taxable year, other than a pre-PFIC year, will be subject to tax at the highest tax rate in effect for individuals or corporations, as appropriate, for that year; and
- the interest charge generally applicable to underpayments of tax will be imposed on the tax attributable to each prior taxable year, other than a pre-PFIC year.

If we are classified as a PFIC for any taxable year during which a U.S. Holder holds our ordinary shares, we generally will continue to be treated as a PFIC with respect to such U.S. Holder for all succeeding years during which the holder holds our ordinary shares. However, if we cease to meet the threshold requirements for PFIC status, provided that the U.S. Holder has not made a mark-to-market election, as described below, such holder may avoid some of the adverse effects of the PFIC regime by making a "deemed sale" election with respect to our ordinary shares held by such U.S. Holder. If such election is made, the U.S. Holder will be deemed to have sold our ordinary shares it holds on the last day of the last taxable year in which we were classified as a PFIC at their fair market value and any gain from such deemed sale will be taxed under the PFIC rules described above. After the deemed sale election, so long as we do not become classified as a PFIC in a subsequent taxable year, the ordinary shares with respect to which such election was made will not be treated as shares in a PFIC and the U.S. Holder will not be subject to the PFIC rules described above with respect to any "excess distribution" received from us or any gain from an actual sale or other disposition of the ordinary shares. The rules dealing with deemed sale elections are very complex. U.S. Holders of our ordinary shares are strongly urged to consult their tax advisors as to the possibility and consequences of making a deemed sale election if we cease to be classified as a PFIC and such election becomes available to such holders.

If we are classified as a PFIC for any taxable year during which a U.S. Holder holds our ordinary shares and any subsidiary we own is also classified as a PFIC, such U.S. Holder would be treated as owning a proportionate amount (by value) of the shares of the lower-tier PFIC for purposes of the application of these rules. As a result, such U.S. Holder may incur liability for the deferred tax and interest charge described above if either (1) we receive any excess distribution from, or dispose of all or part of our interest in, the lower-tier PFIC or (2) the U.S. Holder disposes of all or part of our ordinary shares. It is possible that any subsidiary we own would be a PFIC for the current taxable year or future taxable years. U.S. Holders are urged to consult their tax advisors regarding the application of the PFIC rules to any subsidiary we own.

As an alternative to the foregoing rules, a U.S. Holder of “marketable stock” (as defined below) in a PFIC may make a mark-to-market election with respect to such stock. If a U.S. Holder makes this election with respect to our ordinary shares, the holder will generally (i) include as ordinary income for each taxable year that we are classified as a PFIC the excess, if any, of the fair market value of the ordinary shares held at the end of the taxable year over the adjusted tax basis of such ordinary shares and (ii) deduct as an ordinary loss in each such taxable year the excess, if any, of the adjusted tax basis of the ordinary shares over the fair market value of such ordinary shares held at the end of the taxable year, but such deduction will only be allowed to the extent of the amount previously included in income as a result of the mark-to-market election. The U.S. Holder’s adjusted tax basis in the ordinary shares would be adjusted to reflect any income or loss resulting from the mark-to-market election. If a U.S. Holder makes a mark-to-market election in respect of our ordinary shares and we cease to be classified as a PFIC, the holder will not be required to take into account the gain or loss described above during any period that we are not classified as a PFIC. If a U.S. Holder makes a mark-to-market election, any gain such U.S. Holder recognizes upon the sale or other disposition of our ordinary shares in a year when we are classified as a PFIC will be treated as ordinary income and any loss will be treated as ordinary loss, but such loss will only be treated as ordinary loss to the extent of the net amount previously included in income as a result of the mark-to-market election.

The mark-to-market election is available only for “marketable stock,” which is stock that is regularly traded on a qualified exchange or other market, as defined in applicable U.S. Treasury regulations. Our ordinary shares are listed on the Nasdaq Global Market and should be treated as regularly traded for purposes of the mark-to-market rules. While we anticipate that our ordinary shares will continue to qualify as being regularly traded, no assurances may be given in this regard. If any subsidiary we own is, or becomes, classified as a PFIC, the mark-to-market election will likely not be available with respect to the shares of such subsidiary that are treated as owned by a U.S. Holder. Consequently, a U.S. Holder could be subject to the PFIC rules with respect to income of a lower-tier PFIC the value of which had already been taken into account indirectly via mark-to-market adjustments. U.S. Holders are urged to consult their tax advisors as to the availability and desirability of a mark-to-market election, as well as the impact of such election on interests in any lower-tier PFIC.

Alternatively, a U.S. shareholder of a PFIC may avoid the PFIC tax consequences described above in respect of its shares of PFIC stock by making a timely “qualified electing fund,” or QEF, election. To comply with the requirements of a QEF election, such shareholder must receive certain information from the PFIC. Because we do not intend to provide information necessary for U.S. Holders to make QEF elections, such election will not be available to U.S. Holders of our ordinary shares.

If a U.S. Holder owns our ordinary shares during any taxable year that we are classified as a PFIC, the holder must generally file an annual IRS Form 8621 regarding distributions received on, and any gain realized on the disposition of, our ordinary shares. U.S. Holders are urged to consult their tax advisor regarding our PFIC status and the U.S. federal income tax consequences of owning and disposing of our ordinary shares if we are, or become, classified as a PFIC, including the possibility of making a mark-to-market or deemed sale election.

The summary of U.S. federal income tax consequences set out above is for general informational purposes only. Investors are urged to consult their tax advisors about the application of the U.S. federal tax rules to their particular circumstances as well as the state, local, non-U.S. and other tax consequences to them of the purchase, ownership and disposition of our ordinary shares.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

We have previously filed with the SEC a registration statement on Form F-1 (File No. 333-240209), as amended, and a registration statement on Form F-1 (File No. 333-252860), as amended, each with respect to our ordinary shares. As allowed by the SEC, in Item 19 of this annual report on Form 20-F, we incorporate by reference certain information we previously filed with the SEC. This means that we can disclose important information to you by referring you to another document filed separately with the SEC. The information incorporated by reference is considered to be part of this annual report on Form 20-F.

We are subject to the periodic reporting and other informational requirements of the Exchange Act. Under the Exchange Act, we are required to file reports and other information with the SEC. The SEC maintains a website at www.sec.gov that contains reports and other information regarding registrants that file electronically with the SEC. Our annual report on Form 20-F and other information submitted by us to the SEC may be accessed through this website.

As a foreign private issuer, we are exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders will be exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we will not be required under the Exchange Act to file annual, quarterly and current reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act. However, we are required to file with the SEC, within four months after the end of each fiscal year, or such applicable time as required by the SEC, an annual report on Form 20-F containing financial statements audited by an independent registered public accounting firm, and to submit to the SEC, on Form 6-K, unaudited quarterly financial information for the first three quarters of each fiscal year.

We maintain a corporate website at <http://www.nanox.vision>. In accordance with NASDAQ Stock Market Rule 5250(d), we will post this annual report on Form 20-F on our website. Information contained on our website is not incorporated by reference into this annual report on Form 20-F. In addition, we will provide hardcopies of our annual report on Form 20-F free of charge to shareholders upon request.

I. Subsidiary Information

Not applicable.

Item 11. Qualitative and Quantitative Disclosures About Market Risk

Interest Rate Risk

As of December 31, 2020, we had cash equivalents consisting primarily of U.S. Dollar bank deposits. Our primary exposure to market risk is interest income sensitivity, which is affected by changes in the general level of U.S. interest rates. Consequently, changes in market interest rates would not have a material impact on our financial position or results of operations.

As of December 31, 2020, we had no debt outstanding and are therefore not exposed to interest rate risk with respect to the cost of servicing and repaying debt.

Inflation-related Risks

We do not believe that the rate of inflation in Israel has had a material impact on our business to date, however, our costs in Israel will increase if the inflation rate in Israel exceeds the devaluation of the NIS against the U.S. dollar or if the timing of such devaluation lags behind inflation in Israel.

Foreign Currency Exchange Risk

Our statements of operations and cash flows could be adversely affected in the future due to changes in foreign exchange rates. We expect to have cash and cash equivalents denominated in U.S. Dollars. As a result, changes in foreign currency exchange rates would not have a material impact on our financial position or results of operations.

Item 12. Description of Securities Other than Equity Securities

A. Debt Securities

Not applicable.

B. Warrants and Rights

As of March 20, 2021, there are 13 outstanding warrants to purchase a total of 2,838,496 of our ordinary shares with outstanding exercise prices ranging from \$0.01 per share to \$20.87 per share. These warrants are exercisable immediately and expire on various dates.

The warrants were issued to certain persons in connection with certain corporate, financing and consulting transactions. Eleven of these warrants were issued on September 2, 2019, in the framework of the Asset Purchase Agreement. The remaining two are a warrant issued to A-Labs Finance and Advisory upon the consummation of our initial public offering to purchase 50,000 ordinary shares with an exercise price of \$18, as described above under “Item 4. Information on the Company—B. Business Overview—Letter Agreement with A-Labs” and the Warrant issued to SKT to purchase 2,262,443 ordinary shares with exercise price of \$20.87, as described above under “Item 7. Major Shareholders and Related Party Transactions—B. Relationship With SKT.”

C. Other Securities

Not applicable.

D. American Depositary Shares

Not applicable.

PART II

Item 13. Defaults, Dividend Arrearages and Delinquencies

None.

Item 14. Material Modifications to the Rights of Security Holders and Use of Proceeds

See “Item 10. Additional Information—B. Memorandum and Articles of Association” for a description of the rights of holders of our ordinary shares, which remain unchanged.

Item 15. Controls and Procedures

(a) Disclosure Controls and Procedures

Our management has evaluated, with the participation of our Chief Executive Officer and Chief Financial Officer, the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e) under the Exchange Act) as of the end of the period covered by this report, and has concluded that our disclosure controls and procedures were ineffective as of December 31, 2020, due to the material weaknesses as discussed in “Item 3. Key Information—D. Risk Factors,” to provide reasonable assurance that information required to be disclosed by us in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the applicable rules and forms, and that it is accumulated and communicated to our Management, including our chief executive officer and chief financial officer, as appropriate to allow timely decisions regarding required disclosure.

Remediation Plans

We have implemented measures to remediate the identified material weakness. Those remediation measures are ongoing and have included the following:

- we have hired a corporate controller with U.S. GAAP and SEC reporting experience, an internal auditor (part-time) and a financial planning and analysis professional and are continuing to seek additional financial professionals to increase the number of qualified financial reporting personnel and to strengthen our finance department;
- we are selecting and implementing a new enterprise resource planning system;
- we are developing, communicating, and implementing an accounting policy manual for our financial reporting personnel for recurring transactions and period-end closing processes; and
- we are establishing monitoring and oversight controls for non-recurring and complex transactions to ensure the accuracy and completeness of our consolidated financial statements and related disclosures.

While we believe that these efforts will improve our internal control over financial reporting, the implementation of our remediation is ongoing and will require validation and testing of the design and operating effectiveness of our internal controls over a sustained period of financial reporting cycles.

We believe we are making progress toward achieving the effectiveness of our internal controls and disclosure controls. The actions that we are taking are subject to ongoing senior management review, as well as audit committee oversight. We will not be able to conclude whether the steps we are taking will fully remediate the material weakness in our internal control over financial reporting until we have completed our remediation efforts and subsequent evaluation of their effectiveness. We may also conclude that additional measures may be required to remediate the material weakness in our internal control over financial reporting, which may necessitate additional evaluation and implementation time. We will continue to assess the effectiveness of our internal control over financial reporting and take steps to remediate the material weakness we have identified.

(b) Management’s Annual Report on Internal Control Over Financial Reporting

This annual report does not include a report of management’s assessment regarding internal control over financial reporting or an attestation report of the company’s registered public accounting firm due to a transition period established by rules of the SEC for newly public companies.

(c) Attestation Report of the Registered Public Accounting Firm

As an “emerging growth company,” as defined in the JOBS Act, we may take advantage of certain temporary exemptions from various reporting requirements, including, but not limited to, not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act (and the SEC rules and regulations thereunder). When these exemptions cease to apply, we expect to incur additional expenses and devote increased management effort toward ensuring compliance with them.

(d) Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the period covered by this annual report on Form 20-F that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 16. [Reserved]

(a) Audit Committee Financial Expert

Noga Kainan, an independent director and a member of our audit committee, is an audit committee financial expert.

(b) Code of Ethics

We have adopted a code of ethics and conduct, which is applicable to all of our directors, officers and employees. We have made our code of ethics publicly available on our website.

(c) Principal Accountant Fees and Services

The following table sets forth the aggregate fees by categories specified below in connection with certain professional services rendered by Kesselman & Kesselman, Certified Public Accountants (Isr.), a member firm of PricewaterhouseCoopers International Limited, our principal external auditors, for the periods indicated.

	Year Ended December 31,	
	2019	2020
Audit Fees ⁽¹⁾	\$ 110,000	\$ 376,000
Audit-Related Fees ⁽²⁾	—	—
Tax Fees ⁽³⁾	10,000	10,000
All Other Fees ⁽⁴⁾	—	—
Total	\$ 120,000	\$ 386,000

(1) “Audit Fees” represents the aggregate fees billed or accrued for the interim reviews and audit of our annual financial statements. This category also includes services that generally the independent accountant provides, such as consents and assistance with and review of documents filed with the SEC as well as fees related to audits in connection with our initial public offering in August 2020.

(2) “Audit-Related Fees” represents the aggregate fees billed or accrued for assurance and related services that are reasonably related to the performance of the audit or review of our financial statements and not reported under “Audit Fees.”

(3) “Tax Fees” represents the aggregate fees billed or accrued for professional tax services rendered by our independent registered public accounting firm for tax compliance and tax advice on actual or contemplated transactions.

(4) “All Other Fees” represents the aggregate fees billed or accrued for services rendered by our independent registered public accounting firm other than services reported under “Audit Fees,” “Audit-related Fees” and “Tax Fees.”

Audit Committee Pre-Approval Policies and Procedures

Our Audit Committee has adopted a policy pursuant to which we will not engage our auditors to perform any non-audit services unless the audit committee pre-approves the service.

Item 16D. Exemptions from the Listing Standards for Audit Committees

Not applicable.

Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers

Not applicable.

Item 16F. Change in Registrant's Certifying Accountant

Not applicable.

Item 16G. Corporate Governance

As a foreign private issuer, we are permitted to follow certain Israeli corporate governance practices instead of the Nasdaq corporate governance rules, provided that we disclose which requirements we are not following and the equivalent Israeli requirement. Pursuant to the "foreign private issuer exemption":

- we intend to follow Israeli corporate governance practices instead of the Nasdaq requirements with regard to, among other things, the nomination committee and director nomination procedures.
- we intend to comply with Israeli law, which permits a company to determine in its articles of association the number of shareholders and percentage of holdings required for a quorum at a general meeting, subject to certain minimum requirements. Our amended and restated articles of association provide that a quorum of two or more shareholders holding at least 25% of the voting rights in person or by proxy is required for commencement of business at a general shareholder meeting. The quorum set forth in our amended and restated articles of association with respect to an adjourned meeting shall, subject to a limited exception, consist of one or more shareholders present in person or by proxy (including by voting deed), regardless of the number or percentage of our outstanding shares held by them;
- with the exception of external directors and directors elected by our board of directors due to a vacancy, in accordance with the staggered nomination as described under "Item 6. Directors, Senior Management and Employees—C. Board Practices—Board of Directors," we intend to elect our directors to hold office until the annual general meeting of our shareholders that occurs in the third year following his or her election and until his or her successor shall be elected and qualified. The nominations for directors, which are presented to our shareholders by our board of directors, are generally made by the board of directors itself, in accordance with the provisions of our amended and restated articles of association and the Companies Law;
- we intend to adopt and approve material changes to equity incentive plans in accordance with the Companies Law, which does not impose a requirement of shareholder approval for such actions. In addition, we intend to follow Israeli corporate governance practice, which requires shareholder approval prior to an issuance of securities in connection with equity-based compensation of officers, directors, employees or consultants only under certain circumstances, in lieu of Nasdaq Marketplace Rule 5635(c);
- as opposed to making periodic reports to shareholders and proxy solicitation materials available to shareholders in the manner specified by the Nasdaq corporate governance rules, the Companies Law does not require us to distribute periodic reports directly to shareholders, and the generally accepted business practice in Israel is not to distribute such reports to shareholders but to make such reports available through a public website. We will only mail such reports to shareholders upon request. As a foreign private issuer, we are generally exempt from the SEC's proxy solicitation rules; and

- we follow Israeli corporate governance practices instead of Nasdaq requirements to obtain shareholder approval for all corporate actions requiring such approval under the requirements of the Companies Law such as (i) transactions with directors concerning the terms of their service or indemnification, exemption and insurance for their service (or for any other position that they may hold at our company), (ii) extraordinary transactions with controlling shareholders, (iii) terms of employment or other engagement of the controlling shareholder of the company or such controlling shareholder's relative, (iv) private placements that will result in a change of control, (v) certain transactions, other than a public offering, involving issuances of a 20% or greater interest in us and (vi) certain acquisitions of the stock or assets of another company.

Otherwise, we intend to comply with the rules generally applicable to U.S. domestic companies listed on the Nasdaq. We may in the future decide to use the foreign private issuer exemption with respect to some or all of the other Nasdaq corporate governance rules. We also intend to comply with Israeli corporate governance requirements under the Companies Law applicable to us.

Item 16H. Mine Safety Disclosure

Not applicable.

PART III

Item 17. Financial Statements

We have elected to provide financial statements pursuant to Item 18.

Item 18. Financial Statements

The consolidated financial statements of Nano-X Imaging Ltd. are included at the end of this annual report on Form 20-F.

Item 19. Exhibits

	Exhibits
1.1*	Articles of Association of the Registrant (incorporated by reference to Exhibit 3.1 to the Registrant's Draft Registration Statement on Form F-1 (File No. 377-02938) filed on February 18, 2020 with the SEC)
1.2*	Form of Amended and Restated Articles of Association of the Registrant to become effective immediately prior to the closing of the offering (incorporated by reference to Exhibit 3.2 to the Registrant's Registration Statement on Form F-1/A (File No. 333-240209) filed on August 14, 2020 with the SEC)
2.2†	Description of Securities Registered under Section 12 of the Exchange Act
4.1*	Asset Purchase Agreement, dated September 3, 2019, by and between the Registrant and Nanox Imaging PLC (incorporated by reference to Exhibit 2.1 to the Registrant's Draft Registration Statement on Form F-1 (File No. 377-02938) filed on February 18, 2020 with the SEC)
4.2*	Amendment to the Asset Purchase Agreement, dated December 3, 2019, by and between the Registrant and Nanox Imaging PLC (incorporated by reference to Exhibit 2.2 to the Registrant's Draft Registration Statement on Form F-1 (File No. 377-02938) filed on February 18, 2020 with the SEC)
4.3*	Amendment to the Asset Purchase Agreement, dated December 31, 2019, by and between the Registrant and Nanox Imaging PLC (incorporated by reference to Exhibit 2.3 to the Registrant's Draft Registration Statement on Form F-1 (File No. 377-02938) filed on February 18, 2020 with the SEC)
4.4*	Form of warrants to purchase ordinary shares, dated September 2, 2019, in connection with the warrants originally issued to certain investors by Nanox Imaging PLC in 2016 (incorporated by reference to Exhibit 4.2 to the Registrant's Registration Statement on Form F-1 (File No. 333-240209) filed on July 30, 2020 with the SEC)
4.5*	Form of warrants to purchase ordinary shares, dated September 2, 2019, in connection with the warrants originally issued to certain finders by Nanox Imaging PLC in 2015 (incorporated by reference to Exhibit 4.3 to the Registrant's Registration Statement on Form F-1 (File No. 333-240209) filed on July 30, 2020 with the SEC)
4.6*	Form of warrants to purchase ordinary shares, dated September 2, 2019, in connection with the warrants originally issued to certain finders and employee by Nanox Imaging PLC in 2014 and 2015 (incorporated by reference to Exhibit 4.4 to the Registrant's Registration Statement on Form F-1 (File No. 333-240209) filed on July 30, 2020 with the SEC)
4.7*	Form of warrants to purchase ordinary shares issued to A-Labs Finance and Advisory Ltd. (incorporated by reference to Exhibit 4.5 to the Registrant's Registration Statement on Form F-1 (File No. 333-240209) filed on July 30, 2020 with the SEC)
4.8*	Warrant to purchase ordinary shares, dated September 2, 2019, issued to SK Telecom TMT Investment Corp. (incorporated by reference to Exhibit 4.6 to the Registrant's Registration Statement on Form F-1 (File No. 333-240209) filed on July 30, 2020 with the SEC)
4.9*	Amendment to Warrant to purchase ordinary shares, dated June 4, 2020, issued to SK Telecom TMT Investment Corp. (incorporated by reference to Exhibit 4.7 to the Registrant's Registration Statement on Form F-1 (File No. 333-240209) filed on July 30, 2020 with the SEC)

4.10*	Contract Manufacturing Agreement, dated May 26, 2020, by and between the Registrant and FoxSemicon Integrated Technology, Inc. (incorporated by reference to Exhibit 10.1 to the Registrant's Registration Statement on Form F-1 (File No. 333-240209) filed on July 30, 2020 with the SEC)
4.11*	Registration Rights Agreement by and among the Registrant and the certain shareholders named therein (incorporated by reference to Exhibit 10.2 to the Registrant's Registration Statement on Form F-1/A (File No. 333-240209) filed on August 14, 2020 with the SEC)
4.12*	2019 Equity Incentive Plan (incorporated by reference to Exhibit 10.3 to the Registrant's Registration Statement on Form F-1 (File No. 333-240209) filed on July 30, 2020 with the SEC)
4.13*	U.S. Sub-Plan (incorporated by reference to Exhibit 10.4 to the Registrant's Registration Statement on Form F-1 (File No. 333-240209) filed on July 30, 2020 with the SEC)
4.14*	Form of Indemnification Agreement between the Registrant and each director and executive officer (incorporated by reference to Exhibit 10.5 to the Registrant's Registration Statement on Form F-1/A (File No. 333-240209) filed on August 14, 2020 with the SEC)
8.1*	List of subsidiaries of the Registrant
12.1†	Certification by Principal Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
12.2†	Certification by Principal Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
13.1±	Certification by Principal Executive Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
13.2±	Certification by Principal Financial Officer Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
15.1†	Consent of PricewaterhouseCoopers International Limited, an independent registered public accounting firm
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document

* Previously filed.

† Filed herewith.

± Furnished herewith.

In reviewing the agreements included as exhibits to this annual report on Form 20-F, please remember they are included to provide you with information regarding their terms and are not intended to provide any other factual or disclosure information about us or the other parties to the agreements.

The agreements may contain representations and warranties by each of the parties to the applicable agreement. These representations and warranties have been made solely for the benefit of the other parties to the applicable agreement and:

- should not in all instances be treated as categorical statements of fact, but rather as a way of allocating the risk to one of the parties if those statements prove to be inaccurate;
- have been qualified by disclosures that were made to the other party in connection with the negotiation of the applicable agreement, which disclosures are not necessarily reflected in the agreement;
- may apply standards of materiality in a way that is different from what may be viewed as material to you or other investors; and
- were made only as of the date of the applicable agreement or such other date or dates as may be specified in the agreement and are subject to more recent developments.

Accordingly, these representations and warranties may not describe the actual state of affairs as of the date they were made or at any other time.

SIGNATURES

NANO-X IMAGING LTD hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on Form 20-F on its behalf.

NANO-X IMAGING LTD

By: /s/ Ran Poliakine

Name: Ran Poliakine

Title: Chief Executive Officer

Date: April 6, 2021

NANO-X IMAGING LTD.
CONSOLIDATED FINANCIAL STATEMENTS

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and Shareholders of Nano-X Imaging Ltd.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Nano-X Imaging Ltd. and its subsidiaries (the "Company") as of December 31, 2020 and 2019, and the related consolidated statements of operations, of changes in shareholders' equity (capital deficiency) and of cash flows for each of the three years in the period ended December 31, 2020, including the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the three years in the period ended December 31, 2020 in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these consolidated financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Kesselman & Kesselman
Certified Public Accountants (Isr.)
A member firm of PricewaterhouseCoopers International Limited

Tel Aviv, Israel
April 6, 2021

We have served as the Company's auditor since 2019

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Telephone: +972 -3- 7954555, Fax: +972 -3- 7954556, www.pwc.com/il*

NANO-X IMAGING LTD.

CONSOLIDATED BALANCE SHEETS

	December 31,	
	2020	2019
	U.S. Dollars in thousands	
Assets		
CURRENT ASSETS:		
Cash and cash equivalents	213,468	8,072
Prepaid expenses and other current assets	6,325	1,564
TOTAL CURRENT ASSETS	219,793	9,636
NON-CURRENT ASSETS:		
Restricted cash	316	145
Property and equipment, net	14,020	228
Deferred offering costs	-	1,197
Operating lease right-of-use asset	1,359	526
Other non-current assets	661	139
TOTAL NON-CURRENT ASSETS	16,356	2,235
TOTAL ASSETS	236,149	11,871
Liabilities and Shareholders' Equity (Capital Deficiency)		
CURRENT LIABILITIES:		
Accounts payable	435	475
Accrued expenses and other liabilities	3,526	1,828
Related party liability	-	17,748
Related party accrued liability	-	72
Current maturities of operating leases	519	140
TOTAL CURRENT LIABILITIES	4,480	20,263
NON-CURRENT LIABILITIES:		
Non-current operating leases	923	386
TOTAL NON-CURRENT LIABILITIES	923	386
TOTAL LIABILITIES	5,403	20,649
COMMITMENTS AND CONTINGENCIES		
SHAREHOLDERS' EQUITY (CAPITAL DEFICIENCY):		
Ordinary Shares, par value NIS 0.01 per share, 100,000,000 and 40,000,000 shares authorized at December 31, 2020 and 2019, respectively; 46,100,173 and 27,150,080 issued and outstanding at December 31, 2020 and 2019, respectively.	131	75
Additional paid-in capital	315,031	31,748
Accumulated deficit	(84,416)	(40,601)
TOTAL SHAREHOLDERS' EQUITY (CAPITAL DEFICIENCY)	230,746	(8,778)
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY (CAPITAL DEFICIENCY)	236,149	11,871

The accompanying notes are an integral part of these consolidated financial statements

NANO-X IMAGING LTD.

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year ended December 31,		
	2020	2019	2018
	U.S. Dollars in thousands		
OPERATING EXPENSES:			
Research and development	9,210	2,717	672
Marketing	12,445	1,556	209
General and administrative	22,268	18,298	1,023
TOTAL OPERATING EXPENSES	43,923	22,571	1,904
OPERATING LOSS	(43,923)	(22,571)	(1,904)
FINANCIAL (INCOME) EXPENSES, net	(108)	(8)	5
NET LOSS	(43,815)	(22,563)	(1,909)
BASIC AND DILUTED LOSS PER SHARE	(1.23)	(0.90)	(0.09)
THE WEIGHTED AVERAGE OF THE NUMBER OF ORDINARY SHARES (in thousands)	35,654	25,181	20,793

The accompanying notes are an integral part of these consolidated financial statements

NANO-X IMAGING LTD.

CONSOLIDATED STATEMENT OF CHANGES IN SHAREHOLDERS' EQUITY (CAPITAL DEFICIENCY)

	Ordinary shares		Additional paid-in capital	Accumulated deficit	Total
	Number of shares	Amount			
U.S. Dollars in thousands					
BALANCE AT JANUARY 1, 2018	20,257,434	41	7,814	(16,129)	(8,274)
CHANGES DURING 2018:					
Issuance of ordinary shares	1,666,774	17	3,667		3,684
Share-based compensation			115		115
Net loss for the year				(1,909)	(1,909)
BALANCE AT DECEMBER 31, 2018	21,924,208	58	11,596	(18,038)	(6,384)
CHANGES DURING 2019:					
Issuance of ordinary shares and warrants, net of issuance costs	4,762,656	16	14,022		14,038
Issuance of ordinary shares to employees and non-employees upon exercise of warrants	454,166	1	136		137
Issuance of ordinary shares to investors upon exercise of warrants	9,050	*	25		25
Share-based compensation			16,245		16,245
Additional consideration with respect to an assets purchase agreement, see note 1c and note 6			(10,276)		(10,276)
Net loss for the year				(22,563)	(22,563)
BALANCE AT DECEMBER 31, 2019	27,150,080	75	31,748	(40,601)	(8,778)
CHANGES DURING 2020:					
Issuance of ordinary shares and warrants, net of issuance costs	4,624,500	14	70,999		71,013
Initial public offering of ordinary shares, net of offering costs	10,555,556	31	169,136		169,167
Issuance of ordinary shares to employees and non-employees upon exercise of warrants	997,863	3	497		500
Issuance of ordinary shares to investors upon exercise of warrants	1,662,929	5	125		130
Share-based compensation			24,781		24,781
Conversion of related party liability to shareholders' equity, see note 8a	1,109,245	3	17,745		17,748
Net loss for the year				(43,815)	(43,815)
BALANCE AT DECEMBER 31, 2020	<u>46,100,173</u>	<u>131</u>	<u>315,031</u>	<u>(84,416)</u>	<u>230,746</u>

(*) Less than 1 thousand US dollars.

The accompanying notes are an integral part of these consolidated financial statements

NANO-X IMAGING LTD.

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,		
	2020	2019	2018
	U.S. Dollars in thousands		
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss for the year	(43,815)	(22,563)	(1,909)
Adjustments required to reconcile net loss to net cash used in operating activities:			
Share-based compensation	24,781	16,245	115
Depreciation	208	53	35
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(4,478)	(1,564)	66
Related party prepaid expenses	-	1,081	(1,844)
Other non-current assets	(522)	(139)	-
Accounts payable	(103)	393	(134)
Operating lease	83	*	-
Accrued expenses and other liabilities	2,359	970	-
Net cash used in operating activities	<u>(21,487)</u>	<u>(5,524)</u>	<u>(3,671)</u>
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of property and equipment	(13,937)	(125)	(73)
Net cash used in investing activities	<u>(13,937)</u>	<u>(125)</u>	<u>(73)</u>
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from issuance of ordinary shares and warrants, net of issuance costs	71,013	14,038	3,684
Proceeds from initial public offering of ordinary shares, net of issuance costs	169,348	-	-
Proceeds from issuance of ordinary shares upon exercise of warrants	630	162	-
Deferred offering costs	-	(339)	-
Net cash provided by financing activities	<u>240,991</u>	<u>13,861</u>	<u>3,684</u>
NET CHANGE IN CASH AND CASH EQUIVALENTS AND RESTRICTED CASH	205,567	8,212	(60)
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH AT BEGINNING OF THE YEAR	8,217	5	65
CASH AND CASH EQUIVALENTS AND RESTRICTED CASH AT END OF THE YEAR	<u>213,784</u>	<u>8,217</u>	<u>5</u>
SUPPLEMENTARY INFORMATION ON ACTIVITIES NOT INVOLVING CASH FLOWS:			
Unpaid offering costs	-	858	-
issuance of ordinary shares to investor upon exercise of warrants	200	-	-
Operating lease liabilities arising from obtaining operating right-of-use assets	1,085	548	-
Additional consideration with respect to an assets purchase purchase agreement, see note 1c	-	(10,276)	-
Conversion of related party liability to shareholders' equity	17,748	-	-

(*) Less than 1 thousand US dollars.

The accompanying notes are an integral part of these consolidated financial statements

NANO-X IMAGING LTD.

NOTES TO THE FINANCIAL STATEMENTS

NOTE 1 - GENERAL:

- a. Nano-X Imaging Ltd, an Israeli Company (hereinafter “the Company” or “Nanox IL” or “the Successor Company”), was incorporated on December 20, 2018 and commenced its operations on September 3, 2019.

On September 19, 2019, Nanox IL established Nanox Imaging Inc. (hereinafter “Nanox Inc.”), a wholly owned subsidiary in Japan.

On September 25, 2020, Nanox IL established Nano-X Korea Inc. (hereinafter “Nanox Korea”), a wholly owned subsidiary in Korea.

In August 2020, the Company completed an initial public offering (“IPO”) on the Nasdaq Global Select Market (the “Nasdaq”), in which it issued 9,178,744 ordinary shares, at a price per share of \$18. During August 2020 the underwriters exercised their over-allotment option and purchased an additional 1,376,812 ordinary shares at the same price per share. The proceeds received from the IPO were \$190 million (the net proceeds were approximately \$169 million after deducting underwriting commissions and other offering expenses).

- b. Nanox Imaging PLC is a public limited company incorporated in Gibraltar in 2012 (hereinafter “Nanox PLC” or “the predecessor company”). Nanox PLC developed certain technological capabilities aimed to design and build various applications for x-ray based imaging. Nanox PLC has been a development-stage company since its inception. Nanox PLC has a wholly owned subsidiary, Nanox Japan Inc. (hereinafter “Nanox Japan”). Nanox Japan primarily provided research and development services to Nanox PLC.

On September 3, 2019 (hereinafter “Transaction Date”), Nanox IL signed an Assets Purchase Agreement which was later amended on December 3, 2019 and December 31, 2019 (hereinafter “the APA”) with Nanox PLC.

Under the terms of the APA, Nanox IL purchased from Nanox PLC patents, patent applications and all other intellectual property rights, as well as all cash of Nanox PLC (less an amount of \$200 thousand), with an exclusion of certain assets as defined in the APA (hereinafter “Acquired Assets”).

Under the terms of the APA, Nanox IL shall pay Nanox PLC \$6.127 million as consideration for the purchase of the Acquired Assets, which reflects the fair value of the Acquired Assets (excluding cash) plus the cash balance as of the date of the APA, less \$200 thousand. The purchase price shall be due and payable upon the closing of one of the following events: (a) an M&A event of Nanox IL, (b) an IPO of Nanox IL, or (c) a qualified equity financing of Nanox IL at a minimum company pre-money valuation of \$100 million, with proceeds totaling at least \$30 million.

In the event of an IPO or a qualified equity financing, Nanox IL has the option to pay for the Acquired Assets in cash or by the issuance of Nanox IL shares of the same series to be issued upon such event, in an amount reflecting a 25% discount on the per share price to be determined in such IPO or qualified equity financing. If Nanox IL chooses to pay for the Acquired Assets in cash in any of the events described above, then Nanox PLC has the right, at its sole discretion and in good faith, to reject such payment in cash, and require Nanox IL to pay for the Acquired Assets by the issuance of securities of the same series to be issued upon such equity financing events, in such amount which shall reflect a 25% discount on the per share price to be determined in such equity financing events.

In November 2019, Nanox PLC transferred to Nanox IL an amount of \$7.2 million, which reflects the cash consideration under the APA. The total consideration of the purchase of the Acquired Assets is \$13.3 million. The outstanding balance of \$17.8 million reflects the related party liability of the expected future payment using the Company’s shares, refer to note 6.

NANO-X IMAGING LTD.

NOTES TO THE FINANCIAL STATEMENTS (continued)

NOTE 1 - GENERAL (continued):

In return to the Acquired Assets, the Company issued to Nanox PLC 1,109,245 ordinary shares during January 2020. See also note 6.

- c. As of September, 3 2019, Nanox IL and Nanox PLC had the same shareholders and, therefore, the transaction was treated as a transaction under common control for accounting purposes.

The financial statements of the Company prior to the Transaction Date are the historical financial statements of Nanox PLC, which have been adjusted to reflect the fact that:

- 1) only the net assets that were transferred in the transaction according to the APA. Net assets which were not transferred in the transaction are not reflected in these consolidated financial statements.
 - 2) no interests of Nanox Japan were transferred under the APA. The consolidated statements of operation include the costs incurred for services provided by Nanox Japan to Nanox PLC.
 - 3) the consideration in the transaction (the “Related Party Liability”) was recorded at the beginning of the earliest period presented against a decrease in shareholders’ equity.
 - 4) all of the share-related information reflects the share information of Nanox IL.
- d. The Company’s solution, referred to as the Nanox System, has two integrated components – “Nanox.ARC” and “Nanox. CLOUD”. Nanox.ARC is a medical imaging system incorporating the Company’s novel digital X-ray source. Nanox. CLOUD is a cloud-based system designed to provide end-to-end medical imaging services, including services such as image repository, radiologist matching, online and offline diagnostics review and annotation, connectivity to diagnostic assistive AI systems, billing and reporting.

In January 2020, the Company submitted a 510(k) application for the Nanox Cart X-Ray System, which is a single-source version of the Nanox.ARC (the “Nanox Cart X-Ray System”) to an accredited Review Organization under the FDA’s 510(k) third party review program. During 2020 and the first quarter of 2021, the Company received additional information requests and submitted its official responses. On April 1, 2021, the Company received clearance from the FDA to market the Company’s Nanox Cart X-Ray System. The Company plans to submit an additional 510(k) premarket notification to the FDA with respect to the multi-source Nanox.ARC and the Nanox.CLOUD during 2021.

The Company has experienced net losses and negative cash flows from operations since its inception. The Company anticipates such losses will continue until its product candidates reach commercial profitability. In August 2020, the Company completed an IPO on Nasdaq with net proceeds received from the IPO of approximately \$169 million. Based on the Company’s financing activities during the year ended December 31, 2020, the Company has sufficient funds for its plans for the next twelve months from the issuance of these financial statements.

NANO-X IMAGING LTD.

NOTES TO THE FINANCIAL STATEMENTS (continued)

NOTE 1 - GENERAL (continued):

e. Current Impact of COVID-19

Following the December 2019 outbreak of Coronavirus (COVID-19) in China, it has spread into most countries across the world, including Israel, Japan and all 50 states within the U.S. The COVID-19 pandemic is evolving, and to date has led to the implementation of various responses, including government-imposed quarantines, travel restrictions and other public health safety measures. The COVID-19 pandemic has adversely impacted the Company's operations in various ways. For example, the Company's engineers are unable to make work-related trips to Korea or Israel to test and optimize the Nanox.ARC or to begin development of x-ray chip manufacturing in Korea. The potential business partners are unable to make on-site visits to the Company's facilities or attend industry conferences and meetings to experience the Nanox.ARC, which has negatively impacted the Company's business development and deployment activities. The external labs the Company works with have also been affected by COVID-19, resulting in delays in the Company's timelines for obtaining regulatory approval. COVID-19 has also caused shutdowns or disruptions of business for our manufactures and suppliers. The continued spread of COVID-19 globally could adversely impact the Company's development, manufacture or deployment of the Nanox Systems, which could adversely affect the Company's ability to obtain regulatory approval for and to commercialize the Nanox Systems, increase the operating expenses and have a material adverse effect on the Company's financial results. (For the process with the FDA, see note 1d above).

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES:

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States (hereinafter -"U.S GAAP"). The preparation of our consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are 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. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

a. Use of estimates in the preparation of financial statements

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. Actual results may differ from those estimates and such differences may have a material impact on the Company's consolidated financial statements. As applicable to these consolidated financial statements, the most significant estimates relate to fair value of share-based payments.

NANO-X IMAGING LTD.

NOTES TO THE FINANCIAL STATEMENTS (continued)

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

b. Functional currency

The U.S. dollar is the currency of the primary economic environment in which the operations of the Company and its subsidiary is conducted. A substantial portion of the operational costs are denominated in U.S. dollars. Accordingly, the functional currency of the Company is the U.S. dollar (“primary currency”).

Foreign currency assets and liabilities are translated into the primary currency using the exchange rates in effect on the consolidated balance sheet date. Equity accounts are translated at historical rates, except for the change in accumulated deficit during the year, which is the result of the income statement translation process. Expense accounts are translated using the weighted average exchange rate during the period. Currency transaction gains and losses are presented in financial income and expenses, net.

c. Cash and cash equivalents

The Company considers as cash equivalents all short-term, highly liquid investments, which include short-term bank deposits with original maturities of three months or less from the date of purchase that are not restricted as to withdrawal or use and are readily convertible to known amounts of cash.

d. Restricted Cash

As of December 31, 2020, the Company’s restricted cash consisted of a bank deposit that was denominated in New Israeli Shekel. Restricted deposit is presented at cost including accrued interest. This bank deposits is used as security for credit card use and collateralizing the Company’s lease contracts.

e. Property and equipment, net

Property and equipment are stated at cost, net of accumulated depreciation. Depreciation is calculated on a straight-line basis over the following estimated useful lives:

	%
Computers and electronic equipment	10-33
Office furniture and lab equipment	6-20
Machines	10-20
Leasehold Improvement	10
Land	N/A

The depreciable life of leasehold improvements is limited by the expected lease term, unless there is a transfer of title or a purchase option for the leased asset reasonably certain of exercise.

NANO-X IMAGING LTD.

NOTES TO THE FINANCIAL STATEMENTS (continued)

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

f. Impairment of long-lived assets

The Company tests long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may no longer be recoverable. Recoverability of long-lived assets is measured by comparing the carrying amount of the long-lived asset to the estimated undiscounted future cash flows expected to be generated by the asset. If the sum of the expected undiscounted cash flow is less than the carrying amount of the asset, the Company recognizes an impairment loss, which is the excess of the carrying amount over the fair value of the asset, using the expected future discounted cash flows.

As of December 31, 2020, 2019 and 2018, the Company did not recognize an impairment loss on its long-lived assets.

g. Severance pay

Israeli labor law generally requires severance pay be granted upon dismissal of an employee or upon termination of employment under certain other circumstances. Pursuant to Section 14 of the Severance Compensation Act, 1963 ("Section 14"), all of the Company's employees in Israel are entitled to monthly deposits, at a rate of 8.33% of their monthly salary, made in their name with insurance companies. Payments under Section 14 relieve the Company from any future severance payment obligation with respect to those employees and, as such, the Company may only utilize the insurance policies for the purpose of disbursement of severance pay. As a result, the Company does not recognize an asset nor liability for these employees.

In 2020, all of the Company's employees in Israel are subject to Section 14.

h. Legal and other contingencies

Certain conditions, such as legal proceedings, may exist as of the date the consolidated financial statements are issued that may result in a loss to the Company, but that will only be resolved when one or more future events occur or fail to occur. In assessing loss contingencies related to legal proceedings that are pending against the Company or unasserted claims that may result in such proceedings, the Company's management evaluates with its legal advisors the perceived merits of any legal proceedings or unasserted claims as well as the perceived merits of the amount of relief sought or expected to be sought. Such assessment inherently involves an exercise of judgment. Legal fees are expensed as incurred.

Management applies the guidance in ASC 450-20-25 when assessing losses resulting from contingencies. If the assessment of a contingency indicates that it is probable that a material loss would be incurred and the amount of the liability can be estimated, then the Company records an accrued expense in the Company's consolidated financial statements based on its best estimate. Loss contingencies considered to be remote by management are generally not disclosed unless material. In September 2020, securities class action complaints were filed in the United States by certain of the Company's shareholders against the Company and certain of the Company's current officers and directors. For additional information see note 7.

NANO-X IMAGING LTD.

NOTES TO THE FINANCIAL STATEMENTS (continued)

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

i. Research and development expenses

Research and development expenses are charged to the statement of operations as incurred and consist primarily of personnel, materials and supplies for research and development activities.

j. Income tax

- 1) The Company accounts for income taxes in accordance with ASC 740, "Income Taxes" ("ASC 740"). ASC 740 prescribes the use of the liability method whereby deferred tax asset and liability account balances are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company provides a valuation allowance, if necessary, to reduce deferred tax assets to their estimated realizable value if it is more likely than not that a portion or all of the deferred tax assets will not be realized, based on the weight of available positive and negative evidence. Deferred tax liabilities and assets are classified as non-current in accordance with ASU 2015-17.
- 2) Taxes that would apply in the event of disposal of investments in foreign subsidiaries have not been taken into account in computing the deferred income taxes, as it is the Company's intent and ability to hold these investments.

The Company accounts for uncertain tax positions in accordance with ASC 740-10. ASC 740-10 contains a two-step approach to recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position taken or expected to be taken in a tax return by determining if the weight of available evidence indicates that it is more likely than not that, on an evaluation of the technical merits, the tax position will be sustained on audit, including resolution of any related appeals or litigation processes. The second step is to measure the tax benefit as the largest amount that is more than 50% (cumulative probability) likely to be realized upon ultimate settlement. The Company accrues interest and penalties related to unrecognized tax benefits under taxes on income (tax benefit).

k. Share-based compensation

The Company accounts for share-based compensation under ASC 718, "Compensation - Stock Compensation," which requires the measurement and recognition of compensation expense based on estimated fair values for all share-based payment awards made to non-employees, employees, officers and directors.

ASC 718 requires companies to estimate the fair value of equity-based payment awards on the date of grant. The Company uses the Black-Scholes-Merton option-pricing model as part of such estimation.

Prior to the adoption of ASU 2018-07, warrants issued to consultants and other non-employees, as compensation for services provided to the Company, were accounted for based upon the fair value of the warrants. The fair value of the warrants granted was measured on a final basis at the end of the related service period and was recognized over the related service period using the straight-line method. After the adoption of ASU 2018-07, the measurement date for non-employee awards is the date of the grant. The compensation expense for non-employees is recognized without changes in the fair value of the award, over the requisite service period, which is the vesting period of the respective award using the straight line. The Company adopted ASU 2018-07 as of January 1, 2019 with no impact on its consolidated financial statements as all of the Company's awards were fully vested at the adoption date.

NANO-X IMAGING LTD.

NOTES TO THE FINANCIAL STATEMENTS (continued)

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

l. Loss per share

Basic earnings per share is computed by dividing net income (loss) attributable to holders of ordinary shares of the Company by the weighted average number of ordinary shares outstanding for each reporting period.

In computing the Company's diluted earnings per share, the denominator for diluted earnings per share is a computation of the weighted-average number of ordinary shares and the potential dilutive ordinary shares outstanding during the period. Potential dilutive ordinary shares outstanding include the dilutive effect of in-the-money options using the treasury stock method.

The Company did not take into account any dilutive instruments, such as investor warrants and share-based payments, since their effect, on a fully diluted basis, is anti-dilutive.

m. Fair value measurement

Fair value is based on the price that would be received from the sale of an asset or that would be paid to transfer a liability in an orderly transaction between market participants at the measurement date. In order to increase consistency and comparability in fair value measurements, the guidance establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described as follows:

Level 1: Quoted prices (unadjusted) in active markets that are accessible at the measurement date for assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2: Observable prices that are based on inputs not quoted on active markets, but corroborated by market data.

Level 3: Unobservable inputs are used when little or no market data is available. The fair value hierarchy gives the lowest priority to Level 3 inputs.

In determining fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the use of unobservable inputs to the extent possible and considers counterparty credit risk in its assessment of fair value.

The Company's financial instruments consist mainly of cash and cash equivalents, restricted cash accounts payable, accrued expenses and other liabilities. The fair value of these financial instruments approximates their carrying values.

n. Concentration of Credit Risks

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents and restricted cash.

The Company's cash and cash equivalents and restricted cash are invested with major banks in Israel, Korea and Japan. Generally, these investments may be redeemed upon demand and the Company believes that the financial institutions that hold the Company's cash balances are financially sound and, accordingly, bear minimal risk.

NANO-X IMAGING LTD.

NOTES TO THE FINANCIAL STATEMENTS (continued)

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

o. Offering Costs

Deferred offering costs directly relating to the Company's private and initial public offering, were capitalized and offset against proceeds upon the consummation of the private and IPO transactions in shareholders' equity.

p. Leases

On January 1, 2019 the Company adopted ASU No. 2016-02, Leases (Topic 842), The Company determines if an arrangement is a lease at inception. Balances related to operating leases are included in operating lease right-of-use ("ROU") assets, current maturities of operating leases and Non-current operating leases in the consolidated balance sheets.

The Company also elected not separating lease components from non-lease components and to keep leases with an initial term of 12 months or less off the balance sheet and recognize the associated lease payments in the consolidated statements of operations on a straight-line basis over the lease term.

ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized as of the commencement date based on the present value of lease payments over the lease term. The Company's lease terms may include options to extend or terminate the lease when it is reasonably certain that the Company will exercise that option. The discount rate for the lease is the rate implicit in the lease unless that rate cannot be readily determined. As the Company's leases do not provide an implicit rate, the Company's uses its estimated incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments. Lease expense for lease payments is recognized on a straight-line basis over the lease term (see also note 5).

q. Newly issued and recently adopted accounting pronouncements:

Accounting Pronouncements Adopted in Current year

In June 2016, the FASB issued ASU 2016-13, Financial Instruments-Credit Losses (Topic 326) - Measurement of Credit Losses on Financial Instruments ("the Standard"). This guidance replaces the current incurred loss impairment methodology. Under the new guidance, on initial recognition and at each reporting period, an entity is required to recognize an allowance that reflects its current estimate of credit losses expected to be incurred over the life of the financial instrument based on historical experience, current conditions and reasonable and supportable forecasts. In November 2018, the FASB issued ASU 2018-19, Codification Improvements to Topic 326, Financial Instruments - Credit Losses. ASU 2018-19 clarifies that receivables from operating leases are accounted for using the lease guidance and not as financial instruments. Since the Company has no financial instruments the Standard does not impact the Company's consolidated financial statements.

NANO-X IMAGING LTD.

NOTES TO THE FINANCIAL STATEMENTS (continued)

NOTE 3 - PROPERTY AND EQUIPMENT, NET:

Composition of property and equipment grouped by major classifications is as follows:

	December 31,	
	2020	2019
	(U.S. Dollars in thousands)	
Office furniture and lab equipment	820	325
Computers and electronic equipment	151	39
Machinery	1,762	-
Leasehold improvement	16	-
Land – See b below	6,297	-
Prepayments on account of production line in construction - See b below	5,318	-
	14,364	364
Less: accumulated depreciation	(344)	(136)
Total property and equipment, net	14,020	228

- a. Total depreciation in respect of property and equipment were approximately \$208 thousand, \$53 thousand and \$35 thousand for the years ended December 31, 2020, 2019 and 2018, respectively.
- b. In December 2020, Nanox Korea purchased a land for approximately \$6.2 million upon which it intends to build a manufacturing facility. Nanox Korea also rented a temporary fabrication plant and is in the process of preparing for the commencement of full manufacturing activities, including purchasing certain equipment and transferring certain technology.

NOTE 4 - CASH, CASH EQUIVALENTS AND RESTRICTED CASH:

The following table provides a reconciliation of cash, cash equivalents and restricted cash reported on the consolidated balance sheet that sum to the same total amount as shown in the consolidated statement of cash flows.

	December 31,	
	2020	2019
	(U.S. Dollars in thousands)	
Cash and cash equivalents	213,468	8,072
Restricted bank deposit	316	145
Total cash, cash equivalents and restricted cash shown in the statement of cash flows	213,784	8,217

NANO-X IMAGING LTD.

NOTES TO THE FINANCIAL STATEMENTS (continued)

NOTE 5 - LEASES:

As of December 31, 2020, the Company has four operating lease agreements for its car and facilities, as follows:

During the fourth quarter of 2019, the Company entered into an office lease agreement. This agreement is through December 31, 2021 with an option by the Company to extend the period for an additional 24 months. The monthly rent payment is approximately \$13 thousand.

During June 2020, the Company entered into an additional office lease agreement, expanded the space leased in 2019, through June 30, 2023. The monthly rent payment for this agreement is approximately \$15 thousand.

During November 2020, following the increase of the Company's employees, the Company signed an additional lease agreement, for a leasing of another office complex through June 30, 2023. The monthly rent payment for this agreement is approximately \$12 thousand.

During November 2020, the Company engaged with car lease company, for leasing of 6 vehicles. This agreement is effective through June 30, 2023 and the monthly payment for this agreement is approximately \$6.5 thousand.

The table below presents the effects on the amounts relating to the Company's total lease costs:

	Year ended December 31, 2020	Year ended December 31, 2019
	(U.S. Dollars in thousands)	(U.S. Dollars in thousands)
Operating lease cost:		
Fixed payments	276	25
Short-term lease cost	65	112
Total operating lease cost	341	137

The table below presents supplemental cash flow information related to operating leases:

	Year ended December 31, 2020	Year ended December 31, 2019
	(U.S. Dollars in thousands)	(U.S. Dollars in thousands)
Cash paid for amounts included in the measurement of lease liabilities:		
Operating cash flows from operating leases	169	25
Right-of-use assets obtained in exchange for lease obligations (non-cash):		
Operating leases	1,085	548

NANO-X IMAGING LTD.

NOTES TO THE FINANCIAL STATEMENTS (continued)

NOTE 5 - LEASES (continued):

The table below presents supplemental balance sheet information related to operating leases:

	December 31, 2020	December 31, 2019
	(U.S. Dollars in thousands)	(U.S. Dollars in thousands)
Operating leases:		
Operating lease right-of-use assets	1,359	526
Current maturities of operating leases	519	140
Non-current operating leases	923	386
Total operating lease liabilities	<u>1,442</u>	<u>526</u>
	December 31, 2020	December 31, 2019
Weighted average remaining lease term		
Operating leases	2.67	3.96
Weighted average discount rate		
Operating leases	5.83%	5.6%

The table below presents maturities of operating lease liabilities:

	December 31, 2020
	(U.S. Dollars in thousands)
2020	-
2021	588
2022	588
2023	382
2024 and thereafter	-
Total operating lease payments	<u>1,558</u>
Less: imputed interest	<u>116</u>
Present value of lease liabilities	<u>1,442</u>

NOTE 6 - RELATED PARTY LIABILITY

According to ASC 480, "Distinguishing Liabilities From Equity," a financial instrument that embodies an unconditional obligation, or a financial instrument other than an outstanding share that embodies a conditional obligation, that the issuer must or may settle by issuing a variable number of its equity shares shall be classified as a liability if, at inception, the monetary value of the obligation is based solely or predominantly on a fixed monetary amount known at inception. These liabilities are measured subsequently at fair value with changes in fair value recognized in earnings.

The Company analyzed the instrument's provisions and concluded that it meets the above ASC 480 criteria and therefore accounted the expected future payment under the APA in accordance with ASC 480.

As of December 31, 2019, the Company recorded a Related Party Liability in an amount of \$17.8 million, which represents the fair value of the shares that have been issued to Nanox PLC, based on the last financing round of the Company.

During January 2020, subject to entering into a share purchase agreement in the aggregate amount of at least \$6 million, and a pre-money valuation of more than \$100 million, the Nanox IL's Board approved the issuance and allotment of 1,109,245 ordinary shares to Nanox PLC with the purchase price of \$12.00 per share, which reflects a discount of 25% from the price of the last financing round of the Company. As a result, on January 30, 2020 the related party liability was settled into equity.

NANO-X IMAGING LTD.

NOTES TO THE FINANCIAL STATEMENTS (continued)

NOTE 7 - COMMITMENTS AND CONTINGENCIES:

- a. In September 2020, securities class action complaints were filed in the United States by certain of the Company's shareholders against the Company and certain of the Company's current officers and directors alleging violations of securities laws and seeking unspecified damages. On December 7, 2020, the proposed lead plaintiffs' submissions were fully briefed. The Company believes these lawsuits are without merit and intends to defend the cases vigorously. As of the date of issuance of these financial statements, the Company is unable to estimate a range of loss, if any, that could result were there to be an adverse final decision in these cases.
- b. For services with SixAI Ltd. ("SixAI"), see Note 10d.

NOTE 8 - SHAREHOLDERS' EQUITY:

a. Share capital

Each holder of the Company's ordinary shares is entitled to one vote. The holders of ordinary shares are also entitled to receive dividends whenever funds are legally available, and declared by the Company's Board of Directors (the "Board"). Since inception, the Company has not declared any dividends.

Issuance of Equity

Ordinary Share issuances prior to the APA

During the year ended December 31, 2018, Nanox PLC entered into several agreements with third party investors, pursuant to which it raised an aggregate amount of \$3,684 thousand at a purchase price of \$2.21 per share.

On June 17, 2019, Nanox PLC issued 2,262,443 ordinary shares to third party investors for an aggregate purchase price of approximately \$5,000 thousand. Certain investors were also granted warrants to acquire 2,262,443 of ordinary shares at an exercise price of \$20.87 per share.

Additionally, during 2019, Nanox PLC entered into several agreements with certain third-party investors, pursuant to which it raised an aggregate amount of \$4,038 thousand, net of issuance costs, at a purchase price of \$2.21 per share.

Ordinary Share issuances after the APA

On December 31, 2019, the Company issued 312,500 ordinary shares to a third-party investor for an aggregate purchase price of approximately \$5 million.

During the year 2020, the Company issued an aggregate of 4,624,500 ordinary shares to the certain investors, at a price per share of \$16.00, for an aggregate purchase price of approximately \$74 million (the net proceeds were approximately \$71 million after deducting issuance costs).

In August 2020, the Company completed an initial public offering ("IPO") on the Nasdaq Global Market (the "Nasdaq"), in which it issued 9,178,744 ordinary shares at a price per share of \$18. During August 2020, the underwriters exercised their over-allotment option and purchased an additional 1,376,812 ordinary shares at the same price per share. The proceeds received from the IPO were \$190 million (the net proceeds were approximately \$169 million after deducting underwriting commissions and other offering expenses).

NANO-X IMAGING LTD.

NOTES TO THE FINANCIAL STATEMENTS (continued)

NOTE 8 - SHAREHOLDERS' EQUITY (continued):

Settlement of Related Party Liability

Pursuant to the Asset Purchase Agreement between Nanox IL and Nanox PLC, as more fully described in the Company's annual financial statements, in January 2020, the Company issued 1,109,245 ordinary shares to Nanox PLC with a purchase price of \$12.00 per share, which reflected a discount of 25% from the price of the last financing round of the Company. As a result, the related party liability was settled into shareholders' equity.

b. Share based compensation

On September 3, 2019, the Company's Board resolved to adopt an equity incentive plan (the "Plan"). Based on such Plan, each option will be exercisable for one ordinary share of the Company and will become exercisable at such terms and during such periods, as the Board shall determine. Pursuant to the Plan (and further increase of option pool approved by the Board), 8,041,936 ordinary shares of NIS 0.01 par value of the Company are reserved for issuance upon the exercise of the same amount of awards to be granted to some of the Company's employees, directors and consultants. As of December 31, 2020, 2,978,247 ordinary shares reserved for the equity incentive plan.

The Board also approved the Plan for the purpose of selecting the capital gains tax track, under Section 102 of the Israeli Income Tax Ordinance, for options granted to the Company's Israeli employees.

1) Share-based compensation to non-employees

The following table summarizes share-based awards to non-employees for the years ended December 31, 2020 and December 31, 2019:

	Year ended December 31, 2020		Year ended December 31, 2019	
	Number of share-based payment awards	Weighted average exercise price	Number of share-based payment awards	Weighted average exercise price
Outstanding at beginning of year	3,410,406	\$ 1.89	1,592,874	\$ 1.32
Changes during the year:				
Granted	1,327,957	13.70	2,271,698	\$ 2.77
Exercised	*(1,267,012)	8.94	(454,166)	\$ 0.3
Forfeited	-	-	-	-
Expired	-	-	-	-
Cancelled	(98,725)	1.92	-	-
Outstanding at end of year	3,372,626	5.27	3,410,406	\$ 1.89
Exercisable at end of year	2,191,042	5.67	1,830,809	\$ 3.79

* Out of which 1,027,151 awards were exercised on a cashless basis.

The fair value of each granted award is estimated at the date of grant using the Black- Scholes option-pricing model. The assumptions used for the years ended December 31, 2020 and 2019 are as follows:

	2020	2019
Dividend yield	0	0
Expected volatility	57.34%-44.40%	41.11% - 50.59%
Risk-free interest rate	0.27%-1.61%	1.55%-1.76%
Contractual term (years)	5-10	0.50 - 10.00

NANO-X IMAGING LTD.

NOTES TO THE FINANCIAL STATEMENTS (continued)

NOTE 8 - SHAREHOLDERS' EQUITY (continued):

The expected volatility is based on the historical volatility of comparable companies.

The risk-free interest rate assumption is based on observed interest rates appropriate for the expected term of the awards granted in dollar terms.

The Company does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate expected term. Accordingly, as to ordinary course options granted, the expected term was determined using the simplified method, which takes into consideration the option's contractual life and the vesting periods (for non-employees, the expected term is equal to the option's contractual life).

The following table summarizes information concerning outstanding and exercisable awards as of December 31, 2020 and 2019:

December 31, 2020					
Exercise price	Awards outstanding			Awards exercisable	
	Number of awards outstanding at end of year	Weighted average remaining contractual life (years)	Number of award exercisable at end of year	Weighted average remaining contractual life (years)	
\$ 0.01	186,815	0.33	186,815	0.33	
\$ 1.92	269,714	1.18	269,714	1.18	
\$ 2.21	2,191,349	6.22	1,188,914	6.22	
\$ 16.00	444,748	8.89	283,933	8.89	
\$ 18.00	260,000	3.86	260,000	3.86	
\$ 30.93	20,000	9.81	1,666	9.81	
December 31, 2019					
Exercise price	Awards outstanding			Awards exercisable	
	Number of awards outstanding at end of year	Weighted average remaining contractual life (years)	Number of awards exercisable at end of year	Weighted average remaining contractual Life (years)	
\$ 0.01	186,815	1.33	186,815	1.33	
\$ 1.92	472,606	1.81	472,606	1.81	
\$ 2.21	2,727,028	5.27	1,163,402	5.27	
\$ 20.87	23,957	5.69	7,986	5.69	

2) Share-based compensation to employees, officers and directors

During 2020, the Company granted to certain employees, officers and directors awards to purchase 730,734 of the Company's ordinary shares for an average exercise price of \$13.53.

NANO-X IMAGING LTD.

NOTES TO THE FINANCIAL STATEMENTS (continued)

NOTE 8 - SHAREHOLDERS' EQUITY (continued):

	Year ended December 31, 2020		Year ended December 31, 2019	
	Number of share-based payment awards	Weighted average exercise price	Number of share-based payment awards	Weighted average exercise price
Outstanding at beginning of year	1,667,267	\$ 2.21	1,667,267	\$ 2.21
Changes during the year:				
Granted	730,734	\$ 13.53	-	-
Exercised	-	-	-	-
Forfeited	-	-	-	-
Expired	-	-	-	-
Cancelled	(16,876)	\$ 2.21	-	-
Outstanding at end of year	2,381,125	\$ 4.14	1,667,267	2.21
Exercisable at end of year	1,061,778	\$ 2.80	450,557	2.21

The fair value of each granted award is estimated at the date of grant using the Black- Scholes option-pricing model. The assumptions used as of December 31, 2020 and 2019 are as follows:

	2020	2019
Dividend yield	0	0
Expected volatility	45.11%-55.97%	45.11%-55.97%
Risk-free interest rate	0.23%-1.61%	0.23%-1.61%
Contractual term (years)	10	10

The expected volatility is based on the historical volatility of comparable companies.

The risk-free interest rate assumption is based on observed interest rates appropriate for the expected term of the awards granted in dollar terms.

The Company does not have sufficient historical exercise data to provide a reasonable basis upon which to estimate expected term. Accordingly, as to ordinary course options granted, the expected term was determined using the simplified method, which takes into consideration the option's contractual life and the vesting periods.

The following table summarizes information concerning outstanding and exercisable awards as of December 31, 2020 and 2019:

December 31, 2020					
Awards outstanding			Awards exercisable		
Exercise price	Number of awards outstanding at end of year	Weighted average remaining contractual life (years)	Number of awards exercisable at end of year	Weighted average remaining contractual life (years)	
\$2.21	1,995,625	9.05	1,019,695	9.05	
\$16.00	205,000	9.62	37,917	9.62	
\$26.56-\$59.20	180,500	9.93	4,167	9.93	
December 31, 2019					
Awards outstanding			Awards exercisable		
Exercise price	Number of awards outstanding at end of year	Weighted average remaining contractual life (years)	Number of awards exercisable at end of year	Weighted average remaining contractual life (years)	
\$2.21	1,667,267	9.90	450,557	9.90	

NANO-X IMAGING LTD.

NOTES TO THE FINANCIAL STATEMENTS (continued)

NOTE 8 - SHAREHOLDERS' EQUITY (continued):

3) Share-based compensation expenses

	Year Ended December 31,		
	2020	2019	2018
	(U.S. dollars in thousands)		
Research and development	3,384	661	-
Marketing (*)	9,252	617	-
General and administrative	12,145	14,967	115
	<u>24,781</u>	<u>16,245</u>	<u>115</u>

(*) On October 26, 2020, the Company entered into an amendment to a business development agreement (“the Agreement”) dated February 4, 2020 with two service providers pursuant to which the Company paid an aggregate one-time payment of \$400 thousand plus VAT and issued to them warrants to purchase an aggregate of 650,000 ordinary shares at an exercise price of \$18 per share with a graded vesting ending 10 weeks following the grant date (subject to a standard cashless exercise provision). As a result, the Company recorded an expense of \$6.1 million for the warrants granted. The service providers waived any and all past, present and future compensation to which they are or may be entitled pursuant to the Agreement and all activities undertaken on behalf of the Company, including the right to a percentage from future revenues from any of the Company’s systems and the issuance of warrants.

NOTE 9 - INCOME TAX:

a. Basis of taxation

Current tax is calculated with reference to the profit of the Company and its subsidiary in their respective countries of operation. Set out below are details in respect of the significant jurisdictions where the Company and its subsidiary operates and the factors that influenced the current and deferred taxation in those jurisdictions:

Israel

The Company is taxed under the laws of the State of Israel at a corporate tax rate of 23%. In 2020, the Company was at a loss position and therefore had no corporate tax liability.

Korea

Nanox Korea is subject to a Corporate income tax with accordance with the Korean tax law. The tax rate ranges between 10% to 25%, depending on the companies’ taxable income. In Addition, Nanox Korea is subject to a Local income tax of 10%. In 2020, Nanox Korea was at a loss position and therefore had no corporate tax liability.

NANO-X IMAGING LTD.

NOTES TO THE FINANCIAL STATEMENTS (continued)

NOTE 9 - INCOME TAX (continued):

Japan

Nanox Inc. is subject to national corporate income tax, and enterprise tax, which, in the aggregate resulted in effective tax rate of approximately 33.59% for the year ended December 31, 2020.

Under Japanese tax law and regulations, every company is required to submit an annual tax return to tax authorities. The statute of limitations to request a correction of prior year tax liabilities is five years from when the original tax return was filed. After filling of tax return, the tax authorities may conduct tax inspections on an irregular basis.

b. Tax assessments

Nanox IL, Nanox Korea and Nanox Inc. have not been assessed since inception.

c. Deferred tax assets

Nanox IL's deferred tax asset as of December 31, 2020 was related to tax losses accumulated since September 3, 2019 and carryforward.

A full valuation allowance was created against deferred tax assets arisen from the carryforward tax losses, since the realization of any future benefit from the carryforward tax losses cannot be sufficiently assured as of December 31, 2020.

The reconciling item between the statutory tax rate of the Company and the effective tax rate is the change in valuation allowance in respect of tax benefits from carried forward tax losses due to uncertainty of the realization of such tax benefits.

Change in valuation allowance for the year ended December 31, 2020 was \$3,262 thousand.

NOTE 10 - RELATED PARTIES - TRANSACTIONS AND BALANCES:

a. Balances with related parties:

	December 31,	
	2020	2019
	(U.S. Dollars in thousands)	
Related party accrued liability	-	72
Related party liability, refer to note 6	-	17,748

b. Related parties transactions:

	Year ended December 31,		
	2020	2019	2018
	(U.S. Dollars in thousands)		
Research and development – see c and d below	355	154	542
General and administrative – See c, e and f below	(167)	5,824	892

NANO-X IMAGING LTD.

NOTES TO THE FINANCIAL STATEMENTS (continued)

NOTE 10 - RELATED PARTIES - TRANSACTIONS AND BALANCES (continued):

c. Six-Eye Interactive agreements for services

On June 1 2015, Nanox PLC entered into a consulting agreement with Six-Eye, a company owned by Ran Poliakine, the Company's CEO and one of major shareholders, pursuant to which Ran Poliakine agreed to provide services as Chief Strategy Officer and a member of the Executive Committee to Nanox PLC. On May 1, 2017, Nanox PLC entered into a services agreement with Six-Eye for the supply of ongoing services, which include research and development services, general and financial management (including accountancy), office management services and operational and supply services. According to the agreement between the parties, Nanox PLC reimburses Six-Eye for its actual direct expenses plus a 12% surplus charge. The agreements were terminated in September 2019. During the years ended December 31 2019 and 2018 the total expenses to Six-Eye were \$679 thousand and \$1,434 thousand, respectively. In addition to the services provided by Six-Eye during 2019, Six-Eye also paid directly to third-party consultants and suppliers on behalf of the Company in the amount of approximately \$1,015 thousand prior to the completion of the Company's equity financing.

d. SixAI Ltd Service agreement

On April 16, 2020, the Company entered into an agreement with SixAI Ltd. (hereinafter-"SixAI") a company controlled by Ran Poliakine, the Company's CEO for certain software development and mechanical engineering services. The service agreement is effective as of March 1, 2020 and has been extended by mutual agreement of the parties to March 31, 2021. During the year ended December 31, 2020, the Company recorded an expense of \$355 thousand. Mr. Poliakine currently serves as a member of the board of directors of SixAI and Mr. Poliakine is a significant shareholder of SixAI.

e. Illumigyn Ltd.

Illumigyn Ltd (hereinafter – "Illumigyn") is a company in which Ran Poliakine, the Company's CEO, is a significant shareholder primarily through indirect holdings. Since November 1 2019, Illumigyn sub-leased in transaction approximately 1,800 square feet of private office space, including access to shared public spaces, from the office spaces which the Company leases in Neve Ilan, Israel. Illumigyn pays approximately \$12 thousand per month. During the year ended December 31, 2020, the Company received approximately \$163 thousand in relation to the sub lease.

f. Wellsense Technologies Ltd.

Wellsense Technologies Ltd (hereinafter – "Wellsense") is a company in which Ran Poliakine, the Company's CEO, and Richard Stone, a member of the Company's board of directors, are shareholders. Since February 2020, Wellsense has sub-leased private office space, including access to shared public spaces, from the Company in Neve Ilan, Israel. Wellsense pays approximately \$7.0 thousand per month. During the year ended December 31, 2020, the Company received \$59 thousand, in relation to the sub lease.

g. Pursuant to the Asset Purchase Agreement between Nanox IL and Nanox PLC, as of December 31, 2020, the Company has settled the related party liability balance of \$192 thousand to Nanox Japan and Nanox PLC, mainly for Fixed Assets which were transferred to the Company as part of the APA.

NANO-X IMAGING LTD.

NOTES TO THE FINANCIAL STATEMENTS (continued)

NOTE 11 - LOSS PER SHARE:

a. Basic

Basic loss per share is calculated by dividing the loss attributable to the Company's owners by the weighted average number of ordinary shares in issue.

	<u>Year ended December 31,</u>		
	<u>2020</u>	<u>2019</u>	<u>2018</u>
Net loss attributable to Company's owners	\$ (43,815)	\$ (22,563)	(1,909)
The weighted average of the number of ordinary shares (in thousands)	35,654	25,181	20,793
Basic and diluted loss per share	<u>\$ (1.23)</u>	<u>\$ (0.90)</u>	<u>(0.09)</u>

For the calculation of loss per share, the Company used the net loss attributable to Company's owners divided by the weighted average number of the Company's ordinary shares for the years ended December 31, 2020, 2019 and 2018.

b. Diluted

As of December 31, 2020 and 2019 the Company had 7,846,290 and 9,203,124 investor warrants and employees and non-employees option awards, respectively. These warrants and awards were not taken into account when calculating diluted loss per share since their effect is anti-dilutive.

NOTE 12 - SUBSEQUENT EVENTS:

- a. During 2021, the Company granted a total of 338,929 awards with an average exercise price of \$48.59 per share to employees.
- b. In February 2021 the Company completed a secondary offering of 3,091,635 ordinary shares by certain non-director, non-officer selling pre-IPO shareholders. An additional 845,044 shares were locked up for an additional period as part of the agreed terms. The Company cooperated with the offering lead underwriter while each participating shareholder paid the underwriters fees and the Company covered the legal, accounting, administrative and regulatory fees which totaled approximately \$818 thousand. The Company received no proceeds from the described above public secondary offering.

Description of securities

As of December 31, 2020, NANO-X IMAGING LTD had one class of securities registered under Section 12 of the Securities Exchange Act of 1934, as amended (the “**Exchange Act**”): our ordinary shares. References herein to “we,” “us,” “our” and the “Company” refer to NANO-X IMAGING LTX and not to any of its subsidiaries. The following description may not contain all of the information that is important to you, and we therefore refer you to our amended and restated articles of association (our “**Articles**”), a copy of which is filed with the Securities and Exchange Commission (the “**SEC**”) as an exhibit to this annual report on Form 20-F.

Registration Number and Purposes of the Company

Our registration number with the Israeli Registrar of Companies is 515942076. Our purpose as set forth in our amended and restated articles of association is to engage in any lawful activity.

Share capital

Our authorized share capital consists of 100,000,000 ordinary shares, par value NIS 0.01 per share.

All of our outstanding ordinary shares are validly issued, fully paid and non-assessable. Our ordinary shares are not redeemable and do not have any preemptive rights.

Transfer of Shares

Our fully paid ordinary shares are issued in registered form and may be freely transferred under our Articles, unless the transfer is restricted or prohibited by another instrument, applicable law or the rules of a stock exchange on which the shares are listed for trade. The ownership or voting of our ordinary shares by non-residents of Israel is not restricted in any way by our Articles or the laws of the State of Israel, except for ownership by nationals of some countries that are, or have been, in a state of war with Israel.

Limitation of Liability

The liability of each shareholder for the Company's obligations is limited to the unpaid sum, if any, owing to the Company in consideration for the issuance of the shares held by such shareholder. If at any time the Company shall issue shares with no nominal value, the liability of the Shareholders shall be limited to the payment of the amount which the Shareholders should have paid the Company in respect of each share in accordance with the conditions of such issuance and was not paid to the Company.

Election of Directors

Our ordinary shares do not have cumulative voting rights for the election of directors. As a result, the holders of a majority of the voting power represented at a shareholders meeting have the power to elect our directors, except the External Directors (as defined in the Israel Companies Law, 5759-1999 (the “**Companies Law**”)).

Under our Articles, the number of directors on our board of directors must be no less than five and no more than ten (in each case including at least two External Directors, as defined in the Companies Law). Subject to the aforesaid, the number of directors shall be determined, from time to time, by a majority of the Directors then in office; provided that no determination in respect of a decrease in the number of directors shall shorten the term of any incumbent director.

Other than the External Directors, the vote required to appoint a Director is a simple majority vote. In addition, under our Articles, our board of directors may elect new directors to fill vacancies (whether such vacancy is due to a director no longer serving or due to the number of directors serving being less than the maximum required in our Articles), provided that the total number of directors shall not, at any time, exceed ten. Our Articles provide that the term of a director appointed by our board of directors to fill any vacancy will be for the remaining term of office of the director(s) whose office(s) have been vacated, or in case of a vacancy due to the number of Directors serving being less than the maximum number stated in the Articles, the Board shall determine at the time of appointment the class pursuant to the Articles to which the additional Director shall be assigned. Furthermore, under our Articles, our directors, other than the External Directors, are divided into three classes with staggered three-year terms, in a way that at each Annual General Meeting the term of office of only one class of Directors will expire. Each class of directors consists, as nearly as possible, of 1/3 of the total number of directors constituting the entire board of directors (other than External Directors).

Dividend and Liquidation Rights

We have never declared or paid any cash dividends on our ordinary shares and we anticipate that, for the foreseeable future, we will retain any future earnings to support operations and to finance the growth and development of our business. Therefore, we do not expect to pay cash dividends for at least the next several years.

We may declare a dividend to be paid to the holders of our ordinary shares in proportion to their respective shareholdings. The distribution of dividends may also be limited by the Companies Law, which permits the distribution of dividends only out of retained earnings or earnings derived over the two most recent fiscal years, whichever is higher, provided that there is no reasonable concern that payment of a dividend will prevent a company from satisfying its existing and foreseeable obligations as they become due. Our amended and restated articles of association provide that dividends will be paid at the discretion of, and upon resolution by, our board of directors, subject to the provision of the Companies Law.

In the event of our liquidation, after satisfaction of liabilities to creditors and other payments due as per applicable law, our assets will be distributed to the holders of our ordinary shares in proportion to their shareholdings. This right, as well as the right to receive dividends, may be affected by the grant of preferential dividend or distribution rights to the holders of a class of shares with preferential rights that may be authorized in the future.

Exchange Controls

There are currently no Israeli currency control restrictions on remittances of dividends on our ordinary shares, proceeds from the sale of the shares or interest or other payments to non-residents of Israel, except for shareholders who are subject of certain countries that have been, or are considered to be, in a state of war with Israel.

Shareholder Meetings

Under Israeli law, we are required to hold an annual general meeting of our shareholders once every calendar year that must be held no later than 15 months after the date of the previous annual general meeting. All general meetings other than the annual meeting of shareholders are referred to in our amended and restated articles of association as special meetings. Our board of directors may call special meetings whenever it sees fit, at such time and place, within or outside of Israel, as it may determine. In addition, the Companies Law provides that our board of directors is required to convene a special general meeting upon the written request of (i) any two or more of our directors or one-quarter or more of the members of our board of directors or (ii) one or more shareholders holding, in the aggregate, either (a) 5% or more of our outstanding issued shares and 1% or more of our outstanding voting power or (b) 5% or more of our outstanding voting power.

Under Israeli law, one or more shareholders holding at least 1% of the voting rights at the general meeting may request that the board of directors include a matter in the agenda of a general meeting to be convened in the future, provided that it is appropriate to discuss such a matter at the general meeting. Our Articles contain procedural guidelines and disclosure items with respect to the submission of shareholder proposals for shareholder meetings.

Subject to the provisions of the Companies Law and the regulations promulgated thereunder, shareholders entitled to participate and vote at general meetings are the shareholders of record on a date to be decided by the board of directors, which may be between four and twenty one days prior to the meeting or between twenty right and forty days prior to the date of the meeting, depending on the type of meeting and whether written proxies are being used. Furthermore, the Companies Law requires that resolutions regarding, among other things, the following matters must be passed at a general meeting of our shareholders:

- amendments to our amended and restated articles of association;
- appointment or termination of our auditors;
- election of directors (unless otherwise determined in our amended and restated articles of association);
- approval of certain related party transactions;
- increases or reductions of our authorized share capital;
- a merger; and
- the exercise of our board of directors' powers by a general meeting, if our board of directors is unable to exercise its powers and the exercise of any of its powers is required for our proper management.

Under our Articles, we are required to give notice to our registered shareholders not less than 21 days prior to the meeting. The Companies Law requires that a notice of any annual general meeting or special general meeting be provided to shareholders at least 21 days prior to the meeting and if the agenda of the meeting includes the appointment or removal of directors, the approval of transactions with office holders or interested or related parties, or an approval of a merger, or as otherwise required under applicable law, notice must be provided at least 35 days prior to the meeting. Under the Companies Law, shareholders of a public company are not permitted to take action by written consent in lieu of a meeting. Under Companies Law, whenever we cannot convene or conduct a general meeting in the manner prescribed under the law or our articles of association, the court may, upon our, shareholders' or directors' request, order that we convene and conduct a general meeting in the manner the court deems appropriate.

Voting Rights

All of our ordinary shares have identical voting and other rights in all respects.

Quorum Requirements

Pursuant to our Articles, holders of our ordinary shares have one vote for each ordinary share held on all matters submitted to a vote before the shareholders at a general meeting. In any meeting of shareholders, we will follow the quorum requirements for general meetings as set forth in our amended and restated articles of association, instead of one-third of the issued share capital as required under the Nasdaq Marketplace Rules. Pursuant to our Articles, the quorum required for our general meetings of shareholders will consist of at least two shareholders present in person or by proxy (including by voting deed) and holding shares conferring in the aggregate at least 25% of the voting power of the Company. A meeting adjourned for lack of a quorum will generally be adjourned to the same day of the following week at the same time and place, or to such other day, time or place as indicated by our board of directors if so specified in the notice of the meeting. At the reconvened meeting, subject to a limited exception, any number of shareholders present in person or by proxy shall constitute a lawful quorum.

Vote Requirements

Our Articles provide that all resolutions of our shareholders require a simple majority vote, unless otherwise required by the Companies Law or by our Articles. Pursuant to our Articles, an amendment to our Articles regarding any change of the composition or election procedures of our directors will require a special shareholders majority of at least two-thirds of the voting power represented at the meeting in person or by proxy and voting thereon. Under the Companies Law, among others, each of (i) the approval of an extraordinary transaction with a controlling shareholder and (ii) the terms of employment or other engagement of the controlling shareholder of the company or such controlling shareholder's relative (even if such terms are not extraordinary) requires special approval and certain transactions with respect to remuneration of our office holders and directors, the approval and extension of a compensation policy and certain deviations therefrom require further approvals. Under our Articles, any change to the rights and privileges of the holders of any class of our shares requires a simple majority at a separate meeting of the class so affected (or such other percentage of the relevant class that may be set forth in the governing documents relevant to such class), in addition to the ordinary majority vote of all classes of shares voting together as a single class at a shareholder meeting. Another exception to the simple majority vote requirement is a resolution for an approval of a scheme of arrangement or reorganization, of the company pursuant to Section 350 of the Companies Law, that governs the settlement of debts and reorganization of a company, which requires the approval of holders of 75% of the voting rights represented at the meeting, in person, by proxy or by voting deed and voting on the resolution.

Access to Corporate Records

Under the Companies Law, shareholders generally have the right to review minutes of our general meetings, our shareholders register and material shareholders register, our amended and restated articles of association, our annual audited financial statements and any document that we are required by law to file publicly with the Israeli Registrar of Companies or the Israel Securities Authority. In addition, any shareholder who specifies the purpose of their request may request to be provided with any document related to an action or transaction requiring shareholder approval under the related party transaction provisions of the Companies Law. We may deny this request if we believe it has not been made in good faith or if such denial is necessary to protect our interests or protect a trade secret or patent.

Modification of Class Rights

Under the Companies Law and our Articles, the rights attached to any class of share, such as voting, liquidation and dividend rights, may be amended by adoption of a resolution by the holders of a majority of the shares of that class present at a separate class meeting, or otherwise in accordance with the rights attached to such class of shares, as set forth in our Articles, in addition to the ordinary majority vote of all classes of voting shares voting together as a single class.

Registration Rights

We have entered into a registration rights agreement with shareholders who held 14,533,835 of our ordinary shares and other securities convertible into or exchangeable for ordinary shares; however some of these shares may have been sold on the market so the registration rights are no longer applicable. This amount includes the exercised warrants, as of March 20, 2021, which were entitled to piggyback registration rights (as described below) but exclude the shares that were sold in our secondary offering consummated in February 2021.

Under the terms of such registration rights agreement, and subject to the limitations specified therein, if we register our ordinary shares under the Securities Act for sale to the public, either for our own account or for the account of other security holders or both, the holders of registrable securities are entitled to notice of the intended registration and to include any or all of their registrable securities in the registration. The right of holders of registrable securities to include shares in an underwritten offering is subject to the right of the underwriters to limit the number of shares included in such offering. Holders of registrable securities are generally required to pay all expenses of registration, including the fees and disbursements of its counsel and all underwriting discounts and commissions.

In addition, as of March 20, 2021, holders of warrants to purchase an aggregate of 2,282,443 ordinary shares may be entitled to piggyback registration rights under the terms of such warrants substantially similar to the registration rights described in the preceding paragraph.

Acquisitions under Israeli Law

Full Tender Offer

A person wishing to acquire shares of an Israeli public company and who would as a result hold over 90% of the target company's voting right or issued and outstanding share capital is required by the Companies Law to make a tender offer to all of the company's shareholders for the purchase of all of the issued and outstanding shares of the company. A person wishing to acquire shares of a public Israeli company and who would as a result hold over 90% of the voting right or issued and outstanding share capital of a certain class of shares is required to make a tender offer to all of the shareholders who hold shares of the relevant class for the purchase of all of the issued and outstanding shares of that class. If the shareholders who do not accept the offer hold less than 5% of the issued and outstanding share capital of the company or of the applicable class, and more than half of the shareholders who do not have a personal interest in the offer accept the offer, all of the shares that the acquirer offered to purchase will be transferred to the acquirer by operation of law. However, a tender offer will also be accepted if the shareholders who do not accept the offer hold less than 2% of the issued and outstanding share capital of the company or of the applicable class of shares.

Upon a successful completion of such a full tender offer, any shareholder that was an offeree in such tender offer, whether such shareholder accepted the tender offer or not, may, within six months from the date of acceptance of the tender offer, petition an Israeli court to determine whether the tender offer was for less than fair value and that the fair value should be paid as determined by the court. However, under certain conditions, the offeror may include in the terms of the tender offer that an offeree who accepted the offer will not be entitled to petition the Israeli court as described above.

If the full tender offer was not accepted in accordance with the above alternatives, the acquirer may not acquire shares of the company that will increase its holdings to more than 90% of the company's issued and outstanding share capital or of the applicable class from shareholders who accepted the tender offer.

Special Tender Offer

The Companies Law provides that an acquisition of shares of an Israeli public company must be made by means of a special tender offer if as a result of the acquisition the purchaser would become a holder of 25% or more of the voting rights in the company. This requirement does not apply if there is already another holder of at least 25% of the voting rights in the company. Similarly, the Companies Law provides that an acquisition of shares in a public company must be made by means of a special tender offer if as a result of the acquisition the purchaser would become a holder of more than 45% of the voting rights in the company, if there is no other shareholder of the company who holds more than 45% of the voting rights in the company, subject to certain exceptions.

A special tender offer must be extended to all shareholders of a company but the offeror is not required to purchase shares representing more than 5% of the voting power attached to the company's outstanding shares, regardless of how many shares are tendered by shareholders. A special tender offer may be consummated only if (i) at least 5% of the voting power attached to the company's outstanding shares will be acquired by the offeror and (ii) the number of shares tendered by shareholders who accept the offer exceeds the number of shares whose holders objected to the offer (excluding the purchaser and its controlling shareholders, holders of 25% or more of the voting rights in the company or any person having a personal interest in the acceptance of the tender offer or any other person acting on their behalf, including relatives and entities under such person's control). If a special tender offer is accepted, then the purchaser or any person or entity controlling it or under common control with the purchaser or such controlling person or entity may not make a subsequent tender offer for the purchase of shares of the target company and may not enter into a merger with the target company for a period of one year from the date of the offer, unless the purchaser or such person or entity undertook to effect such an offer or merger in the initial special tender offer. Shares purchased in contradiction to the tender offer rules under the Companies Law, will have no rights and will become dormant shares.

Merger

The Companies Law permits merger transactions if approved by each party's board of directors and, unless certain requirements described under the Companies Law are met, by a majority vote of each party's shares, and, in the case of the target company, a majority vote of each class of its shares voted on the proposed merger at a shareholders meeting.

For purposes of the shareholder vote, unless a court rules otherwise, the merger will not be deemed approved if a majority of the votes of the shares represented at the shareholders meeting that are held by parties other than the other party to the merger, or by any person (or group of persons acting in concert) who holds (or hold, as the case may be) 25% or more of the voting rights or the right to appoint 25% or more of the directors of the other party, vote against the merger. If, however, the merger involves a merger with a company's own controlling shareholder or if the controlling shareholder has a personal interest in the merger, then the merger is instead subject to the same special majority approval that governs all extraordinary transactions with controlling shareholders.

If the transaction would have been approved by the shareholders of a merging company but for the separate approval of each class or the exclusion of the votes of certain shareholders as provided above, a court may still approve the merger upon the request of holders of at least 25% of the voting rights of a company, if the court holds that the merger is fair and reasonable, taking into account the value to the parties to the merger and the consideration offered to the shareholders of the target company.

Upon the request of a creditor of either party to the proposed merger, the court may delay or prevent the merger if it concludes that there exists a reasonable concern that, as a result of the merger, the surviving company will be unable to satisfy the obligations of the merging entities, and may further give instructions to secure the rights of creditors.

In addition, a merger may not be consummated unless at least 50 days have passed from the date on which a proposal for approval of the merger was filed by each party with the Israeli Registrar of Companies and at least 30 days have passed from the date on which the merger was approved by the shareholders of each party.

Israeli tax law treats some acquisitions, such as share for share exchanges between an Israeli company and a foreign company, less favorably than U.S. tax laws. For example, Israeli tax law may, under certain circumstances, subject a shareholder who exchanges his ordinary shares for shares in another corporation to taxation prior to the sale of the shares received in such share-for-share swap.

Anti-Takeover Measures under Israeli Law

The Companies Law allows us to create and issue shares having rights different from those attached to our ordinary shares, including shares providing certain preferred rights with respect to voting, distributions or other matters and shares having preemptive rights. No preferred shares are authorized under our Articles. In the future, if we do authorize, create and issue a specific class of preferred shares, such class of shares, depending on the specific rights that may be attached to it, may have the ability to frustrate or prevent a takeover or otherwise prevent our shareholders from realizing a potential premium over the market value of their ordinary shares. The authorization and designation of a class of preferred shares will require an amendment to our Articles, which requires the prior approval of the holders of a majority of the voting power attaching to our issued and outstanding shares at a general meeting. The convening of the meeting, the shareholders entitled to participate and the majority vote required to be obtained at such a meeting will be subject to the requirements set forth in the Companies Law as described above in "—Voting Rights."

Borrowing Powers

Pursuant to the Companies Law and our Articles, our board of directors may exercise all powers and take all actions that are not required under law or under our amended and restated articles of association to be exercised or taken by our shareholders, including the power to borrow money for company purposes.

Changes in Capital

Our Articles enable us to increase or reduce our share capital. Any such changes are subject to the provisions of the Companies Law and must be approved by a resolution duly adopted by our shareholders at a general meeting. In addition, transactions that have the effect of reducing capital, such as the declaration and payment of dividends in the absence of sufficient retained earnings or profits, require the approval of both our board of directors and an Israeli court.

Choice of Forum

Our Articles provide that the federal district courts of the United States of America will, to the fullest extent permitted by law, be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act (the “**Federal Forum Provision**”). While there can be no assurance that U.S. federal or state courts or Israeli courts will follow the holding of the Delaware Supreme Court which recently found that such provisions are facially valid under Delaware law or determine that the Federal Forum Provision should be enforced in a particular case, application of the Federal Forum Provision means that suits brought by our shareholders to enforce any duty or liability created by the Securities Act must be brought in federal court and cannot be brought in state court. The Federal Forum Provision does not apply to suits brought to enforce any duty or liability created by the Exchange Act. Section 27 of the Exchange Act creates exclusive federal jurisdiction over all claims brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. Accordingly, actions by our shareholders to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder also must be brought in federal court. Our shareholders will not be deemed to have waived our compliance with the federal securities laws and the regulations promulgated thereunder. Any person or entity purchasing or otherwise acquiring or holding any interest in any of our securities shall be deemed to have notice of and consented to the Federal Forum Provision. This provision may limit a shareholder’s ability to bring a claim in a judicial forum of their choosing for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees.

Establishment

We were incorporated under the laws of the State of Israel on December 20, 2018. We are registered with the Israeli Registrar of Companies in Jerusalem.

Transfer Agent and Registrar

The transfer agent and registrar for our ordinary shares is Continental Stock Transfer & Trust Co.

Listing

Our ordinary shares are listed on The Nasdaq Global Market under the symbol “NNOX.”

**Certification by Principal Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Ran Poliakine, certify that:

1. I have reviewed this annual report on Form 20-F of Nano-X Imaging Ltd (the "Company");
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;
4. The Company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the Company and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. [Reserved];
 - c. Evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and
5. The Company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

Date: April 6, 2021

By:

/s/ Ran Poliakine

Name: Ran Poliakine

Title: Chief Executive Officer

**Certification by Principal Financial Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002**

I, Itzhak Maayan, certify that:

1. I have reviewed this annual report on Form 20-F of Nano-X Imaging Ltd (the "Company");
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this report;
4. The Company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the Company and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. [Reserved];
 - c. Evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and
5. The Company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Company's auditors and the audit committee of the Company's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Company's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the Company's internal control over financial reporting.

Date: April 6, 2021

By:

/s/ Itzhak Maayan

Name: Itzhak Maayan

Title: Chief Financial Officer

**Certification by Principal Executive Officer
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**

I, Ran Poliakine, Chief Executive Officer of Nano-X Imaging Ltd (the “Company”), hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

- the Company’s annual report on Form 20-F for the year ended December 31, 2020 (the “Report”) fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented therein.

Date: April 6, 2021

By: /s/ Ran Poliakine

Name: Ran Poliakine

Title: Chief Executive Officer

**Certification by Principal Financial Officer
Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002**

I, Itzhak Maayan, Chief Financial Officer of Nano-X Imaging Ltd (the "Company"), hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that to the best of my knowledge:

- the Company's annual report on Form 20-F for the year ended December 31, 2020 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the periods presented therein.

Date: April 6, 2021

By: /s/ Itzhak Maayan

Name: Itzhak Maayan

Title: Chief Financial Officer



CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statement on Form S-8 (No. 333-248322) of Nano-X Imaging Ltd. of our report dated April 6, 2021 relating to the financial statements, which appears in this Form 20-F.

Tel-Aviv, Israel
April 6, 2021

/s/Kesselman & Kesselman
Certified Public Accountants (Isr.)
A member firm of PricewaterhouseCoopers International Limited

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Kesselman & Kesselman is a member firm of PricewaterhouseCoopers International Limited, each member firm of which is a separate legal entity
