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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2022

OR

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

COMMISSION FILE NUMBER: 001-35731

InspireMD, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**26-2123838**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification Number)
4 Menorat Hamaor St. Tel Aviv, Israel	**6744832**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(888) 776-6804**

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	NSPR	Nasdaq Capital Market

Securities registered pursuant to Section 12(g) of the Act: none

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

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐	Accelerated filer ☐
Non-accelerated filer ☒	Smaller reporting company ☒
	Emerging growth company ☐

If an emerging growth company, 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. ☐

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. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act) Yes ☐ No ☒

The aggregate market value of the voting and non-voting stock held by non-affiliates of the registrant as of June 30, 2022, based on the price at which the common equity was last sold on such date, was $15,650,407. For purposes of this computation only, all officers, directors and 10% or greater stockholders of the registrant are deemed to be affiliates.

Indicate the number of shares outstanding of each of the registrant's classes of common stock as of the latest practicable date.

Class	Outstanding at March 28, 2023
Common Stock, $0.0001 par value	8,326,648

Documents incorporated by reference:
None

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains "forward-looking statements," which include information relating to future events, future financial performance, strategies, expectations, competitive environment and regulation, including, revenue growth. Words such as "may," "will," "should," "could," "would," "predicts," "potential," "continue," "expects," "anticipates," "future," "intends," "plans," "believes," "estimates," and similar expressions, as well as statements in future tense, identify forward-looking statements. Forward-looking statements should not be read as a guarantee of future performance or results and will probably not be accurate indications of when such performance or results will be achieved. 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. Important factors that could cause such differences include, but are not limited to:

- our history of recurring losses and negative cash flows from operating activities, significant future commitments and the uncertainty regarding the adequacy of our liquidity to pursue our complete business objectives, and substantial doubt regarding our ability to continue as a going concern;
- our need to raise additional capital to meet our business requirements in the future and such capital raising may be costly or difficult to obtain and could dilute out stockholders' ownership interests;
- market acceptance of our products;
- an inability to secure and maintain regulatory approvals for the sale of our products;
- negative clinical trial results or lengthy product delays in key markets;
- our ability to maintain compliance with the Nasdaq listing standards;
- our ability to generate revenues from our products and obtain and maintain regulatory approvals for our products;
- our ability to adequately protect our intellectual property;
- our dependence on a single manufacturing facility and our ability to comply with stringent manufacturing quality standards and to increase production as necessary;
- the risk that the data collected from our current and planned clinical trials may not be sufficient to demonstrate that our technology is an attractive alternative to other procedures and products;
- intense competition in our industry, with competitors having substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do;
- entry of new competitors and products and potential technological obsolescence of our products;
- inability to carry out research, development and commercialization plans;
- loss of a key customer or supplier;
- technical problems with our research and products and potential product liability claims;
- product malfunctions;
- price increases for supplies and components;
- insufficient or inadequate reimbursement by governmental and other third-party payers for our products;
- our efforts to successfully obtain and maintain intellectual property protection covering our products, which may not be successful;
- adverse federal, state and local government regulation, in the United States, Europe or Israel and other foreign jurisdictions;
- the fact that we conduct business in multiple foreign jurisdictions, exposing us to foreign currency exchange rate fluctuations, logistical and communications challenges, burdens and costs of compliance with foreign laws and political and economic instability in each jurisdiction;
- the escalation of hostilities in Israel, which could impair our ability to manufacture our products; and
- current or future unfavorable economic and market conditions and adverse developments with respect to financial institutions and associated liquidity risk

The foregoing does not represent an exhaustive list of matters that may be covered by the forward-looking statements contained herein or risk factors that we are faced with that may cause our actual results to differ from those anticipated in our forward-looking statements. You should review carefully the risks and uncertainties described under the heading "Item 1A. Risk Factors" in this Annual Report on Form 10-K for a discussion of these and other risks that relate to our business and investing in shares of our common stock. Moreover, new risks regularly emerge, and it is not possible for our management to predict or articulate all the risks we face, nor can we assess the impact of all risks on our business or the extent to which any risk, or combination of risks, may cause actual results to differ from those contained in any forward-looking statements. All forward-looking statements included in this Annual Report are based on information available to us on the date of this Annual Report. Except to the extent required by applicable laws or rules, we undertake no obligation to publicly update or revise any forward-looking statement, whether as a result of new information, future events or otherwise. All subsequent written and oral forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the cautionary statements contained above and throughout this Annual Report.

The forward-looking statements contained in this Annual Report on Form 10-K are expressly qualified in their entirety by this cautionary statement. We do not undertake any obligation to publicly update any forward-looking statement to reflect events or circumstances after the date on which any such statement is made or to reflect the occurrence of unanticipated events.

All information in this Annual Report on Form 10-K relating to shares or price per share reflects the 1-for-15 reverse stock split effected by us on April 26, 2021.

PART I

In this Annual Report on Form 10-K, unless the context requires otherwise, the terms "we," "our," "us," or "the Company" refer to InspireMD, Inc., a Delaware corporation, and its subsidiaries, including InspireMD Ltd., taken as a whole.

Item 1. Business.

Overview

We are a medical device company focusing on the development and commercialization of our proprietary MicroNet™ stent platform for the treatment of carotid artery disease and other vascular disease. A stent is an expandable "scaffold-like" device, usually constructed of a metallic material, that is inserted into the lumen of the artery to create patency and revascularization of blood flow. MicroNet, a micron mesh sleeve, is attached over a stent to provide embolic protection both during and after stenting procedures.

Our CGuard™ carotid embolic prevention system ("CGuard EPS™") combines MicroNet and a unique self-expandable nitinol stent in a single device for use in carotid artery revascularization. Our CGuard EPS originally received CE mark approval under Medical Device Directive 93/42/EEC ("MDD") in the European Union ("EU") in March 2013 and was fully launched in Europe in September 2015. Subsequently, we launched CGuard EPS in over 30 countries and on February 3, 2021, we executed a distribution agreement with Chinese partners for the purpose of expanding our presence in the Asian markets. Currently, we are seeking strategic partners for a potential launch of CGuard EPS in Japan and other Asian countries.

Our CE mark for CGuard EPS under the MDD expired on November 12, 2022 and we are in the final stages of technical documentation review by the Notified Body auditor to meet the Medical Device Regulation ("MDR") (MDR 2017/745) requirements (which replaced the MDD) for recertification. In the meantime, on February 14, 2023, we received a derogation per Article 97 paragraph 1 of Regulation 2017/745 from the Agency for Medicines and Health Products (FAMHP) allowing us to continue marketing CGuard EPS in the EU until August 15, 2023 subject to certain procedural requirements. Subsequently, on March 20, 2023, Regulation (EU) 2023/607 was published allowing us to continue marketing CGuard EPS in EU countries under the MDD directive until December 31, 2027. As a result of the foregoing, we may market and sell CGuard EPS in the EU and certain other jurisdictions subject to certain procedural requirements while our MDR CE recertification is pending. We continue to expedite the review process for recertification under the MDR.

On September 8, 2020, we received approval from the U.S. Food and Drug Administration ("FDA") of our Investigation Device Exemption ("IDE"), thereby allowing us to proceed with a pivotal study of our CGuard™ Carotid Stent System, C-Guardians, for prevention of stroke in patients in the United States. C-Guardians is a prospective, multicenter, single-arm, pivotal study to evaluate the safety and efficacy of the CGuard™ Carotid Sten System when used to treat symptomatic and asymptomatic carotid artery stenosis in patients undergoing carotid artery stenting. The trial was designed to enroll approximately 315 subjects in a maximum of 40 study sites located in the United States and Europe. Study sites in Europe may contribute a maximum of approximately 50% of the total enrollees. The primary endpoint of the study will be the composite of incidence of death (all-cause mortality), all stroke, and myocardial infarction (DSMI) through 30-days post-index procedure, based on the clinical events committee (CEC) adjudication and ipsilateral stroke from 31-365 day follow-up, based on Clinical Events Committee (CEC) adjudication. The composite index will be compared to a performance goal based on the observed rate of the two components of the primary endpoint from previous pivotal stent trials which are considered industry standard. The performance goal will be considered met if the upper bound of the two-sided 95% confidence interval calculated from the observed primary endpoint rate is < 11.6% and the p-value is less than 0.025.

On July 23, 2021, we announced the initiation of enrollment and successful completion of the first cases of our C-Guardian trial of CGuard EPS. These are 315 patients who are expected to be enrolled in the trial and receive CGuard EPS in the treatment of carotid artery stenosis in symptomatic and asymptomatic patients undergoing carotid artery stenting. We are currently continuing with the enrolment phase at approximately 20 trial sites and expect it to be completed approximately at the end of the second quarter of 2023.

Additionally, we intend to continue to invest in current and future potential new indications, products and manufacturing enhancements for CGuard EPS that are expected to reduce cost of goods and/or provide the best-in-class performing delivery systems, such as CGuard Prime™for transfemoral access. In furtherance of our strategy that focuses on establishing CGuard EPS as a viable alternative to vascular surgery, we are developing a new transcarotid artery revascularization (TCAR) delivery system, SwitchGuard™, for transcarotid access and neuro protection. In addition, we intend to explore new indications for CGuard EPS to leverage the advantages of stent design and mesh protection, well suited in labels such as acute stroke with tandem lesions.

We consider our current addressable market for our CGuard EPS to be individuals with diagnosed, symptomatic high-grade carotid artery stenosis (HGCS, ≥70% occlusion) for whom intervention is preferable to medical (drug) therapy. This group includes not only carotid artery stenting patients but also individuals undergoing carotid endarterectomy, as the two approaches compete for the same patient population. Assuming full penetration of the intervention caseload by CGuard EPS, we estimate that the addressable market for CGuard EPS will be approximately $1.3 billion in 2023 (source: Health Research International Personal Medical Systems, Inc. September 13, 2021 Results of Update Report on Global Carotid Stenting Procedures and Markets by Major Geography and Addressable Markets and internal estimates). According to this same report, and internal estimates, assuming full penetration of the caseload for all individuals diagnosed with high-grade carotid artery stenosis, we estimate that the total available market for CGuard EPS in 2022 will be approximately $9.3 billion. Our mission is to offer a comprehensive set of delivery solutions (TCAR and Transfemoral) in order to deliver best in class results through patient outcomes by way of stent performance with CGuard EPS.

We were organized in the State of Delaware on February 29, 2008.

Our Industry

Carotid

Carotid arteries are located on each side of the neck and provide the primary blood supply to the brain. Carotid artery disease, also called carotid artery stenosis, is a type of atherosclerosis (hardening of the arteries) that is one of the major risk factors for ischemic stroke. In carotid artery disease, plaque accumulates in the artery walls, narrowing the artery and disrupting the blood supply to the brain. This disruption in blood supply, together with plaque debris breaking off the artery walls and traveling to the brain, are the primary causes of stroke. According to the World Health Organization (https://www.who.int/cardiovascular_diseases/resources/atlas/en/) every year, 15 million people worldwide suffer a stroke, and nearly six million die and another five million are left permanently disabled. According to the same source, stroke is the second leading cause of disability, after dementia.

In 2022, 3.0 million people between the age of 50 and 89 years old were estimated to be diagnosed with high grade carotid artery disease, of which, approximately 394,000 of those diagnosed required intervention for carotid artery disease (according to the Health Research International Personal Medical Systems, Inc. September 13, 2021 Results of Update Report on Global Carotid Stenting Procedures and Markets by Major Geography and Addressable Markets). There are three current intervention treatments used for carotid artery disease. The first is a carotid endarterectomy where a surgeon accesses the blocked carotid artery though an incision in the neck, and then surgically removes the plaque. The second is transcarotid artery revascularization where a surgeon accesses the blocked carotid artery though an incision in the neck, and then surgically removes the plaque while combining high-rate blood flow reversal to protect the brain. The third is carotid artery stenting, which is a minimally invasive endovascular treatment for carotid artery disease and an alternative to carotid endarterectomy. Endovascular techniques using stents and carotid embolic prevention system protect against plaque and debris traveling downstream, blocking off the vessel and disrupting blood flow. We believe that the use of a stent with an embolic protection system should increase the number of patients being treated since it would avoid the need for complex surgery.

Our Products and Product Candidates

MicroNet Mesh Platform Technology

MicroNet is our proprietary circular knitted mesh which wraps around a stent to protect patients from plaque debris flowing downstream upon deployment. MicroNet is made of a single fiber from a biocompatible polymer widely used in medical implantations. The size, or aperture, of the current MicroNet 'pore' is only 150-180 microns in order to maximize protection against the potentially dangerous plaque and thrombus. The MicroNet mesh is the core technology around which we have developed products for specific applications.

CGuard EPS – Carotid Artery Applications

Our CGuard EPS combines our MicroNet mesh and a self-expandable nitinol stent (a stent that expands without balloon dilation pressure or need of an inflation balloon) in a single device for use in carotid artery applications. MicroNet is placed over and attached to an open cell nitinol metal stent platform which is designed to trap debris and emboli that can dislodge from the diseased carotid artery and potentially travel to the brain and cause a stroke. This danger is one of the greatest limitations of carotid artery stenting with conventional carotid stents and stenting methods. The CGuard EPS technology is a highly flexible stent system that conforms to the carotid anatomy.

We believe that our CGuard EPS design provides advantages over existing therapies in treating carotid artery stenosis, such as conventional carotid stenting and surgical endarterectomy, given the superior embolic protection characteristics provided by the MicroNet. We believe the MicroNet will provide acute embolic protection at the time of the procedure, but more importantly, we believe that CGuard EPS will provide post-procedure protection against embolic dislodgement, which can occur up to 48 hours post-procedure. It is in this post-procedure time frame that embolization is the source of post-procedural strokes in the brain. Schofer, et al. ("Late cerebral embolization after emboli-protected carotid artery stenting assessed by sequential diffusion-weighted magnetic resonance imaging," *Journal of American College of Cardiology Cardiovascular Interventions*, Volume 1, 2008) have shown that the majority of the incidents of embolic showers associated with carotid stenting occur post-procedure.

Our CGuard EPS original received CE mark approval in the EU in March 2013 and was fully launched in Europe in September 2015. Subsequently, we launched CGuard EPS in 30 plus countries and on February 3, 2021, we executed a distribution agreement with Chinese partners for the purpose of expanding our presence in China. On October 13, 2021, we announced that our CGuard EPS stent system received a positive opinion regarding reimbursement in France. Currently, we are seeking strategic partners for a potential launch of CGuard EPS in Japan and other Asian countries.

Our CE mark for CGuard EPS under the MDD expired on November 12, 2022 and we are in the final stages of technical documentation review by the Notified Body auditor to meet the MDR requirements for recertification. In the meantime, on February 14, 2023, we received a derogation per Article 97 paragraph 1 of Regulation 2017/745 from the Agency for Medicines and Health Products (FAMHP) allowing us to continue marketing CGuard EPS in the EU until August 15, 2023, subject to certain procedural requirements. Subsequently, on March 20, 2023, Regulation (EU) 2023/607 was published allowing us to continue marketing CGuard EPS in EU countries under the MDD directive until December 31, 2027. As a result of the foregoing, we may market and sell CGuard EPS in the EU and certain other jurisdictions subject to certain procedural requirements while our MDR CE recertification is pending. We continue to expedite the review process for recertification under the MDR.

On September 8, 2020, we received approval from the FDA of our IDE, thereby allowing us to proceed with a pivotal study of our CGuard™ Carotid Stent System, C-Guardians, for prevention of stroke in patients in the United States. C-Guardians is a prospective, multicenter, single-arm, pivotal study to evaluate the safety and efficacy of the CGuard™ Carotid Stent System when used to treat symptomatic and asymptomatic carotid artery stenosis in patients undergoing carotid artery stenting. The trial was designed to enroll approximately 315 subjects in a maximum of 40 study sites located in the United States and Europe. Study sites in Europe may contribute a maximum of approximately 50% of the total enrollees. The primary endpoint of the study will be the composite of incidence of death (all-cause mortality), all stroke, and myocardial infarction (DSMI) through 30-days post-index procedure, based on the clinical events committee (CEC) adjudication and ipsilateral stroke from 31-365 day follow-up, based on Clinical Events Committee (CEC) adjudication. The composite index will be compared to a performance goal based on the observed rate of the two components of the primary endpoint from previous pivotal stent trials which are considered industry standard. The performance goal will be considered met if the upper bound of the two-sided 95% confidence interval calculated from the observed primary endpoint rate is < 11.6% and the p-value is less than 0.025.

On July 23, 2021, we announced the initiation of enrollment and successful completion of the first cases of our C-Guardian trial of CGuard EPS. Since then we have continue to enroll subjects in the trial at approximately 20 trial sites and expect to complete enrollment approximately at the end the second quarter of 2023.

CGuard Prime Delivery System

The CGuard Prime™ System is a mesh-covered self-expanding carotid stent that is loaded into a transfemoral rapid exchange (Rx) delivery system that we are developing and that is subject to regulatory approval.

The CGuard Prime Carotid Stent is a self-expanding nitinol stent covered with a MicroNet bio-stable sleeve woven from a single strand of 23 µm Polyethylene Terephthalate (PET). The MicroNet sleeve is designed to trap and seal thrombus and plaque against the vessel wall, providing continuous embolic prevention. The CGuard Prime Carotid Stent is available in diameters ranging from 6.0mm to 10mm and in lengths of 20, 30, 40 and 60mm. The CGuard Prime Delivery System is a rapid exchange (Rx), delivery system with a 6Fr profile that can accommodate all stent sizes from 6mm to 10mm. The CGuard Prime Rx Delivery Systems are available in two lengths: 80 cm and 135 cm.

CGuard Prime™ advances the first generation CGuard transfemoral delivery system with new handle design for deployment accuracy, new catheter design for more flexible navigation of tortuous anatomy especially in acute revascularize settings as well as two lengths, 135cm and 80cm for booth transfemoral and trans ,carotid access.

Switchguard

SwitchGuard is a Class IIa, non-invasive transcarotid artery revascularization (TCAR) device that we are developing and that is subject to regulatory approval that is composed of medical grade tubing with male Luer lock connectors at each end and an in-line 200-micron blood filter. The device is intended as an external arterial-venous (A-V) shunt, allowing arterial blood to flow into the venous system, while filtering particulate before returning blood to the patient on the venous side.

The SwitchGuard arterio-venous extension line with filter is intended for flow circuit and particle removal when connecting arterial and/or venous introducers during interventional procedures.

SwitchGuard is being developed to answer a need of flow reversal for cerebral protection in CAS since symptomatic distal embolization, caused by the release of material (thrombotic, necrotic, or atherosclerotic) from the site of the lesion during the intervention, is the most frequent and important complication of CAS. Reversing blood flow has been shown to reduce stroke risk during carotid artery procedures.

Physicians frequently use extension lines constructed from blood filter transfusion sets during interventional procedures for the purpose of A-V shunting.

NGuard EPS – Acute Stroke with Tandem Lesions

In approximately 20% of acute strokes, the carotid artery is included in the cerebral occlusion pathway. Currently there is no indicated use of CAS for these lesions during stroke treatment. We believe CGuard EPS is optimally suited for intervention in this acute setting by way for design (flexible / low metal structure) as well as MicroNet mesh offering embolic protection both during and post procedural implantation. Our goal is to develop CGuard EPS to mitigate strokes in this acute setting.

MGuard Prime

We historically developed and sold MGuard Prime embolic protection system ("MGuard Prime EPS") which was marketed for use in patients with acute coronary syndromes, notably acute myocardial infarction (heart attack) and saphenous vein graft coronary interventions, or bypass surgery. Over the past years there has been a shift in industry preferences away from bare-metal stents, such as MGuard Prime and as a result of declining sales and practical market utilization of the MGuard Prime EPS, which we believe was largely driven by the predominant industry preferences favoring drug-eluting or drug-coated, stents, during the second quarter of 2022 we ceased sales of our MGuard Prime EPS following a phase out period.

Completed Clinical Trials for CGuard EPS

CARENET

The CARENET trial was the first multi-center study of CGuard EPS following the receipt of CE mark of this device in March 2013. The CARENET trial was designed to evaluate feasibility and safety of CGuard EPS in treatment of carotid lesions in consecutive patients suitable for coronary artery stenting ("CAS") in a multi-operator, real-life setting. The acute, 30 day, magnetic resonance imaging ("MRI"), ultrasound and six month clinical event results were presented at the LINC conference in Leipzig, Germany in February, 2015. In the third quarter of 2015, the results of the CGuard CARENET trial were published in the Journal of the American College of Cardiology. In November 2015, positive twelve month follow-up data from the CGuard CARENET trial was presented at the 42nd Annual Symposium on Vascular and Endovascular Issues, documenting the benefits of the CGuard MicroNet technology as well as the patency benefits (maintaining the artery open) of the internal and external carotid arteries at twelve months. In September 2022, the results of the CGuard CARENET trial five year follow up were published in the Journal of the American College of Cardiology: Cardiovascular Interventions Vol. 15, No 18, 2022 September 26, 2022:1883-1891. There was no ipsilateral stroke or ipsilateral stroke-related death which occurred throughout the five years. In addition, no stent restenosis or external carotid artery occlusion occurred in CARENET by 5 years, indicating normal healing and uncompromised side-branch patency.

MACCE (myocardial infarction ("MI"), stroke or death) rate was 0.0% at 30 days. At six months, there was one death, which was not device or procedure-related but did result in a MACCE rate of 3.6% at six months. At twelve months there were two additional deaths, which were not device or procedure-related resulting in a MACCE rate of 10.7% at one year.

	30 days (n=30)	**6 months (n=28)**	**12 months (n=28)**
MACCE (MI, stroke, death)	(0) 0.0%	(1) 3.6%	(3) 10.7%
MI	(0) 0.0%	(0) 0.0%	(0) 0.0%
stroke	(0) 0.0%	(0) 0.0%	(0) 0.0%
death	(0) 0.0%	(1) 3.6%	(3) 10.7%

CAS carries the risk of cerebral embolization during and following the procedure, leading to life-threatening complications, mainly cerebral ischemic events. Diffusion-weighted magnetic resonance imaging (DW-MRI) is a sensitive tool used to identify cerebral emboli during CAS by measuring "lesions" within the brain which are areas that are ischemic and do not receive oxygenated blood due to cerebral emboli. In the CARENET trial, 37.0% of patients treated with CGuard EPS had new ischemic lesions at 48 hours after the procedure, with an average volume of 0.039 cm3. Of these lesions, there was only one that remained at 30 days following the procedure and all others had resolved. Complete details appear in the following table. Where there is a second number shown below after a ± symbol, it indicates the potential error in the measurement.

	48 hours n=27	**30 days n=26**
Subjects with new Acute Ischemic Lesions ("AIL")	10	1
Incidence of new lesions	37.0%	4.0%
Total number new AIL	83	1
Avg. number new AIL per patient	3.19 ± 10.33	0.04 ± 0.20
Average lesion volume (cm^3)	0.039 ± 0.08	0.08 ± 0.00
Maximum lesion volume (cm^3)	0.445	0.116
Permanent AIL at 30 days	—	1

The healing process of the tissue and in-stent restenosis can be measured by a non-invasive form of ultrasound called duplex ultrasound. This type of ultrasound measures the velocity of the blood that flows within the carotid arteries, which increases exponentially as the lumen of the internal carotid artery narrows and the percent stenosis increases. One of the measurements is called PSV (peak systolic volume) and is known to be highly correlated to the degree of in-stent restenosis; PSV values higher than 300 cm/sec are indicative of> 70% stenosis, while PSV values lower than 104 cm/sec are indicative of <30% restenosis and healthy healing. In the CARENET trial, duplex ultrasound measurements done at 30 days, 6 months and 12 months following the stenting procedure all attest to healthy normal healing without restenosis concerns, as the PSV values were 60.96 cm/sec ± 22.31, 85.24 cm/sec ± 39.56, and 90.22 cm/sec ± 37.72 respectively. The internal carotid artery was patent in all patients (100%).

The conclusions of the CARENET trial were:

- The CARENET trial demonstrated safety of the CGuard EPS stent, with a 30 day MACCE rate of 0%.
- Incidence of new ipsilateral lesions (percent of patients with new lesions on the ipsilateral side (same side where the stent was employed)) at 48 hours was reduced by almost half compared to published data, and volume was reduced almost tenfold.
- All but one lesion had resolved completely by 30 days.
- Twelve month data showed no stroke or stroke-related deaths, and no cardiac adverse events.
- Five year data showed no ipsilateral stroke or ipsilateral stroke-related deaths, and no stent restenosis or external carotid artery occlusion occurred in CARENET by 5 years, indicating normal healing and uncompromised side-branch patency.
- CGuard EPS offers enhanced benefits for patients undergoing CAS with unprecedented safety.

Physician-Sponsored Clinical Trials for CGuard—PARADIGM-101 and PARADIGM -500 Studies

PARADIGM-101 (**P**rospective evaluation of **A**ll-comer pe**R**cutaneous c**A**roti**D** revascularization **I**n symptomatic and increased-risk asymptomatic carotid artery stenosis, using C**G**uard™ **M**esh-covered embolic prevention stent system-101) was an investigator-led, single center study with the objective of evaluating feasibility and outcome of routine use of CGuard EPS in 101 consecutive unselected all-comer patients referred for carotid revascularization, initiated in 2015. In May 2016, the 30-day results were presented at the EuroPCR 2016 Late-Breaking Clinical Trial Session in Paris, and in the Journal of EuroIntervention. In Dec 2020, the 12 month results were presented in the Official Journal of the EuroPCR and the European Association of Percutaneous Coronary Interventions, EuroIntervention 2020;16:e950-e952. DOI: 10.4244/EIJ-D-19-01014) Key findings from the PARADIGM-101 study and the follow-up data are as follows.

- CGuard EPS delivery success was 99.1%. The clinical evaluation also found no device foreshortening or elongation;
- Angiographic diameter stenosis or vessel narrowing was reduced from 83±9% to only 6.7±5% ($p<0.001$);
- Periprocedural death/major stroke/ myocardial infarction ("MI") rates were 0%;
- Between 30 days and 12 months, there were no strokes or stroke-related deaths. There were four non -device related deaths (heart failure exacerbation, urosepsis, pulmonary embolism and microcellular pulmonary cancer).

The results of the PARADIGM-101 study demonstrated that CGuard EPS can safely be used in a high risk, all-comer population of patients with carotid artery stenosis and indicated that routine use of CGuard EPS may prevent cerebral events, such as strokes, by holding plaque against the vessel wall, preventing emboli from being released into the blood stream. The PARADIGM-101 study found that CGuard EPS is applicable in up to 90% of all-comer patients with carotid stenosis.

PARADIGM-101 was subsequently increased to include 500 consecutive patients with symptomatic or increased stroke risk asymptomatic atherosclerotic carotid stenosis patients. The new study is known as PARADIGM -500. In June 2022, the 1 year results were presented at the EuroPCR in Leipzig, Germany.

Key findings from the PARADIGM-500 study are as follows.

- 30 Day Death/Stroke rate of 0.75%; 30 day death/stroke/myocardial infarction rate of 0.94%;
- 12 month freedom from ipsilateral stroke, in stent restenosis and target lesion revascularization rate of 99.6%.

Clinical Results and Mechanical Properties of the Carotid CGUARD Double-Layered Embolic Prevention Stent Study

"Clinical Results and Mechanical Properties of the Carotid CGUARD Double-Layered Embolic Prevention Stent Study" was an investigator-led, prospective single-center study which evaluated CGuard EPS in 30 consecutive patients with internal carotid artery stenosis disease with the objective of reporting early clinical outcomes with a novel MicroNet covered stent for the internal carotid artery and the in vitro investigation of the device's mechanical properties. In October 2016, the 30-day positive results were published online-ahead-of-print in the Journal of Endovascular Therapy.

Key findings from the study are as follows:

- 100% success in implanting CGuard EPS without residual stenosis;
- No peri- or post-procedural complications;
- No deaths, major adverse events, minor or major strokes, or new neurologic symptoms during the six months following the procedure;
- Modified Rankin Scale improved for the symptomatic patients from 1.56 prior to the procedure to 0 afterwards;
- All vessels treated with CGuard EPS remained patent (open) at six months; and
- DW-MRI performed in 19 of 30 patients found no new ipsilateral lesions after 30 days and after six months compared with the baseline DW-MRI studies.

Additionally, based on engineering evaluations, the study concluded that CGuard EPS provides a high radial force and strong support in stenotic lesions. The stent is easy to use and safe to implant because it does not foreshorten and its structure adapts well to changes in diameter and direction of tortuous vascular anatomies. The MicroNet mesh of CGuard did not cause any changes to specific mechanical parameters of the underlying stent.

Safety and Efficacy of the New Micromesh-Covered Stent CGuard in Patients Undergoing Cartoid Artery Stenting: Early Experience From a Single Center

"Safety and Efficacy of the New Micromesh-Covered Stent CGuard in Patients Undergoing Carotid Artery Stenting: Early Experience From a Single Center" was an investigator-led, single-center study which evaluated CGuard EPS in 82 consecutive patients. The aim of the study was to evaluate the safety (technical success) and efficacy (clinical success) of the CGuard stent system – a new nitinol stent covered by a closed-cell polyethylene and terephthalate mesh designed to prevent embolic events. In 2017, the 30-day positive results were published online-ahead-of-print in the European Journal of Vascular and Endovascular Surgery (2017), https://doi.org/10.1016/j.ejvs.2017.09.015.

Key findings from the study are as follows:

- 100% success in implanting CGuard EPS;
- One case of acute stent thrombosis occurred within 4 hours of the procedure:
- One minor stroke was recorded within the peri-operative period following the acute stent thrombosis, mentioned above;
- No new adverse neurological events were recorded at the post-operative period.
- DW-MRI was performed to assess the occurrence of new ischaemic brain lesions from the target vessel following placement of the CGuard stent peri- (48-72 hours) and post-operatively (30 days) in 21 and 11 patients, respectively. Five of 21 patients (23.8%) had new ischaemic brain lesions peri-operatively (48-72 hours) on the ipsilateral side, for a total number of 30 lesions, with an average lesion volume of 0.039 +/- 0.025 cm3. Four patients (19.1%) had new ischaemic brain lesions on the contralateral side, for a total number of nine lesions, with an average lesion volume of 0.019 +/- 0.011 cm3 (range 0.016-0.034 cm3). At the postoperative period, spontaneous resolution was noted in all the lesions recorded in the peri-operative period in the 11 patients participating. Only one symptomatic patient had two new ischaemic brain lesions (1 ipsilateral and 1 contralateral).

CGUARD Mesh-Covered Stent in Real World: The IRON-Guard Registry

"CGUARD Mesh-Covered Stent in Real World: The IRON-Guard Registry using CGuard EPS" was a physician initiated prospective multi-center registry that included 200 patients from 12 medical centers in Italy. The objective of the study was to report 30-day outcomes (including MACCE) in a prospective series of patients who were treated with CGuard EPS between April 2015 and June 2016. In January 2017, 30-day results were presented at the Leipzig Interventional Course (LINC) 2017 and published in the Journal of EuroIntervention in May 2017. The 12 month follow-up was published in the Journal of EuroIntevention in October 2018.

Key 30-day results presented were:

- 100% success in implanting CGuard EPS;
- No MI, major stroke or death at 30 days;
- There were two transient ischemic attacks and five periprocedural minor strokes, including one thrombosis solved by surgery.
- Total elimination of post-procedural neurologic complications by 30 days;
- DW-MRI performed pre-procedure and between 24 and 72 hours post-procedure in 61 patients, indicated that 12 patients had new micro emboli (19%).
- At 12 months, there were no new major neurological adverse events, thrombosis or external carotid occlusion recorded;
- One myocardial infarction occurred at 12 months.

Initial Clinical Study of the New CGuard EPS MicroNet Covered Carotid Stent: "One Size Fits All"

"Initial Clinical Study of the New CGuard EPS MicroNet Covered Carotid Stent: 'One Size Fits All'" was an investigator-led, single-center study, which evaluated CGuard EPS in 30 consecutive patients with symptomatic stenosis of the internal carotid artery with the objective of evaluating the CGuard EPS MicroNet covered stent for its ability to adjust to different vessel diameters. The results of the study were published in the Journal of Endovascular Therapy in May 2019. The conclusion of the study as reported was that CGuard EPS has high conformability combined with an almost equivalent outward radial force at expansion diameters ranging from 5.5 to 9.0 mm. The first clinical results demonstrate the "One Size Fits All" stent can be implanted in internal carotid arteries with reference diameters within this range.

Key findings from the study were as follows:

- 100% technical success in implanting CGuard EPS;
- No neurological events within 30 days;
- The chronic outward force normalized by stent length demonstrated a near-equivalent radial force outcome; and
- The stent displayed only a minor difference between the minimal radial force at 9.0 mm (0.195 N/mm) and the maximal radial force at 5.5 mm (0.330 N/mm).

Preliminary Results from a Prospective Real-World Multicenter Clinical Practice of Carotid Artery Stenting Using the CGuard Embolic Prevention System: The IRONGUARD 2 Study

"Preliminary Results From a Prospective Real-World Multicenter Clinical Practice of Carotid Artery Stenting Using the CGuard Embolic Prevention System: The IRONGUARD 2 Study" is a physician initiated prospective multi-center registry enrolling 733 patients from 20 medical centers in Italy, from January 2017 to June 2019. The objective of the study is to evaluate periprocedural (24 hours), post-procedural (up to 30 days), and 12-month outcomes in a largest, prospective, multicenter series of patients submitted for protected carotid artery stenting with the CGuard Embolic Prevention System. The 24-hour, 30-day and 12-month preliminary results (data available on 726 patients out of the 733 treated) were presented at the Leipzig Interventional Course (LINC) in January 2021. The study's preliminary results from the IRONGUAURD 2 study suggested in a real-world evaluation of carotid artery stenting, Cguard EPS can be safely used for treatment of extracranial carotid artery stenosis, allowing a low rate of post procedural adverse events by 12 months.

Key findings from the study are as follows:

- 100% procedural success in implanting CGuard EPS;
- 1 death from hemorrhagic stroke (patient was admitted for immediate treatment of CAS due to stroke), 2 minor strokes, 6 TIAs and one nonfatal AMI at 24 hours;
- 1 minor stroke, 2 TIAs, three AMIs, no deaths and no stent thrombosis/occlusions between 24 hours and 30 days; and
- 1 minor stroke, 4 TIAs, 2 AMIs and 8 deaths (the 2 mentioned AMIs, 4 malignancies, 1 suicide and 1 undefined complication in Guillain-Barré Syndrome) between 30 days and 1 year.

Thirty-Day Results of the Novel CGuard-Covered Stent in Patients Undergoing Carotid Artery Stenting

"Thirty-Day Results of the Novel CGuard-Covered Stent in Patients Undergoing Carotid Artery Stenting" was an investigator-led, prospective single-center study which evaluated CGuard EPS in 103 patients that underwent carotid artery stenting procedures. The aim of the study was to provide early-term evaluation, safety, and efficacy of the novel CGuard micromesh self-expanding stent with embolic protection system (EPS). In April 2021, the 30-day positive results were published in the Journal of Endovascular Therapy, DOI: 10.1177/15266028211007466.

Key findings from the study are as follows:

- 100% technical success was achieved in all patients:
- No major adverse events (death, stroke, or myocardial infarction) at 30 days.

The SIBERIA Trial for Carotid Artery Stenosis: A Randomized Controlled Trial of Conventional Versus Micronet™-Covered Stent Use in Percutaneous Neuroprotected Carotid Artery Revascularization: Peri-procedural and 30-day Diffusion-Weighted Magnetic Resonance Imaging and Clinical Outcomes (RCT trial)

"The SIBERIA Trial for Carotid Artery Stenosis: A Randomized Controlled Trial of Conventional Versus Micronet™-Covered Stent Use in Percutaneous Neuroprotected Carotid Artery Revascularization: Peri-procedural and 30-day Diffusion-Weighted Magnetic Resonance Imaging and Clinical Outcomes" was an investigator-initiated randomized clinical trial, single-center study, which evaluated one hundred patients who qualified for carotid revascularization with high risk for surgery and were randomized 1:1 to either CGuard EPS or Acculink™. The primary endpoints were incidence and volume of new cerebral embolic post-procedural lesions (24-48 hours) as determined by diffusion weighted magnetic resonance imaging (DW-MRI). The principal secondary endpoints included incidence of periprocedural or postprocedural stroke, myocardial infarction and death at 30 days. The 30 day results of the study were presented in a late-breaking session at the EuroPCR in June 2020 and published (Randomized Controlled Trial of Conventional Versus MicroNet-Covered Stent in Carotid Artery Revascularization, JACC Cardiovascular Interventions, Vol. 14, November 21, 2021). The conclusion of the study was that the CGuard™ Micronet™-covered stent use in consecutive unselected patients subjected to neuroprotected carotid artery stenting was associated with a greater than three-fold reduction in the procedure-generated mean cerebral lesion volume, and with zero post-procedural cerebral embolisms observed. The MicroNet covered stent significantly reduced periprocedural and abolished post procedural cerebral embolism in relation to a conventional carotid stent. This is consistent with the MicroNet covered stent's sustained embolism prevention, translating into cerebral protection not only during but after carotid artery stenting. The incidence of restenosis and vessel occlusion according to the ICA (internal carotid artery) ultrasound and the incidence of strokes, myocardial infarctions or deaths between the study arms at 365 days were presented at the LINC conference in Leipzig, Germany in June , 2022. The 12 month outcomes demonstrated a significantly higher prevalence of the combined endpoint of death, stroke or myocardial infarctions and in-stent restenosis and vessel occlusion rate in the first generation (single layer) carotid stent, Acculink™, versus the MicroNet-Covered Stent, CGuard™.

Key findings from the study are as follows:

- Peri Procedure, the CGuard™ arm was observed to have a 57% reduction in new cerebral lesion average volume per patient (171 mm^3 vs. 73 mm^3), a statistically significant improvement (p=0.017) and 222 mm^3 vs. 84 mm^3 (p=0.038);
- Post Procedure (24-48 hours), the CGuard™ arm was observed to have a 78% reduction in the average volume of new cerebral lesions (157 mm^3 vs. 700 mm^3), a statistically significant improvement (p=0.007);
- At 30 days, DW-MRI showed zero new cerebral lessons in the CGuard™ arm versus six in the Acculink™ arm (p=0.03);
- At 30 days, there were zero strokes, myocardial infarctions or deaths in the CGuard arm and two events the Acculink™ arm (two strokes);
- At 365 there were zero cases of restenosis and vessel occlusion in the CGuard™ arm versus 3 cases of restenosis and 1 case of vessel occlusion in the Acculink™ arm;
- At 365 days, there were one event in the CGuard arm (one death) and five events the Acculink™ arm (two strokes, two deaths and one myocardial infarction).

Future Clinical Trials

Pre and post-marketing clinical trials (outside the United States) could be conducted to further evaluate the safety and efficacy of CGuard EPS in specific indications and new products, such as SwitchGuard. These trials would be designed to facilitate market acceptance and expand the use of the product.

Growth Strategy

Our primary business objective is to utilize our proprietary MicroNet technology and products to become the industry standard for treatment of stroke and complex vascular disease and to provide a superior solution to the common acute problems caused by current stenting procedures, such as restenosis, embolic showers and late thrombosis. We are pursuing the following business strategies to achieve this objective.

- **Widen the adoption of CGuard EPS**. We are seeking to expand the population of CGuard EPS patients in those countries in which CGuard EPS is commercially available. In particular, our focus is on establishing CGuard EPS as a viable alternative (in appropriate cases) to conventional carotid stents and vascular surgery within the applicable medical communities. We intend to accomplish this goal by continuing to publish and present our clinical data, support investigator-initiated clinical registries and exploring addition of a procedural protection device to our portfolio incorporating the principal of reverse flow of the carotid artery as an adjunctive alternative to femoral access. We have partnered and will continue to seek out partnerships with organizations focused on the treatment of stroke. We will also continue to engage advisory boards and to develop a network of key opinion leaders to assist us in our efforts to widen the adoption of CGuard EPS. We aim to be the only company focusing on the broadest category of sub specialists treating Carotid Artery Disease, both surgeons and interventional sub specialists and the only company offering both a TCAR and TFEM delivery option.

- **Portfolio expansion and pipeline development** We plan to continue to invest in advancing our portfolio with new delivery system alternatives to facilitate the use of CGuard by all physicians. We believe our delivery systems, if approved, will enable all endovascular access points including accessory devices for trans carotid artery revascularization**.**

- **Grow our presence in existing and new markets for CGuard EPS.** We have launched CGuard EPS in most European and Latin American countries through a comprehensive distributor sales organizations network. We are continuing to focus on larger growing markets through this network by supporting our distributors with a comprehensive marketing and clinical education programs. In additional we have begun to sell direct to hospitals in certain markets and continue to evaluate the transition to a direct selling to hospitals model in certain currently served distributor markets, increasing our control on the market and gross profit margins. We are pursuing additional product registrations and distribution contracts with local distributors in other countries in Europe, Asia and Latin America. In February 2021, we executed a distribution agreement with Chinese partners for the purpose of expanding our presence in China. Currently, we are seeking strategic partners for a potential launch of CGuard EPS in Japan and other Asian countries. In addition, we are conducting a pivotal study of our CGuard™ Carotid Stent System, C-Guardians, for prevention of stroke in patients in the United States.

- **CMS approval of National Coverage Determination** – During January 2023, CMS approved the first step of reimbursement of a national Coverage Decision for standard risk stent intervention of carotid disease. This decision has the potential to profoundly increase the available market to endovascular procedures as payment is pending for approval for a much boarder definition of surgical risk. Currently, only high-risk patients to surgery are paid through the CMS coverage, NCA - Percutaneous Transluminal Angioplasty (PTA) of the Carotid Artery Concurrent with Stenting (CAG-00085R8) - Tracking Sheet (cms.gov)

- **Continue to leverage our MicroNet technology to develop additional applications for interventional cardiologists and vascular surgeons.** In addition to the applications described above, we believe that we will eventually be able to utilize our proprietary MicroNet technology to address imminent market needs for new product innovations to significantly improve patients' care. We continue to broadly develop and protect intellectual property using our mesh technology. Examples of some areas include peripheral vascular disease and neurovascular disease.

- **Establish relationships with collaborative and development partners to fully develop and market our existing and future products.** We are seeking strategic partners for collaborative research, development, marketing, distribution, or other agreements, which could assist with our development and commercialization efforts for CGuard EPS and other potential products that are based on our MicroNet technology.

Competition

The markets in which we compete are highly competitive, subject to change and impacted by new product introductions and other activities of industry participants.

Carotid

With respect to competition for our carotid embolic prevention system, CGuard EPS™, the manufacturers of products used in connection with CAS procedures in the United States, is comprised of a number of large companies, including Abbott Laboratories, Boston Scientific Corporation, Covidien Ltd. (currently part of Medtronic, Inc.) and Cordis Corporation. In Europe, in addition to the above mentioned manufacturers, Terumo Medical Corporation is also a market participant that has a share of the market for products used in connection with CAS procedures. As we develop and seek regulatory approval in the United States and Europe for our new TCAR delivery system, SwitchGuard™, and continue to seek greater market share for CGuard EPS™, we expect to compete with Silk Road Medical in the total carotid artery revascularization market that comprises both CAS and carotid endarterectomy ("CEA").

Many of these companies are larger companies or divisions of publicly-traded companies that have certain competitive advantages, including greater capital resources, larger customer bases, broader product lines, larger sales forces, greater marketing and management resources, larger research and development staffs and larger facilities than ours and have established reputations, relationships with our target customers and worldwide distribution methods that are more effective than ours. However, while there are currently many market participants in the U.S. carotid stent market, we believe that the European market is somewhat more fragmented for CEA and CAS products, and, in our opinion, smaller competitors may be able to gain market share with greater flexibility and more efficiently than in the United States.

We believe the principal competitive factors in our market include the following:

- Patient outcomes and adverse event rates;
- Patient experience;
- Acceptance by treating physicians and referral sources;
- Physician learning curve;
- Ease-of-use and reliability;
- Patient recovery time and level of discomfort;
- Economic benefits and cost savings;
- Availability of reimbursement; and
- Strength of clinical evidence.

Sales and Marketing

Sales and Marketing

Based on the positive CGuard EPS clinical data, we initiated the commercial launch of CGuard EPS in CE marked countries in early 2015. In September 2015, we announced full market launch of CGuard EPS in Europe. Since 2017 we are focusing on sales of our products through local distribution partners and our own internal sales initiatives to gain greater reach into all the relevant clinical specialties and to expand our geographic coverage. Our current strategy seeks to broaden our sales efforts to increase CGuard EPS penetration within the community of interventionalists. In parallel, we aim at transitioning vascular surgeons from carotid endarterectomy procedures to carotid stenting with CGuard EPS and accessory devices, which we believe can greatly expand our customer base. We have focused and we plan to continue to focus our marketing efforts primarily on key growth markets and to evaluate opportunities in new territories if and when they become available. In addition, we are using international trade shows and industry conferences to gain market exposure and brand recognition. We continue to work with leading physicians to enhance our marketing effort and are developing relationships with new key opinion leaders to champion our technology and work with us in clinical studies. In additional we have begun to sell direct to hospitals in certain markets, such as France and the United Kingdom, in order to increase our growth in the market and gross profit margins.

Product Positioning

When treating carotid artery disease, we believe that CGuard has potential to become the standard of care in treading carotid artery disease. It is a second-generation stent with positive patient outcomes demonstrating significant reduction in post-procedural neurological events.

Additionally, we intend to continue to evaluate potential product enhancements and manufacturing enhancements for CGuard EPS expected to reduce cost of goods or provide the best-in-class performing delivery system and accessory solutions. We believe these improvements may allow us to reduce cost of goods and increase penetration in our existing geographies and better position us for entry into new markets. Finally, we do not expect that it would be crucial to use a drug-eluting stent platform to compete in certain new markets such as the neurovascular market, and hence, we plan to continue to explore this area of opportunity.

Insurance Reimbursement

In most countries, a significant portion of a patient's medical expenses is covered by third-party payors. Third-party payors can include both government-funded insurance programs and private insurance programs. While each payor develops and maintains its own coverage and reimbursement policies, payors, in many instances, have similarly established policies, and in the U.S., for example, coverage policies and reimbursement rates of private payors are often influenced by those established by the U.S. Department of Health and Human Services Centers for Medicare and Medicaid Services (CMS). The CGuard product sold to-date in applicable foreign countries have been designed and labeled to facilitate the utilization of existing reimbursement codes for such countries, and we intend to continue to design and label our present and future products in a manner consistent with this goal.

While most countries have established reimbursement codes for stenting procedures, certain countries may require additional clinical data before recognizing coverage and/or to obtain a certain level of reimbursement for one or more of our products. In these situations, we intend to complete the required clinical studies to obtain reimbursement approval in countries where it makes economic sense to do so.

Intellectual Property

Patents

We have 58 issued patents, including 16 patents issued in the U.S., and 17 pending patent applications, 6 of which are pending in the United States. Many of these patents and applications cover aspects of our CGuard and MGuard technology. Patents outside the U.S. have been filed in Canada, China, Europe, Israel, India, Japan, Australia, and South Africa. The patents and applications fall into a number of patent families, as listed below:

Base Title of Patent Family	Pending patent applications (Countries)	Issued patents (Country and Patent No.)	Issue Date
Bifurcated Stent Assemblies		US 8,961,586	02/24/2015
		China ZL200780046676.2	9/26/2012
Deformable Tip for Stent Delivery and Methods of Use		US 10,258,491	4/16/2019
		Israel 260,945	07/01/2020
Handle for Two-Stage Deployment of a Stent	US		
	EP		
	CN		
	JP		
	IN		
Shunts with Blood-Flow Indicators	US		
	PCT		
Device for Shunting Blood Between the Arterial and Venous Systems	PCT		
Devices for shunting blood	US		
In Vivo Filter Assembly		US 9,132,261	09/15/2015
Knitted Stent Jackets		Canada 2,666,728	6/23/2015
		Canada 2,887,189	5/1/2018
		China ZL200780046697.4	10/10/2012
		China ZL201210320950.3	12/2/2015
		EP 2076212	3/29/2017
		Germany, France, & UK	
		US 10,137,015	11/27/2018
		India 323792	10/28/2019
Optimized Stent Jacket	US		12/11/2018
		Canada 2,670,724	09/14/2021
		Canada 3,013,758	12/09/2015
		China ZL201210454357.8	01/02/2013
		China ZL200780043259.2	05/30/2018
		India 297,257	10/01/2020
		Israel 230,922	09/15/2015
		US 9,132,003	10/10/2017
		US 9,526,644	12/27/2016
		US 9,782,281	09/11/2018
		US 10,070,976	09/10/2019
		US 10,406,006	09/10/2019
		US 10,406,008	07/06/2021
		US 11,051,959	
		EP 2088962	10/11/2017
		(BE, CH, DE, FR, UK, IT, IE, LX, NL)	
		EP3292837	11/09/2022
		(UK, DE, FR, IE)	
Stent Apparatuses for Treatment Via Body Lumens and Methods of Use	US	South Africa 2007/10751	10/27/2010
	EPO	Canada 2,609,687	4/22/2014
		Canada 2,843,097	10/27/2015
		EP 1885281	2/13/2019
		(CH, DE, FR, GB, IE, IT)	
		US 10,932,926	03/02/2021
		US 10,058,440	8/28/2018
		US 10,070,977	9/11/2018
Stent Thermoforming Apparatus and Methods		JP 6553178	7/12/2019
		US 9,527,234	12/27/2016
		US 10,376,393	8/13/2019
		Australia 2015326517	05/21/2020
		Canada 2962713	02/19/2019
Methods or using a self-adjusting stent assembly and kits including the same	US (allowed)		
	EP	China ZL 2019800679437	05/03/2022
	IN		
	CN (div)		
	JP		

The patents and patent applications listed above cover various aspects of our products, specifically focusing on the mesh sleeve covering our stents, as well as methods for production and delivery mechanisms of the stents. We believe that our patents, in particular those covering the use of a knitted micron-level mesh sleeve over a stent for various indications, as well as our pending patent applications (if issued as patents with claims substantially in their present form), create a significant barrier against other companies seeking to use similar technology. We believe these patents and patent applications collectively cover all our existing products and may be useful in protecting our future technological developments. We intend to aggressively continue patenting new technologies and to actively pursue any infringement of our key patents.

Trade Secrets

We also rely on trade secret protection to protect our interests in proprietary know-how and/or for processes for which patents are difficult to obtain or enforce. As part of our trade secret policy, we rely on non-disclosure and confidentiality agreements with employees, consultants and other parties to protect trade secrets and other proprietary technology.

Trademarks

We have registered or applied to register the following trademarks, which we use in connection with our products:

- InspireMD® (US, European Union, and UK)
- MGuard® (European Union, and UK)
- CGuard® (US, European Union, and UK)
- MGuard Prime® (European Union, and UK)
- NGuard® (European Union and UK)
- PVGuard® (European Union, and UK)
- Micronet® (US)
- (MNP Micronet Protection logo) (European Union and UK)
- Carenet®)European Union and UK)
- SmartFit™ (US, UK and CN)
- SmartFit Logo (EP, UK, CN)
- CGuard Prime (EP, UK, US, CN, JP)
- SwitchGuard (EP, UK, US, JP)
- True North Medical (US, EP, UK)
- MicroMesh (US)
- MicroMesh logo (US, EP, UK CN, JP)
- Micronet logo (updated version) (US, EP, UK, CN, JP)

The trademarks are renewable indefinitely, so long as we continue using the marks and make the appropriate filings when required. We also use and may have common-law rights to various trademarks, trade names, and service marks.

Government Regulation

The manufacture and sale of our products are subject to regulation by numerous governmental authorities, principally the European Union CE mark and other corresponding foreign agencies.

Sales of medical devices outside the United States are subject to foreign regulatory requirements that vary widely from country to country. These laws and regulations range from simple product registration requirements in some countries to complex approval process, clinical trials and production controls in others. As a result, the processes and time periods required to obtain foreign marketing approval may be longer or shorter than those necessary to obtain FDA market authorization. These differences may affect the timeliness of international market introduction of our products. For the European Union nations, medical devices must obtain a CE mark before they may be placed on the market. In order to obtain and maintain the CE mark, we must comply with EU law on medical devices, which, until May 26, 2021 was governed by the MDD, by presenting comprehensive technical files for our products demonstrating safety and efficacy of the product to be placed on the market and passing initial and annual quality management system audit as per ISO 13485 standard by a European Notified Body. We have obtained ISO 13485 quality system certification and CGuard EPS that we currently distribute into the European Union, displays the required CE mark. In order to maintain certification, we are required to pass an annual surveillance audit conducted by Notified Body auditors. The European Union replaced the MDD with the new MDR regulation. The MDR entered into force after a transitional period of three years and a one year extension of that transition period due to the COVID-19 pandemic on May 26, 2021 and which changes several aspects of the regulatory framework in the European Union. Manufacturers had the duration of the transition period to update their technical documentation and processes to meet the new requirements in order to obtain a CE Mark.

In our specific case, our CE mark for CGuard EPS under the MDD expired on November 12, 2022, and we are in the final stages of technical documentation review by the Notified Body auditor to meet the MDR requirements for recertification. In the meantime, on February 14, 2023, we received a derogation per Article 97 paragraph 1 of Regulation 2017/745 from the Agency for Medicines and Health Products (FAMHP) allowing us to continue marketing CGuard EPS in the EU until August 15, 2023, subject to certain procedural requirements. Subsequently, on March 20, 2023, Regulation (EU) 2023/607 was published allowing us to continue marketing CGuard EPS in EU countries under the MDD directive until December 31, 2027. As a result of the foregoing, we may market and sell CGuard EPS in the EU and certain other jurisdictions subject to certain procedural requirements while our MDR CE recertification is pending. We continue to expedite the review process for recertification under the MDR.

We have or had regulatory approval and made sales of CGuard EPS either through distributors pursuant to distribution agreements or directly, in the countries listed in the table below. While each of the European Union member countries accepts the CE mark as its sole requirement for marketing approval, some of these countries still require us to take additional steps in order to gain reimbursement rights for our products. Furthermore, while we believe that certain of the below-listed countries that are not members of the European Union and accept the CE mark as a primary requirement for marketing approval, each such country requires additional regulatory requirements for final marketing approval of our products. Furthermore, we are currently targeting additional countries in Europe, Asia, and Latin America; however, even if all governmental regulatory requirements are satisfied in each such country, we anticipate that obtaining marketing approval in each country could take as few as three months or as many as twelve months or more, due to the nature of the approval process in each individual country, including typical wait times for application processing and review, as discussed in greater detail below.

Please refer to the table below setting forth the approvals and sales made for CGuard EPS on a country-by-country basis

Approvals and Sales of CGuard EPS on a Country-by-Country Basis*

Countries	CGuard EPS Approval	CGuard EPS Sales
Argentina	Y	Y
Australia	N	Y(2)
Austria	Y	Y
Belarus	Y	Y
Belgium	Y	Y
Brazil	Y	Y
Bulgaria	N	N
Chile	N	N
Colombia	Y	Y
Croatia	Y	N
Cyprus	Y	Y
Czech Republic	Y	Y
Denmark	Y	N
Dominican Republic	N	N
Ecuador	Y	N
Estonia	Y	Y
Finland	Y	Y
France	Y	Y
Germany	Y	Y
Greece	Y	Y
Netherlands	Y	Y
Hong Kong	N	N
Hungary	Y	Y
Iceland	Y	N
India	Y	Y
Ireland	Y	Y
Israel	Y	Y
Italy	Y	Y
Kazakhstan	Y	Y
Latvia	Y	Y
Lithuania	Y	Y
Liechtenstein	Y	N
Luxembourg	Y	N
Malaysia	N	N
Malta	Y	N
Mexico	Y	Y
Montenegro	N	N
New Zealand	N	N
Norway	Y	N
Peru	N	Y(2)
Poland	Y	Y
Portugal	Y	Y
Romania	Y	Y
Russia	Y	Y
Saudi Arabia	N	N
Serbia	Y	Y
Slovakia	N	N
Slovenia	Y	Y
South Africa	Y	Y
Spain	Y	Y
Sweden	Y	Y
Switzerland	Y	Y
Turkey	N	N
Taiwan	Y	Y
Venezuela	N	N
Vietnam	N	Y(2)
Ukraine	Y	Y
United Kingdom	N(3)	Y(2)
United States	N	Y(1)

* As discussed elsewhere, our CE mark for the marketing and sale of CGuard EPS in the EU under the MDD expired on November 12, 2022 and was reinstated during March 2023.

(1) Refers to units used in our ongoing FDA trial.
(2) CGuard EPS approval to sell expired during prior twelve months.
(3) The FAMHP derogation does not apply.

FDA Government Regulation of Medical Devices for Human Subjects

Many of our activities are subject to regulatory oversight by the FDA under provisions of the Federal Food, Drug, and Cosmetic Act and regulations thereunder, including regulations governing the development, marketing, labeling, promotion, manufacturing, and export of medical devices.

FDA Approval/Clearance Requirements

In the United States, most Class II or III medical devices must be cleared or approved by the FDA prior to commercialization. Unless an exemption applies, each medical device that we market or wish to market in the United States must receive 510(k) clearance or premarket approval. Medical devices that are class II devices receive 510(k) clearance are "cleared" by the FDA to market, distribute, and sell in the United States. Medical devices that are class III devices obtain a premarket approval by the FDA are "approved" to market, distribute, and sell in the United States. We anticipate filing a premarket approval application, or PMA, in the future for our product and do not anticipate filing a 510(k) premarket notification, provided that the FDA will not instruct us otherwise. We cannot guarantee that we will obtain premarket approval, which will likely include clinical testing. Descriptions of the premarket approval and 510(k) clearance processes are provided below.

Class I devices are those for which safety and effectiveness can be assured by adherence to the FDA's general regulatory controls for medical devices, or the General Controls, which include compliance with the applicable portions of the FDA's quality system regulations, facility registration and product listing, reporting of adverse medical events, and appropriate, truthful and non-misleading labeling, advertising, and promotional materials. Some Class I devices also require premarket clearance by the FDA through the 510(k) process described below.

Class II devices are subject to the FDA's General Controls, and any other special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) process. Pursuant to the Medical Device User Fee and Modernization Act of 2002 (MDUFMA), as of October 2002, unless a specific exemption applies, 510(k) submissions are subject to user fees. Certain Class II devices are exempt from this premarket review process. The FDA has recently indicated that it intends to modernize the 510(k) process and has issued new guidance documents that may change the way that devices are cleared by the FDA.

Class III includes devices with the greatest risk. Devices in this class must meet all of the requirements in Classes I and II. In addition, Class III devices cannot generally be marketed until they receive a premarket approval. The safety and effectiveness of Class III devices cannot be assured solely by the General Controls and the other requirements described above. These devices require formal clinical studies to demonstrate safety and effectiveness. Under MDFUMA, PMAs (and supplemental PMAs) are subject to significantly higher user fees than 510(k) applications, and they also require considerably more time and resources.

The FDA decides whether a device line must undergo either the 510(k) clearance or premarket approval based on statutory criteria that utilize a risk-based classification system. Premarket approval is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices and, in many cases, Class II medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. The FDA uses these criteria to decide whether a premarket approval or a 510(k) is appropriate, including the level of risk that the agency perceives is associated with the device and a determination by the agency of whether the product is a type of device that is similar to devices that are already legally marketed. Devices deemed to pose relatively less risk are placed in either Class I or II. In many cases, the FDA requires the manufacturer to submit a 510(k) requesting clearance (also referred to as a premarket notification), unless an exemption applies. The 510(k) must demonstrate that the manufacturer's proposed device is "substantially equivalent" in intended use and in safety and effectiveness to a legally marketed predicate device. A "predicate device" is a pre-existing medical device to which equivalence can be drawn, that is either in Class I, Class II, or is a Class III device that was in commercial distribution before May 28, 1976, for which the FDA has not yet called for submission of a PMA. A product that lacks a predicate device will default to a Class III device, although a company may seek to submit a De Novo classification request, rather than a PMA. The De Novo request allows a regulatory pathway to classify novel medical devices for which general controls alone, or general and special controls, provide reasonable occurrence of safety and effectiveness for the intended use, but for which there is no legally marketed predicate device.

We expect that unless an exemption applies, each medical device that we market or wish to market in the United States must receive 510(k) clearance or premarket approval. Medical devices that receive 510(k) clearance are "cleared" by the FDA to market, distribute, and sell in the United States. Medical devices that obtain a premarket approval by the FDA are "approved" to market, distribute, and sell in the United States. We anticipate that each device that we wish to commercialize will be considered a Class III device by the FDA and therefore we anticipate filing a PMA in the future and do not anticipate filing a 510(k) premarket notification, provided that the FDA will not instruct us otherwise. We cannot guaranty that we will obtain a premarket approval. Descriptions of the premarket approval and 510(k) clearance processes are provided below.

Premarket Approval Pathway

We expect that current and future applications of our technology will result in medical devices that are considered Class III devices subject to premarket approval. A PMA must be submitted if a device cannot be cleared through the 510(k) process, unless FDA permits a De Novo application. A PMA must be supported by extensive data including, but not limited to, analytical, preclinical, clinical trials, manufacturing, statutory preapproval inspections, and labeling to demonstrate to the FDA's satisfaction the safety and effectiveness of the device for its intended use. Before a premarket approval application is submitted, a manufacturer must apply for an Investigational Device Exemption (IDE) to conduct clinical trials. If the device presents a "significant risk," as defined by the FDA, to human health, the FDA requires the device sponsor to file an IDE application with the FDA and obtain IDE approval prior to initiation of enrollment of human subjects for clinical trials. The IDE provides the manufacturer with a legal pathway to perform clinical trials on human subjects where without the IDE, only approved medical devices may be used on human subjects.

The IDE application must be supported by appropriate data, such as analytical, animal and laboratory testing results, manufacturing information, and an Investigational Review Board (IRB) approved protocol showing that it is safe to test the device in humans and that the testing protocol is scientifically sound, as well as ensuring patient informed consent is obtained. If the clinical trial design is deemed to have "non-significant risk," the clinical trial may be eligible for "abbreviated" IDE requirements.

A clinical trial may be suspended by either the FDA or the IRB at any time for various reasons, including a belief that the risks to the study participants outweigh the benefits of participation in the study. Even if a study is completed, clinical testing results may not demonstrate the safety and efficacy of the device, or they may be equivocal or otherwise insufficient to obtain approval of the product being tested. After the clinical trials have been completed, if at all, and the clinical trial data and results are collected and organized, a manufacturer may complete a premarket approval application.

After a PMA is sufficiently complete, the FDA will accept the application and begin an in-depth review of the submitted information. By statute, the FDA has 180 days to review the "accepted application," although, generally, review of the application can take between one and three years, but it may take significantly longer. During this review period, the FDA may request additional information or clarification of information already provided. Also, during the review period, 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 preapproval inspections conducted by the FDA include an evaluation of the manufacturing facility to ensure compliance with the Quality Systems Regulations, as well as inspections of the clinical trial sites by the Bioresearch Monitoring group to evaluate compliance with good clinical practice and human subject protections. New premarket approval applications or premarket approval supplements are required for modifications that affect the safety or effectiveness of the device, including, for example, certain types of modifications to the device's indication for use, manufacturing process, labeling and design. Significant changes to an approved premarket approval require a 180-day supplement, whereas less substantive changes may utilize a 30-day notice, or a 135-day supplement. Premarket approval supplements often require submission of the same type of information as a premarket approval application, except that the supplement is limited to information needed to support any changes from the device covered by the original premarket approval application, and it may not require as extensive clinical data or the convening of an advisory panel.

510(k) Clearance Pathway

We do not currently market, distribute, or sell any products that have market clearance by the FDA under its 510(k) process. If, in the future, we develop products where 510(k) clearance is required, we would be required to submit a 510(k) demonstrating that such proposed devices are substantially equivalent to a respective previously cleared 510 (k) device or a device that was in commercial distribution before May 28, 1976, for which the FDA has not yet called for the submission of 510(k). The FDA's 510(k) clearance pathway usually takes from three to twelve months but could take longer. In some cases, the FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence.

If a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, will require a new 510(k) clearance or, depending on the modification, a premarket approval. The FDA requires each device manufacturer to determine whether the proposed change requires submission of a new 510(k) or a premarket approval, but the FDA can review any such decision and can 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 recall the modified device until 510(k) clearance or premarket approval of the modified device is obtained.

Pervasive and Continuing FDA Regulation

A host of regulatory requirements apply to our approved devices, including the quality system regulation (which requires manufacturers to follow elaborate design, testing, control, documentation and other quality assurance procedures), the Medical Device Reporting regulations (which require that manufacturers report to the FDA specified types of adverse events involving their products), labeling regulations, and the FDA's general prohibition against promoting products for unapproved or "off-label" uses. Class II devices also can have special controls such as performance standards, post-market surveillance, patient registries, and certain FDA guidelines do apply to Class I devices.

A noncomprehensive list of the regulatory requirements that apply to our approved products classified as medical devices include:

- product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;
- Quality Systems Regulations, which requires manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the development and manufacturing process;

- labeling regulations and FDA prohibitions against the promotion of products for uncleared, unapproved or off-label use or indication;
- clearance of product modifications that could significantly affect safety or efficacy or that would constitute a major change in intended use of one of our cleared devices (if obtained);
- approval of product modifications that affect the safety or effectiveness of one of our cleared devices (if obtained);
- medical device reporting regulations, which require that manufacturers comply with FDA requirements to report if their device may have caused or contributed to a death or serious injury, or has malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the device or a similar device were to recur;
- post-approval restrictions or conditions, including post-approval study commitments;
- post-market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device;
- the FDA's recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of governing laws and regulations;
- regulations pertaining to voluntary recalls; and,
- notices of corrections or removals.

We do not currently have a registered establishment with the FDA. If we are approved or cleared to manufacture, prepare, or process a device in the United States, we and any third-party manufacturers that we may use will be required to register our establishments with the FDA. As such, we and our manufacturing facilities will be subject to FDA inspections for compliance with the FDA's Quality System Regulation. Additionally, some of our subcontractors may also be subject to FDA announced and unannounced inspections for compliance with the FDA's Quality System Regulation. These regulations will require that we manufacture our products and maintain our documents in a prescribed manner with respect to design, manufacturing, testing and quality control activities. As a medical device manufacturer, we will further be required to comply with FDA requirements regarding the reporting of adverse events associated with the use of our medical devices, as well as product malfunctions that would likely cause or contribute to death or serious injury if the malfunction were to recur. FDA regulations also govern product labeling and prohibit a manufacturer from marketing a medical device for unapproved applications.

Our CGuard EPS is classified as a Class III medical device by the FDA. Class III medical devices are generally the highest risk devices and are therefore subject to the highest level of regulatory control by the FDA, since the FDA process of premarket approval involves scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices for the purpose(s) intended. The FDA will either approve or deny a premarket approval application and we cannot market a device unless or until the FDA approves a premarket approval application.

We expect the approval process in the U.S. to take a significant amount of time, require the expenditure of significant resources, involve rigorous clinical investigations and testing, and potentially require changes to products. The approval process may result in limitations on the indicated uses of the medical devices for which we are able to obtain approval (since the FDA can take action against a company that promotes off-label uses) and will also require increased post-market surveillance.

U.S. Healthcare Laws and Regulations

In addition to the FDA regulations, there are a variety of other healthcare laws and regulations to which we may be subject if any of our products are marketed, sold, distributed, and/or utilized in the United States. In the United States, we may be subject to the oversight of FDA, Office of the Inspector General within the Department of Health and Human Services (OIG), the Center for Medicare/Medicaid Services (CMS), the Department of Justice (DOJ), in addition to others. We supply products that may be reimbursed by federally funded programs such as Medicare. As a result, our activities may be subject to regulation by CMS and enforcement by OIG and DOJ. Of specific note are federal and state fraud and abuse laws, which prohibit the payment or receipt of kickbacks, bribes or other remuneration, including the offer or solicitation of such payment, intended to induce or reward the purchase, recommendation or generation of business involving healthcare products any item or service payable by a health-care program. Other provisions of federal and state laws prohibit presenting, or causing to be presented, to third party payors (including, government programs, such as Medicare and Medicaid) for reimbursement, claims that are false or fraudulent, or which are for items or services that were not provided as claimed. In addition, other healthcare laws and regulations may apply, such as transparency and reporting requirements, and privacy and security requirements. Violations of these laws can lead to civil and criminal penalties, including exclusion from participation in federal and state healthcare programs, any of which could have a material adverse effect on our business. These laws are potentially applicable to manufacturers of products regulated by the FDA as medical devices, such as us, and hospitals, physicians and other institutional or individual providers that may refer or purchase such products. The healthcare laws that may be applicable to our business or operations include, but are not limited to:

- The federal Anti-Kickback Statute, which prohibits a person from knowingly and willfully offering, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for or to induce referring or recommending an individual to another person to receive items or services or to purchase, lease, order, or arrange for any good, facility, item or service payable in whole or in part under a Federal health care program;

- Federal false claims laws and civil monetary penalty laws, including the False Claims Act, prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid or other government healthcare programs that are false or fraudulent, or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. 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 health care program, knowingly makes, uses or causes to be made or used, a false record or statement material to a false or fraudulent claim, or knowingly makes a false statement to avoid, decrease or conceal an obligation to pay money to the U.S. federal government. The federal Civil Monetary Penalties Law prohibits, among other things, the offering or transferring of remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary's selection of a particular supplier of Medicare or Medicaid payable items or services;

- The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which includes provisions that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, and for knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and its implementing regulations, also imposes obligations and requirements on healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform certain services for them that involve the use or disclosure of individually identifiable health information, with respect to safeguarding the privacy and security of certain individually identifiable health information;

- The federal transparency requirements under the Affordable Care Act, including the provision commonly referred to as the Open Payments Act or Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics and medical supplies that are reimbursable under Medicare, Medicaid or Children's Health Insurance Program to report annually to Centers for Medicare and Medicaid Services, or CMS, information related to payments and other transfers of value to physicians and teaching hospitals, and ownership and investment interests held by physicians and their immediate family members; and

- Analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may be broader in scope and apply to referrals and items or services reimbursed by both governmental and non-governmental third-party payors, including private insurers, many of which differ from each other in significant ways and often are not preempted by federal law, thus complicating compliance efforts.

Customers

Our customer base is varied. We currently have distribution agreements for our CE mark-approved CGuard EPS with medical product distributors based in Europe, the Middle East, Asia Pacific and Latin America. We are currently in discussions with additional distribution companies in Europe, Asia, and Latin America.

Most of our current agreements with our distributors stipulate that, and we expect our future agreements with our distributors to stipulate that, while we shall assist in training by providing training materials, marketing guidance, marketing materials, and technical guidance, each distributor will be responsible for carrying out local registration, sales and marketing activities. In addition, in most cases, all sales costs, including sales representatives, incentive programs, and marketing trials, will be borne by the distributor. Under current agreements, distributors purchase stents from us at a fixed price. Our current agreements with distributors are generally for a term of two to three years.

On February 3, 2021, we entered into a Distribution Agreement with three China-based partners, pursuant to which the Chinese partners will be responsible for conducting the necessary registration trials for commercial approval of our products in China, followed by an exclusive distribution right to sell our products in China. Under the Distribution Agreement, the China-based partners will be subject to minimum purchase obligations.

We have also engaged in direct sales in certain geographic markets such as United Kingdom and France.

Manufacturing and Suppliers

The polymer fiber for MicroNet is supplied by Biogeneral, Inc., a San Diego, California-based specialty polymer manufacturer for medical and engineering applications.

Our catheter supplier for CGuard EPS supplies us with catheters that help create the base for our CGuard EPS stents. Our agreement with with the supplier may be terminated by us upon eight months' notice. On September 17, 2019, we amended the agreement with the supplier so that we are responsible for purchasing and handling inventory of CGuard EPS delivery system, and they are responsible for the manufacturing process.

Our catheter supplier for CGuard Prime supplies us with catheters that help create the base for our CGuard Prime. Our agreement with the supplier which may be terminated by us upon 9 months' notice, calls for non-binding minimum orders.

We manufacture our CGuard EPS and our CGuard Prime at our own facility. The self-expanding bare-metal stents for our CGuard EPS and our CGuard Prime are being manufactured and supplied by a supplier. Our agreement with the supplier for the production of electro polished L605 bare-metal stents for CGuard EPS and CGuard Prime is priced on a per-stent basis, subject to the quantity of stents ordered. The complete assembly process for CGuard EPS and CGuard Prime, including knitting and securing the sleeve to the stent and the crimping of the sleeve stent on to a delivery catheter, is done at our Israel manufacturing site. Once CGuard EPS and CGuard Prime have been assembled, they are sent for sterilization in a third-party facility in Israel, and then back to our facility for final packaging and distribution.

A CGuard EPS and CGuard Prime consists of a CGuard stent and the delivery system. Each CGuard stent is manufactured from two main components, a self-expending nickel-titanium stent and the mesh polymer. This material is readily available and we acquire it in the open market. The mesh is made from polyethylene terephthalate (polyester). We have patent rights that cover the proposed CGuard stent with mesh. During the last year our mesh supplier informed us that it will not be able to supply the polymer fiber in the future due to issues with raw materials, therefore we purchased inventory which should be sufficient to support our production needs in the next 2.5 years. We are currently in the process of finding and qualifying another supplier or other material source which could take up to a year. The delivery system for CGuard is made out of polymer tubes we acquire from an original equipment manufacturer. In the event that our supplier can no longer supply this material, we would need to qualify another supplier, which could take up to a year. In addition, in order to retain the approval of the CE mark, we are required to perform periodic audits of the quality control systems of our key suppliers in order to ensure that their products meet our predetermined specifications.

Properties

Our headquarters are located in Tel Aviv, Israel, where we lease a 1,250 square meter office and manufacturing facility that has the capacity to manufacture and assemble 1,750 stents per month, based upon the production schedule of one shift per day. We believe that our current facility is sufficient to meet anticipated future demand by adding additional shifts to our current production schedule.

Human Capital Management

As of December 31, 2022, we had 56 employees, 55 full-time and 1 part-time, consisting of 2 in executive management, 6 in research and development, 8 in quality assurance and compliance, 5 in finance and accounting, 21 in operations/production, 12 in sales, marketing and clinical, and 2 in all other miscellaneous roles, Human resources, and administration. Except for 5 of our employees in Europe, our employees are not party to any collective bargaining agreements. We do not expect the collective bargaining agreements to which our employees are party to have a material effect on our business or results of operations. We also employ 3 independent contractors in Poland and 1 in Brazil.

We believe that our future success will depend, in part, on our continued ability to attract, hire and retain qualified personnel. In particular, we depend on the skills, experience and performance of our senior management and research personnel. We compete for qualified personnel with other medical device, biotechnology, pharmaceutical and healthcare companies, as well as universities and non-profit research institutions.

We provide competitive compensation and benefits programs to help meet the needs of our employees. In addition to salaries, these programs (which vary by country/region and employment classification) include incentive compensation plan, pension, healthcare and insurance benefits, paid time off, family leave, and on-site services, among others. We also use targeted equity-based grants with vesting conditions to facilitate retention of personnel, particularly for our key employees.

We consider our relations with our employees to be good.

Item 1A. Risk Factors.

There are numerous and varied risks, known and unknown, that may prevent us from achieving our goals. You should carefully consider the risks described below and the other information included in this Annual Report on Form 10-K, including the consolidated financial statements and related notes. If any of the following risks, or any other risks not described below, actually occur, it is likely that our business, financial condition, and/or operating results could be materially adversely affected. The risks and uncertainties described below include forward-looking statements and our actual results may differ from those discussed in these forward-looking statements.

Summary Risk Factors

Our business is subject to numerous risks and uncertainties, including those highlighted in the section titled “Risk Factors” immediately following this prospectus summary. These risks include, among others, the following:

- we have a history of net losses and may experience future losses;
- our history of recurring losses and negative cash flows from operating activities, significant future commitments and the uncertainty regarding the adequacy of our liquidity to pursue our complete business objectives, and substantial doubt regarding our ability to continue as a going concern;

- we will need to raise additional capital to meet our business requirements in the future, and such capital raising may be costly or difficult to obtain and could dilute our stockholders' ownership interests;

- failure to satisfy regulatory requirements of the new European Medical Device Regulation may prevent us from marketing CGuard EPS in countries requiring the CE mark.

- we may become subject to claims by much larger and better capitalized competitors enforcing their intellectual property rights against us or seeking to invalidate our intellectual property or our rights thereto;

- completing clinical trials for CGuard EPS in the United States require meeting a number of regulatory requirements and must be conducted in compliance with the FDA's IDE regulations. Failure to maintain compliance with IDE regulations could have a material adverse effect on our business;

- clinical trials necessary to support a pre-market approval application will be lengthy and expensive and will require the enrollment of a large number of patients, and suitable patients may be difficult to identify and recruit. Any such delay or failure of clinical trials could prevent us from commercializing our stent products, which would materially and adversely affect our results of operations and the value of our business;

- the results of our clinical trials may be insufficient to obtain regulatory approval for our product candidates;

- our products may in the future be subject to product notifications, recalls, or voluntary market withdrawals that could harm our reputation, business and financial results;

- we may be subject, directly or indirectly, to applicable U.S. federal and state anti-kickback, false claims laws, physician payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings;

- we may be exposed to product liability claims and insurance may not be sufficient to cover these claims;

- even if one or more of our products are approved by the FDA, we may fail to obtain an adequate level of reimbursement for our products by third party payors, such that there may be no commercially viable markets for our products or the markets may be much smaller than expected;

- in the United States and European Union, our business could be significantly and adversely affected by healthcare reform initiatives and/or other legislation or judicial interpretations of existing or future healthcare laws and/or regulations;

- if we are unable to obtain and maintain intellectual property protection covering our products, others may be able to make, use or sell our products, which would adversely affect our revenue;

- we are an international business, and we are exposed to various global and local risks that could have a material adverse effect on our financial condition and results of operations venue;

- our business, operating results and growth rates may be adversely affected by current or future unfavorable economic and market conditions and adverse developments with respect to financial institutions and associated liquidity risk;

- there are inherent limitations in all control systems, and misstatements due to error or fraud may occur and not be detected;

- we anticipate being subject to fluctuations in currency exchange rates because we expect a substantial portion of our revenues will be generated in Euros and U.S. dollars, while a significant portion of our expenses will be incurred in New Israeli Shekels;

- if there are significant shifts in the political, economic and military conditions in Israel and its neighbours, it could have a material adverse effect on our business relationships and profitability;

- it may be difficult for investors in the United States to enforce any judgments obtained against us or some of our directors or officers;

- the market prices of our common stock and our publicly traded warrants are subject to fluctuation and have been and may continue to be volatile, which could result in substantial losses for investors; and

- our common stock could be delisted from the Nasdaq Stock Market if we fail to meet its continued listing requirements, including requirements with respect to the market value of publicly-held-shares, market value of listed shares, minimum bid price per share, and minimum stockholder's equity, among others, and requirements relating to board and committee independence.

Risks Related to Our Financial Condition

We have a history of net losses and may experience future losses.

We have yet to establish any history of profitable operations. We reported a net loss of $18.5 million for the fiscal year ended December 31, 2022, and had a net loss of approximately $14.9 million during the fiscal year ended December 31, 2021. As of December 31, 2022, we had an accumulated deficit of $202 million. We expect to incur additional operating losses for the foreseeable future. There can be no assurance that we will be able to achieve sufficient revenues throughout the year or be profitable in the future.

Management has concluded that there is substantial doubt about our ability to continue as a going concern, and the report of our independent registered public accounting firm contains an explanatory paragraph as to our ability to continue as a going concern, which could prevent us from obtaining new financing on reasonable terms or at all.

Because we have had recurring losses and negative cash flows from operating activities, substantial doubt exists regarding our ability to remain as a going concern at the same level at which we are currently performing. Accordingly, the report of Kesselman & Kesselman, our independent registered public accounting firm, with respect to our financial statements for the year ended December 31, 2022, includes an explanatory paragraph as to our potential inability to continue as a going concern. The doubts regarding our potential ability to continue as a going concern may adversely affect our ability to obtain new financing on reasonable terms or at all.

We will need to raise additional capital to meet our business requirements in the future, and such capital raising may be costly or difficult to obtain and could dilute our stockholders' ownership interests.

In order for us to pursue our business objectives without materially curtailing our operations, we will need to raise additional capital, which additional capital may not be available on reasonable terms or at all. For instance, we will need to raise additional funds to accomplish the following:

- furthering our efforts to ultimately seek the FDA approval for commercial sales of CGuard EPS in the United States;

- development of our current and future products, including CGuard EPS enhancements;

- pursuing growth opportunities, including more rapid expansion and funding regional distribution systems;

- making capital improvements to improve our infrastructure;

- hiring and retaining qualified management and key employees;

- responding to competitive pressures;

- complying with regulatory requirements such as licensing and registration; and

- maintaining compliance with applicable laws.

Any additional capital raised through the sale of equity or equity-backed securities may dilute our stockholders' ownership percentages and could also result in a decrease in the market value of our equity securities.

The terms of any securities issued by us in future capital transactions may be more favorable to new investors, and may include preferences, superior voting rights and the issuance of warrants or other derivative securities, which may have a further dilutive effect on the holders of any of our securities then outstanding.

In addition, we may incur substantial costs in pursuing future capital financing, including investment banking fees, legal fees, accounting fees, securities law compliance fees, printing and distribution expenses and other costs. We may also be required to recognize non-cash expenses in connection with certain securities we issue, such as convertible notes and warrants, which may adversely impact our financial condition.

Risk Related to Commercialization of Our Products

While we derive most of our revenue from the sale of CGuard EPS in CE marked countries, our ability to generate significant revenues and achieve profitability depends, among other things, on our ability to receive FDA approval of CGuard EPS and other products we may develop, such as CGuard Prime™ and SwitchGuard™. If we fail to obtain FDA approval for CGuard EPS or any other products we may develop, our results of operations and the value of our business would be materially and adversely affected.

We derive most of our revenue from sales of our CGuard EPS in CE marked countries and certain other select jurisdictions. We have not received approvals in the United States and other jurisdictions and there can be no assurance that we will be able to receive regulatory approvals to commence marketing and sales for our CGuard EPS and other products we may develop, such as CGuard Prime™ and SwitchGuard™ in the United States or in such other jurisdictions. Our ability to generate significant revenues and achieve profitability depends on our ability to successfully obtain required regulatory approvals in the U.S. as well as to demonstrate sufficient clinical evidence and manufacture commercial quantities of our CGuard EPS or any other products we may develop at an acceptable cost. In addition, there may be insufficient demand for CGuard EPS or any other products we develop, such as CGuard Prime™ and SwitchGuard™. If we fail to generate sufficient revenues from these products, our results of operations and the value of our business and securities would be materially and adversely affected.

The future success of our business cannot be determined at this time, and we do not anticipate generating significant revenues from product sales for the foreseeable future. In addition, we have no experience in commercializing our CGuard EPS on a mass scale and face a number of challenges with respect to our commercialization efforts, including, among others, that:

- we may not have adequate financial or other resources to demonstrate adequate clinical results, attain required regulatory approvals and licensures, and begin the commercialization efforts for our CGuard EPS in our target markets;
- we may fail to obtain or maintain required regulatory approvals and licensures for our CGuard EPS in our target markets or may face adverse regulatory or legal actions relating to our products even if regulatory approval is obtained;
- we may not demonstrate adequate clinical safety and clinical effectiveness results from our CGuard EPS, to support regulatory body approval or market acceptance and adoption;
- we may not be able to scale up the manufacture of our CGuard EPS to commercial quantities at an adequate quality or at an acceptable cost;
- we may not be able to establish adequate sales, marketing and distribution channels;

- healthcare professionals and patients may not accept our CGuard EPS;
- other technological may reduce the demand for our CGuard EPS;
- new alliances between existing market participants and the entrance of new market participants may interfere with our market penetration efforts;
- government and private third-party payors may not agree to provide coding, coverage and payment adequate to reimburse healthcare providers and patients for any or all of the purchase price of CGuard EPS, which may adversely affect healthcare providers' and patients' willingness to purchase our C-Scan system;
- uncertainty as to market demand may result in inefficient pricing of our CGuard EPS;
- we may not be able to adequately protect our intellectual property or may face third-party claims of intellectual property infringement; and
- we are dependent upon the results of ongoing clinical studies relating to our CGuard EPS and the products of our competitors.

If we are unable to meet any one or more of these challenges successfully, our ability to effectively commercialize our CGuard EPS system could be limited, which in turn could have a material adverse effect on our business, financial condition and results of operations.

Although we are nearing completion of enrollment in our C-Guardian trial of CGuard EPS study, the outcome of the study is inherently uncertain.

On September 8, 2020, we received approval from the FDA of our IDE for C-Guardian trial of CGuard EPS and we expect to complete enrollment in the second quarter of 2023. Clinical failure can occur at any stage of clinical development. Our clinical trials have been conducted under differing protocols, while using specific inclusion criteria and we cannot assure you that its actual clinical performances will be satisfactory to support proposed indications and regulatory approvals and clinical acceptance and adoption, or that its use will not result in unanticipated complications. Furthermore, the results of our clinical trials are subject to human analyses and interpretation of the data accumulated, which could be affected by various errors due to, among others, lack of sufficient clinical experience with CGuard EPS, assumptions used in the statistical analysis of results, and interpretation errors in the analysis of the clinical trials results. Failure can occur at any time during the clinical trial process. If CGuard EPS does not function as expected over time, we may not achieve regulatory clearances, and may not be widely adopted by healthcare providers and patients.

Physicians may not widely adopt our products unless they determine, based on experience, long-term clinical data and published peer reviewed journal articles, among other standard-of-care considerations, that the use of our stents provides a safe and effective alternative to other existing treatments for coronary artery disease and carotid artery disease.

We believe that physicians will not widely adopt our products unless they determine, based on experience, long-term clinical data, published peer reviewed journal articles and payor coverage policies, among other factors, that the use of our products provide a safe and effective alternative to other existing treatments for the conditions we are seeking to address.

If we fail to demonstrate safety and efficacy that is at least comparable to existing and future therapies available on the market, our ability to successfully market our products will be significantly limited. Even if the data collected from clinical studies or clinical experience indicate positive results, each physician's actual experience with our products will vary. Clinical trials conducted with our products may involve procedures performed by physicians who are technically proficient and are high-volume stent users of such products. Consequently, both short-term and long-term results reported in these clinical trials may be significantly more favorable than typical results of practicing physicians, which could negatively affect rates of adoptions of our products. We also believe that published peer-reviewed journal articles and recommendations and support by influential physicians regarding our products will be important for market acceptance and adoption, and we cannot assure you that we will receive these recommendations and support, or that supportive articles will be published.

Failure to satisfy regulatory requirements of the new European Medical Device Regulation may prevent us from marketing CGuard EPS in countries requiring the CE mark.

For the European Union nations, medical devices must obtain a CE mark before they may be placed on the market. In order to obtain and maintain the CE mark, we must comply with EU law on medical devices, which, until May 26, 2021 was governed by the MDD, by presenting comprehensive technical files for our products demonstrating safety and efficacy of the product to be placed on the market and passing initial and annual quality management system audit as per ISO 13485 standard by a European Notified Body. We have obtained ISO 13485 quality system certification and CGuard EPS that we currently distribute into the European Union, displays the required CE mark. In order to maintain certification, we are required to pass an annual surveillance audit conducted by Notified Body auditors. The European Union replaced the MDD with the new MDR regulations. The MDR entered into force after a transitional period of three years and a one year extension of that transition period due to the COVID-19 pandemic on May 26, 2021 and which changes several aspects of the regulatory framework in the European Union. Manufacturers had the duration of the transition period to update their technical documentation and processes to meet the new requirements in order to obtain a CE Mark. In our specific case, our CE mark for CGuard EPS under the MDD expired on November 12, 2022, and we are in the final stages of technical documentation review by the Notified Body auditor to meet the MDR requirements for recertification. In the meantime, on February 14, 2023, we received a derogation per Article 97 paragraph 1 of Regulation 2017/745 from the Agency for Medicines and Health Products (FAMHP) allowing us to continue marketing CGuard EPS in the EU until August 15, 2023, subject to certain procedural requirements. Subsequently, on March 20, 2023 Regulation (EU) 2023/607 was published allowing us to continue marketing CGuard EPS in EU countries under the MDD directive until December 31, 2027. As a result of the foregoing, we may market and sell CGuard EPS in the EU and certain other jurisdictions subject to certain procedural requirements while our MDR CE recertification is pending. We continue to expedite the review process for recertification under the MDR however no assurance can be provided as to the length of time it will take to obtain recertification. If we are unable to obtain recertification in the future then this could have a material adverse effect on our business, financial condition, results of operations or cash flows.

If our manufacturing facilities are unable to provide an adequate supply of products, our growth could be limited and our business could be harmed.

We currently manufacture our CGuard EPS at our facility in Tel Aviv, Israel. If there were a disruption to our existing manufacturing facility, we would have no other means of manufacturing our CGuard EPS stents until we were able to restore the manufacturing capability at our facility or develop alternative manufacturing facilities. If we were unable to produce sufficient quantities of our CGuard EPS stents to meet market demand or for use in our current and planned clinical trials, or if our manufacturing process yields substandard stents, our development and commercialization efforts would be delayed.

To manufacture our CGuard EPS in quantities to meet anticipated market demand if we were to receive FDA approval, we will need to increase manufacturing capacity, which will involve significant challenges. In addition, the development of U.S. commercial-scale, regulation-compliant manufacturing capabilities will require us to invest substantial additional funds and hire and retain the technical personnel who have the necessary manufacturing experience. We may not successfully complete any required increase to existing manufacturing processes in a timely manner, or at all.

Additionally, any damage to or destruction of our Tel Aviv facility or its equipment, prolonged power outage or contamination at our facility would significantly impair our ability to produce CGuard EPS stents.

Finally, the production of our stents must occur in a highly controlled, clean environment to minimize particles and other yield and quality-limiting contaminants. In spite of stringent quality controls, weaknesses in process control or minute impurities in materials may cause a substantial percentage of defective products in a lot. If we are unable to maintain stringent quality controls, or if contamination problems arise, our clinical development and commercialization efforts could be delayed, which would harm our business and results of operations.

CGuard EPS is a complex medical device that requires training for qualified personal.

CGuard EPS is a complex medical device that requires training for qualified personal, including physicians. Although our distributors will be required to ensure that CGuard EPS is prescribed only by trained clinicians, the potential for misuse of CGuard EPS still exists due to its complexity. Such misuse could result in adverse medical consequences for patients that could damage our reputation, subject us to costly product liability litigation and otherwise have a material adverse effect on our business, financial condition and results of operations.

We operate in an intensely competitive and rapidly changing business environment, and there is a substantial risk our products could become obsolete or uncompetitive.

The medical device market is highly competitive. We compete with many medical device companies globally in connection with our current products and products under development. We face intense competition from numerous pharmaceutical and biotechnology companies in the therapeutics area, as well as competition from academic institutions, government agencies and research institutions. Abbott Laboratories, Boston Scientific Corporation, Covidien Ltd. (currently part of Medtronic, Inc.), Cordis Corporation and Terumo Medical Corporation produce a polytetrafluoroethylene mesh-covered stent and a double layer metal stent, respectively. Most of our current and potential competitors, including but not limited to those listed above, have, and will continue to have, substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do. There can be no assurance that we will have sufficient resources to successfully commercialize our products, if and when they are approved for sale. The worldwide market for stent products is characterized by intensive development efforts and rapidly advancing technology. For example, during the second quarter of 2022 we ceased sales of our MGuard Prime EPS following a phase out period due to a shift in industry preferences. Our future success will depend largely upon our ability to anticipate and keep pace with those developments and advances. Current or future competitors could develop alternative technologies, products or materials that are more effective, easier to use or more economical than what we or any potential licensee develop. If our technologies or products become obsolete or uncompetitive, our related product sales and licensing revenue would decrease. This would have a material adverse effect on our business, financial condition and results of operations.

We may become subject to claims by much larger and better capitalized competitors enforcing their intellectual property rights against us or seeking to invalidate our intellectual property or our rights thereto.

Based on the prolific litigation that has occurred in the stent industry and the fact that we may pose a competitive threat to some large and well-capitalized companies that own or control patents relating to stents and their use, manufacture and delivery, we believe that it is possible that one or more third parties will assert a patent infringement claim against the manufacture, use or sale of our stents based on one or more of these patents. These companies also own patents relating to the use of drugs to treat restenosis, stent architecture, catheters to deliver stents, and stent manufacturing and coating processes and compositions, as well as general delivery mechanism patents like rapid exchange, which might be alleged to cover one or more of our products. In addition, it is possible that a lawsuit of which we are not aware asserting patent infringement, misappropriation of intellectual property, or related claims may have already been filed against us. As the number of competitors in the stent market grows and as the geographies in which we commercially market grow in number and scope, the possibility of patent infringement by us, and/or a patent infringement or misappropriation claim against us, increases.

Our competitors have maintained their positions in the market by, among other things, establishing intellectual property rights relating to their products and enforcing these rights aggressively against their competitors and new entrants into the market. All the major companies in the field of stents and related markets, including Boston Scientific Corporation, C.R. Bard, Inc., W.L. Gore & Associates, Inc. and Medtronic, Inc., have been repeatedly involved in patent litigation relating to stents since at least 1997. The field of stents and related markets have experienced rapid technological change and obsolescence in the past, and our competitors have strong incentives to stop or delay the introduction of new products and technologies. We may pose a competitive threat to many of the companies in these markets. Accordingly, these companies will have a strong incentive to take steps, through patent litigation or otherwise, to prevent us from distributing our products. Such litigation or claims would divert attention and resources away from the development and/or commercialization of our products and could result in an adverse court judgment that would make it impossible or impractical to sell our products in one or more territories.

If we fail to maintain or establish satisfactory agreements or arrangements with suppliers or if we experience an interruption of the supply of materials from suppliers, we may not be able to obtain materials that are necessary to develop our products.

We depend on outside suppliers for certain raw materials. These raw materials or components may not always be available at our standards or on acceptable terms, if at all, and we may be unable to locate alternative suppliers or produce necessary materials or components on our own.

Some of the components of our products are currently provided by only one vendor, or a single-source supplier. We may have difficulty obtaining similar components from other suppliers that are acceptable to the FDA or foreign regulatory authorities if it becomes necessary. During the last year our mesh supplier informed us that it will not be able to supply the polymer fiber in the future due to issues with raw materials, therefore we purchased inventory which should be sufficient to support our production needs in the next 2.5 years. We are currently in the process of finding and qualifying another supplier or other material source which could take up to a year.

If we have to switch to a replacement supplier, we will face additional regulatory delays and the interruption of the manufacture and delivery of our stents for an extended period of time, which would delay completion of our clinical trials or commercialization of our products. In addition, we will be required to obtain prior regulatory approval from the FDA or foreign regulatory authorities to use different suppliers or components that may not be as safe or as effective. As a result, regulatory approval of our products may not be received on a timely basis or at all.

In addition, we rely on a third-party vendor to perform the sterilization process. A third-party vendor's failure to properly sterilize a component may cause delays or disruptions in our manufacturing process.

The COVID-19 pandemic has caused interruptions or delays of our business plan and if there is a renewed outbreak it may have a significant adverse effect on our business.

In the past, we have been impacted by the COVID-19 pandemic which has caused interruptions or delays of our business plan. In particular, we experienced a significant COVID-19 related impact on our financial condition and results of operations, primarily during the year ended December 31, 2020, which we primarily attribute to the postponement of CGuard EPS procedures (non-emergency procedures), as hospitals shifted resources to patients affected by COVID-19. If there is a renewed outbreak of COVID-19 it may result in restrictions and safety measures that could cause fluctuations in sales of our products, ability to manufacture, as well as potential disruptions to our supply chain.

In addition, if there is a renewed outbreak of COVID-19, this may cause disruptions that could have a material adverse impact on our FDA clinical trial plans and timelines, including:

- Delays in receiving authorizations from local regulatory authorities, ethics committees and institutional review boards to initiate planned clinical trials;
- Delays or difficulties in enrolling patients in our clinical trials;
- Delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- Delays in clinical sites receiving the supplies and materials needed to conduct our clinical trials, including interruptions in global shipping that may affect the transport of clinical trial materials;
- Changes in local regulations as part of a response to the COVID-19 pandemic which may require us to change the ways in which our clinical trials are conducted, which may result in unexpected costs, or to discontinue the clinical trials altogether;
- Diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- Diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- Interruption of key clinical trial activities, such as clinical trial site monitoring, due to limitations on travel imposed or recommended by federal or state governments, employers and others, or interruption of clinical trial subject visits and study procedures, the occurrence of which could affect the integrity of clinical trial data;

- Risk that participants enrolled in our clinical trials will acquire COVID-19 while the clinical trial is ongoing, which could impact the results of the clinical trial, including by increasing the number of observed adverse events;

- Delays in necessary interactions with local regulators, ethics committees and other third parties and contractors due to limitations in employee resources or forced furlough of government employees;

- Limitations in employee resources that would otherwise be focused on the conduct of our clinical trials, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; and

- Refusal of the FDA to accept data from clinical trials in affected geographies.

Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the delay or denial of regulatory approvals or clearances of our product.

The extent to which any future outbreak of COVID-19 will impact our results will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the virus.

Increasing inflation could adversely affect our business, financial condition, results of operations or cash flows.

Inflation and some of the measures taken by or that may be taken by the governments in countries where we operate in an attempt to curb inflation may have negative effects on the economies of those countries generally. If the United States or other countries where we operate experience substantial inflation in the future, our business may be adversely affected. This could have a material adverse impact on our business, financial condition, results of operations or cash flows.

Risks Related to our Clinical Trials and Regulatory Matters

Completing clinical trials for CGuard EPS in the United States require meeting a number of regulatory requirements and must be conducted in compliance with the FDA's IDE regulations. Failure to maintain compliance with IDE regulations could have a material adverse effect on our business.

Clinical trials involve use of a medical device candidate (or drug, biological, or other product candidate, as applicable) on human subjects under the supervision of qualified investigators in accordance with current Good Clinical Practices, including the requirement that all research subjects provide informed consent for their participation in the clinical study. The FDA classifies medical device candidates into "significant risk" and "non-significant risk" devices. Significant risk devices present a potential for serious risk to the health, safety, or welfare of a subject. Examples may include implants, devices that support or sustain human life, and devices that are substantially important in diagnosing, curing, mitigating, or treating disease or in preventing impairment to human health. If a medical device candidate presents a significant risk, an IDE application must be submitted and approved prior to commencing any human clinical trials in the United States in connection with such device. The FDA may approve, conditionally approve, or deny an IDE or it may require further information and, thus, delay approval. On September 8, 2020, we received IDE approval for CGuard™ Carotid Stent System, CARENET-III.

In addition to our IDE approval, we must apply for and obtain IRB approval in connection with each clinical site before commencing any study activities. A written protocol with predefined end points, an appropriate sample size, and pre-determined patient inclusion and exclusion criteria, is also required before we may initiate or conduct the trial.

Importantly, the CGuard EPS clinical trial and any others that we may conduct in the future, must be conducted in accordance with the FDA's IDE regulations, which, among other things, establish requirements for investigational device labeling, prohibit pre-approval promotion of a device candidate, and specify recordkeeping, reporting, and monitoring responsibilities of study sponsors and study investigators.

We may not be able to obtain IRB approval to undertake clinical trials in the United States for any products we intend to market in the United States in the future. If we do obtain such approvals, we may not be able to conduct studies which comply with the IDE and other regulations governing clinical investigations or the data from any such trials may not support clearance or approval of the investigational device. Failure to obtain such approvals or to comply with such regulations could have a material adverse effect on our business, financial condition and results of operations.

Relatedly, certainty that clinical trials will meet desired endpoints, produce meaningful or useful data, and be free of unexpected adverse effects, or that the FDA will accept the validity of foreign clinical study data, as applicable, cannot be guaranteed, and such uncertainty could preclude or delay regulatory approvals and commercialization, resulting in significant financial costs and reduced revenue. Moreover, the timing of the commencement, continuation, and completion of any future clinical trial may be subject to significant delays attributable to various causes, including, but not limited to, scheduling conflicts with participating clinicians and clinical institutions, difficulties in identifying and enrolling patients who meet trial eligibility criteria, failure of patients to complete the clinical trial, delay in or failure to meet regulatory and/or IRB requirements to conduct a clinical trial at a one or more prospective sites, and shortages of supply in the investigational device.

Clinical trials necessary to support a pre-market approval application are lengthy and expensive and require the enrollment of a large number of patients, and suitable patients may be difficult to identify and recruit. Any such delay or failure of clinical trials could prevent us from commercializing our stent products, which would materially and adversely affect our results of operations and the value of our business.

Clinical trials necessary to support a pre-market approval application to the FDA for our products, including CGuard EPS stent are expensive and require the enrollment of a large number of patients, and suitable patients may be difficult to identify and recruit, which may cause a delay in the development and commercialization of our product candidates. Patient enrollment in clinical trials and the ability to successfully complete patient follow-up depends on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial and patient compliance. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post-treatment procedures or follow-up to assess the safety and efficacy of our products, or they may be persuaded to participate in contemporaneous clinical trials of competitive products. In addition, patients participating in our clinical trials may die before completion of the trial or suffer adverse medical events unrelated to or related to our products. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may cause an increase in costs and delays or result in the failure of the clinical trial.

In addition, the length of time required to complete clinical trials for pharmaceutical and medical device products varies substantially according to the degree of regulation and the type, complexity, novelty and intended use of a product, and can continue for several years and cost millions of dollars. The commencement and completion of clinical trials for our products under development may be delayed by many factors, including governmental or regulatory delays and changes in regulatory requirements, policy and guidelines or our inability or the inability of any potential licensee to manufacture or obtain from third parties materials sufficient for use in preclinical studies and clinical trials.

The results of our clinical trials may be insufficient to obtain regulatory approval for our product candidates.

We will only receive regulatory approval to commercialize a product candidate if we can demonstrate to the satisfaction of the FDA or the applicable foreign regulatory agency, in well designed and conducted clinical trials, that the product candidate is safe and effective. If we are unable to demonstrate that a product candidate is safe and effective in advanced clinical trials involving large numbers of patients, we will be unable to submit the necessary application to receive regulatory approval to commercialize the product candidate. We face risks that:

- the product candidate may not prove to be safe or effective;
- the product candidate’s benefits may not outweigh its risks;
- the results from advanced clinical trials may not confirm the positive results from pre-clinical studies and early clinical trials;

- the FDA or comparable foreign regulatory authorities may interpret data from pre-clinical and clinical testing in different ways than us; and
- the FDA or other regulatory agencies may require additional or expanded trials and data.

Patients may discontinue their participation in our clinical studies, which may negatively impact the results of these studies and extend the timeline for completion of our development programs.

Clinical trials for our product candidates require sufficient patient enrollment. We may not be able to enroll a sufficient number of patients in a timely or cost-effective manner. Patients enrolled in our clinical studies may discontinue their participation at any time during the study as a result of a number of factors, including withdrawing their consent or experiencing adverse clinical events, which may or may not be judged to be related to our product candidates under evaluation. If a large number of patients in a study discontinue their participation in the study, the results from that study may not be positive or may not support a filing for regulatory approval of the product candidate.

In addition, the time required to complete clinical trials is dependent upon, among other factors, the rate of patient enrollment. Patient enrollment is a function of many factors, including the following:

- the size of the patient population;
- the nature of the clinical protocol requirements;
- the availability of other treatments or marketed therapies (whether approved or experimental);
- our ability to recruit and manage clinical centers and associated trials;
- the proximity of patients to clinical sites; and
- the patient eligibility criteria for the study.

Our products may in the future be subject to product notifications, recalls, or voluntary market withdrawals that could harm our reputation, business and financial results.

After regulatory approval has been obtained for medical device products, the product and the manufacturer are subject to continual review, including the review of adverse events and clinical results that are reported after our products are made available to patients, and there can be no assurance that such approval will not be withdrawn or restricted. Regulators may also subject approvals to restrictions or conditions or impose post-approval obligations on the holders of these approvals, and the regulatory status of such products may be jeopardized if such obligations are not fulfilled. If post-approval studies are required, such studies may involve significant time and expense.

The manufacturing and marketing of medical devices involves an inherent risk that our products may prove to be defective and cause a health risk even after regulatory clearances have been obtained. Medical devices may also be modified after regulatory clearance is obtained to such an extent that additional regulatory clearance is necessary before the device can be further marketed. In these events, we may voluntarily implement a recall or market withdrawal or may be required to do so by a regulatory authority.

In the European Economic Area, we must comply with the EU Medical Device Vigilance System. Under this system, manufacturers are required to take Field Safety Corrective Actions ("FSCAs") to reduce a risk of death or serious deterioration in the state of health associated with the use of a medical device that is already placed on the market. A FSCA may include the recall, modification, exchange, destruction or retrofitting of the device. FSCAs must be communicated by the manufacturer or its legal representative to its customers and/or to the end users of the device through Field Safety Notices.

Any adverse event involving our products could result in other future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Adverse events have been reported to us in the past, and we cannot guarantee that they will not occur in the future. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, would require the dedication of our time and capital, distract management from operating our business and could harm our reputation and financial results.

We have only limited experience in regulatory affairs, which may affect our ability, or the time required, to navigate complex regulatory requirements and obtain necessary regulatory approvals, if such approvals are received at all. Regulatory delays or denials may increase our costs, cause us to lose revenue and materially and adversely affect our results of operations and the value of our business.

Because long-term success measures have not been completely validated for our products, especially CGuard EPS, regulatory agencies may take a significant amount of time in evaluating product approval applications. Treatments may exhibit a favorable measure using one metric and an unfavorable measure using another metric. Any change in accepted metrics may result in reconfiguration of, and delays in, our clinical trials. Additionally, we have only limited experience in filing and prosecuting the applications necessary to gain regulatory approvals, and our clinical, regulatory and quality assurance personnel are currently composed of only five employees. As a result, we may experience delays in connection with obtaining regulatory approvals for our products.

In addition, the products we and any potential licensees license, develop, manufacture and market are subject to complex regulatory requirements, particularly in the United States, Europe and Asia, which can be costly and time-consuming. There can be no assurance that such approvals will be granted on a timely basis, if at all. Furthermore, there can be no assurance of continued compliance with all regulatory requirements necessary for the manufacture, marketing and sale of the products we will offer in each market where such products are expected to be sold, or that products we have commercialized will continue to comply with applicable regulatory requirements. If a government regulatory agency were to conclude that we were not in compliance with applicable laws or regulations, the agency could institute proceedings to detain or seize our products, issue a recall, impose operating restrictions, enjoin future violations and assess civil and criminal penalties against us, our officers or employees and could recommend criminal prosecution. Furthermore, regulators may proceed to ban, or request the recall, repair, replacement or refund of the cost of, any device manufactured or sold by us. Furthermore, there can be no assurance that all necessary regulatory approvals will be obtained for the manufacture, marketing and sale in any market of any new product developed or that any potential licensee will develop using our licensed technology.

Even if our products are approved by regulatory authorities, if we or our suppliers fail to comply with ongoing regulatory requirements, or if we experience unanticipated problems with our products, these products could be subject to restrictions or withdrawal from the market.

Any regulatory approvals that we receive for our products will require surveillance to monitor the safety and efficacy of the product and may require us to conduct post-approval clinical studies. In addition, if a regulatory authority approves our products, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, import, export and recordkeeping for our products will be subject to extensive and ongoing regulatory requirements.

Moreover, if we obtain regulatory approval for any of our products, we will only be permitted to market our products for the indication approved by the regulatory authority, and such approval may involve limitations on the indicated uses or promotional claims we may make for our products. In addition, later discovery of previously unknown problems with our products, including adverse events of unanticipated severity or frequency, or with our suppliers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- restrictions on the marketing or manufacturing of our product candidates, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters, or untitled letters;
- holds on clinical trials;
- refusal by the regulatory authority to approve pending applications or supplements to approved applications filed by us or suspension or revocation of license approvals;
- product seizure or detention, or refusal to permit the import or export of our product candidates; and
- injunctions, the imposition of civil penalties or criminal prosecution.

The FDA also requires that our sales and marketing efforts, as well as promotions, be consistent with various laws and regulations. Approved medical device promotions must be consistent with and not contrary to labeling, balanced, truthful and not false or misleading, adequately substantiated (when required), and include adequate directions for use. In addition to the requirements applicable to approved products, we may also be subject to enforcement action in connection with any promotion of an investigational new device. A sponsor or investigator, or any person acting on behalf of a sponsor or investigator, may not represent in a promotional context that an investigational new device is safe or effective for the purposes for which it is under investigation or otherwise promote the device.

If the FDA investigates our marketing and promotional materials or other communications and finds that any of our investigational devices, or future commercial products, if any, are being marketed or promoted in violation of the applicable regulatory restrictions, we could be subject to the enforcement actions listed above, among others. Any enforcement action (or related lawsuit, which could follow such action) brought against us in connection with alleged violations of applicable device promotion requirements, or prohibitions, could harm our business and our reputation, as well as the reputation of any devices that may be approved for marketing in the U.S. in the future.

The applicable regulatory authorities' policies may change, and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our 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 that we may have obtained and we may not achieve or sustain profitability.

Failure to obtain regulatory approval in foreign jurisdictions will prevent us from marketing our products in such jurisdictions.

We market our products in international markets. In order to market our products in other foreign jurisdictions, we must obtain separate regulatory approvals from the appropriate governing body in each applicable country. The approval processes vary among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain CE mark or FDA approval. Foreign regulatory approval processes may include all of the risks associated with obtaining CE mark or FDA approval in addition to other risks. We may not obtain foreign regulatory approvals on a timely basis, if at all. CE mark approval or any future FDA approval does not ensure approval by regulatory authorities in other countries. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in certain markets.

We are, or may be, subject to federal, state and foreign healthcare laws and regulations and implementation of or changes to such healthcare laws and regulations could adversely affect our business and results of operations.

In both the United States and certain foreign jurisdictions, there are laws and regulations specific to the healthcare industry which may affect all aspects of our business, including development, testing, marketing, sales, pricing, and reimbursement. Additionally, there have been a number of legislative and regulatory proposals in recent years to change the healthcare system in ways that could impact our ability to sell our products. If we are found to be in violation of any of these laws or any other federal or state regulations, we may be subject to administrative, civil and/or criminal penalties, damages, fines, individual imprisonment, exclusion from federal healthcare programs and the restructuring of our operations. Any of these could have a material adverse effect on our business and financial results. Since many of these laws have not been fully interpreted by the courts, there is an increased risk that we may be found in violation of one or more of their provisions. Any action against us for violation of these laws, even if we ultimately are successful in our defense, will cause us to incur significant legal expenses and divert our management's attention away from the operation of our business.

We may be subject, directly or indirectly, to applicable U.S. federal and state anti-kickback, false claims laws, physician payment transparency laws, fraud and abuse laws or similar healthcare and security laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and others will play a primary role in the recommendation, ordering and utilization of any products for which we obtain regulatory approval. If we obtain U.S. Food & Drug Administration approval for any of our products and begin commercializing those products in the United States, our operations may be subject to various federal and state fraud and abuse laws, including, without limitation, the federal Anti-Kickback Statute, the federal False Claims Act, and physician payment sunshine laws and regulations. These laws may impact, among other things, our potential sales, marketing and education programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

● the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs;

● federal civil and criminal false claims laws and civil monetary penalty laws, including the False Claims Act, which may be pursued through civil whistleblower or qui tam actions, impose criminal and civil penalties against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval from Medicare, Medicaid or other third-party payors that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government;

● federal criminal statutes created through the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), which prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters;

● HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 and their respective implementing regulations, which imposes requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information;

● the federal transparency requirements under The Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act, enacted into law in the United States in March 2010 (known collectively as the "Affordable Care Act"), including the provision commonly referred to as the Physician Payments Sunshine Act, which requires manufacturers of drugs, biologics, devices and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program to report annually to the U.S. Department of Health and Human Services information related to payments or other transfers of value made to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and

● state and federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.

Additionally, we may be subject to state and non-U.S. equivalents of each of the healthcare laws described above, among others, some of which may be broader in scope and may apply regardless of the payor. Many U.S. states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare services reimbursed by any source, not just governmental payors, including private insurers. Several states impose marketing restrictions or require medical device companies to make marketing or price disclosures to the state. There are ambiguities as to what is required to comply with these state requirements, and if we fail to comply with an applicable state law requirement, we could be subject to penalties.

Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available, it is possible that some of our future business activities could be subject to challenge under one or more of such laws. In addition, healthcare reform legislation has strengthened these laws. For example, the Affordable Care Act, among other things, amended the intent requirement of the federal Anti-Kickback and criminal healthcare fraud statutes. As a result of such amendment, a person or entity no longer needs to have actual knowledge of these statutes or specific intent to violate them in order to have committed a violation. Moreover, the Affordable Care Act provides that 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 False Claims Act.

Violations of fraud and abuse laws may be punishable by criminal and/or civil sanctions, including penalties, fines and/or exclusion or suspension from federal and state healthcare programs such as Medicare and Medicaid and debarment from contracting with the U.S. government. In addition, private individuals have the ability to bring actions on behalf of the U.S. government under the False Claims Act as well, as under the false claim laws of several states.

Efforts to ensure that our business arrangements with third parties comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our existing or future business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. Any such actions instituted against us could have a significant adverse impact on our business, including the imposition of civil, criminal and administrative penalties, damages, disgorgement, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Even if we are successful in defending against such actions, we may nonetheless be subject to substantial costs, reputational harm and adverse effects on our ability to operate our business. In addition, the approval and commercialization of any of our products outside the United States will also likely subject us to non-U.S. equivalents of the healthcare laws mentioned above, among other non-U.S. laws.

If any of our employees, agents, or the physicians or other providers or entities with whom we expect to do business are found to have violated applicable laws, we may be subject to criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs, or, if we are not subject to such actions, we may suffer reputational harm for conducting business with persons or entities found, or accused of being, in violation of such laws. Any such events could adversely affect our ability to operate our business and our results of operations.

We may be exposed to product liability claims and insurance may not be sufficient to cover these claims.

We may be exposed to product liability claims based on the use of any of our products, or products incorporating our licensed technology, in the market or clinical trials. We may also be exposed to product liability claims based on the sale of any products under development following the receipt of regulatory approval. Product liability claims could be asserted directly by consumers, health-care providers or others. We have obtained product liability insurance coverage; however ,such insurance may not provide full coverage for our future clinical trials, products to be sold, and other aspects of our business. Insurance coverage is becoming increasingly expensive, and we may not be able to maintain current coverage, or expand our insurance coverage to include future clinical trials or the sale of new products or existing products in new territories, at a reasonable cost or in sufficient amounts to protect against losses due to product liability or at all. A successful product liability claim, or series of claims brought against us could result in judgments, fines, damages and liabilities that could have a material adverse effect on our business, financial condition and results of operations. We may incur significant expense investigating and defending these claims, even if they do not result in liability. Moreover, even if no judgments, fines, damages or liabilities are imposed on us, our reputation could suffer, which could have a material adverse effect on our business, financial condition and results of operations.

Even if one or more of our products are approved by the FDA, we may fail to obtain an adequate level of reimbursement for our products by third party payors, such that there may be no commercially viable markets for our products, or the markets, may be much smaller than expected.

The availability and levels of reimbursement by governmental and other third-party payors affect the market for our products. The efficacy, safety, performance and cost-effectiveness of our products and of any competing products are factors that may impact the availability and level of reimbursement. Reimbursement and healthcare payment systems in international markets vary significantly by country and include both government sponsored healthcare and private insurance. To obtain reimbursement or pricing approval in some countries, we may be required to produce clinical data, which may involve one or more clinical trials that compares the cost-effectiveness of our products to other available therapies. We may not obtain international reimbursement or pricing approvals in a timely manner, if at all. Our failure to receive international reimbursement or pricing approvals would negatively impact market acceptance of our products in the international markets in which those approvals are sought.

We believe that future reimbursement may be subject to increased restrictions both in the U.S. and in international markets. There is increasing pressure by governments worldwide to contain healthcare costs by limiting both the coverage and the level of reimbursement for therapeutic products and by refusing, in some cases, to provide any coverage for products that have not been approved by the relevant regulatory agency. Future legislation, regulation or reimbursement policies of third party payors may adversely affect the demand for our products and limit our ability to sell our products on a profitable basis. In addition, third party payors continually attempt to contain or reduce the costs of healthcare by challenging the prices charged for healthcare products and services. If reimbursement for our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, market acceptance of our products would be impaired, and future revenues, if any, would be adversely affected.

In the United States and European Union, our business could be significantly and adversely affected by healthcare reform initiatives and/or other legislation or judicial interpretations of existing or future healthcare laws and/or regulations.

The Affordable Care Act, signed into law in the United States in March 2010, contains certain provisions which can be modified through the regulatory process and for which it is unclear what the full impact and changes will be under the law.

The law also focuses on a number of provisions aimed at improving quality, broadening access to health insurance, enhancing remedies for fraud and abuse, adding transparency requirements, and decreasing healthcare costs, among others. Uncertainties remain regarding what negative unintended consequences these provisions will have on patient access to new technologies, pricing and the market for our products, and the healthcare industry in general. The Affordable Care Act includes provisions affecting the Medicare program, such as value-based payment programs, increased funding of comparative effectiveness research, reduced hospital payments for avoidable readmissions and hospital acquired conditions, and pilot programs to evaluate alternative payment methodologies that promote care coordination (such as bundled physician and hospital payments). Additionally, the provisions include a reduction in the annual rate of inflation for hospitals which started in 2011 and the establishment of an independent payment advisory board to recommend ways of reducing the rate of growth in Medicare spending. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

Since its enactment, there have been judicial and Congressional challenges to certain aspects of the Affordable Care Act, to modify, repeal or otherwise invalidate all, or certain provisions of, the Affordable Care Act. Following the enactment of the Tax Act, on December 14, 2018 in a case in the United States District Court for the Northern District of Texas, a federal judge ruled that the individual mandate imposed by the Affordable Care Act is unconstitutional and inseverable from the other provisions of the Affordable Care Act and, therefore, the remaining provisions of the Affordable Care Act are invalid. On November 10, 2020, the United States Supreme Court heard arguments on whether the Affordable Care Act is constitutional, in whole or in part, and determined that the case lacked standing.. The regulatory process of implementation of the Affordable Care Act will remain ongoing and may also increase our regulatory burdens and operating costs. Litigation and legislation related to the Affordable Care Act are likely to continue, with unpredictable and uncertain results. We cannot predict with certainty what affect further changes to the Affordable Care Act, and other similar health care laws that are enacted, would have on our business.

In addition, other legislative changes have been proposed and adopted since the Affordable Care Act was enacted. These changes included aggregate reductions to Medicare payments to providers of up to two percent per fiscal year, which will remain in effect through 2027 unless additional Congressional action is taken. It is unclear what impact new quality and payment programs may have on our business, financial condition, results of operations or cash flows. Individual states in the United States have also become increasingly aggressive in passing legislation and implementing regulations designed to control product pricing, including price or patient reimbursement constraints, and discounts, and require marketing cost disclosure and transparency measures. We believe that additional state and federal health care reform measures may be adopted in the future that could have a material adverse effect on our industry generally and on our customers. Any changes in, or uncertainty with respect to, future reimbursement rates could impact our customers' demand for our products, which in turn could have a material adverse effect on our business, financial condition, results of operations, or cash flows. Further, the federal, state and local governments, Medicare, Medicaid, managed care organizations, and foreign governments have in the past considered, are currently considering, and may in the future consider healthcare policies and proposals intended to curb rising healthcare costs, including those that could significantly affect both private and public reimbursement for healthcare services. Future significant changes in the healthcare systems in the United States or other countries, including changes intended to reduce expenditures along with uncertainty about whether and how changes may be implemented, could have a negative impact on the demand for our products. We are unable to predict with certainty whether other healthcare policies, including policies stemming from legislation or regulations affecting our business, may be proposed or enacted in the future; what effect such policies would have on our business; or the effect ongoing uncertainty about these matters will have on our customers' purchasing decisions.

We cannot predict the impact that such actions against the Affordable Care Act and other laws enacted after its enactment will have on our business, and there is uncertainty as to what healthcare programs and regulations may be implemented or changed at the federal and/or state level in the United States, or the effect of any future legislation or regulation. Furthermore, we cannot predict what actions the Biden administration will implement in connection with laws impacting us. However, it is possible that such initiatives could have an adverse effect on our ability to obtain approval and/or successfully commercialize products in the United States in the future. For example, any changes that reduce, or impede the ability to obtain, reimbursement for the type of products we intend to commercialize in the United States (or our products more specifically, if approved) or reduce medical procedure volumes could adversely affect our business plan to introduce our products in the United States.

In May 2017, the European parliament and the council of the European Union approved the MDR which has replaced the existing medical device directives (93/42/EEC). The new regulations entered into full application in May 26, 2021. The new Medical Device Regulation imposes stricter requirements on medical device manufacturers and strengthens the supervising competences of the competent authorities of European Union member states, the notified bodies and the authorized representatives. If we fail to comply with the modified regulation and requirements, it can adversely affect our business, operating results and prospects. Any new regulations or revisions or reinterpretations of existing regulations may impose additional costs or lengthen review times of future products. See "Risk Factors – "Failure to satisfy regulatory requirements of the new European Medical Device Regulation may prevent us from marketing CGuard EPS in countries requiring the CE mark."

Risk Factors Related to Our Intellectual Property

If we are unable to obtain and maintain intellectual property protection covering our products, others may be able to make, use or sell our products, which would adversely affect our revenue.

Our ability to protect our products from unauthorized or infringing use by third parties depends substantially on our ability to obtain and maintain valid and enforceable patents. Similarly, the ability to protect our trademark rights might be important to prevent third party counterfeiters from selling poor quality goods using our designated trademarks, and trade names. Due to evolving legal standards relating to the patentability, validity and enforceability of patents covering medical devices and pharmaceutical inventions and the scope of claims made under these patents, our ability to enforce patents is uncertain and involves complex legal and factual questions. Accordingly, rights under any of our pending patent applications and patents may not provide us with commercially meaningful protection for our products or may not afford a commercial advantage against our competitors or their competitive products or processes. In addition, patents may not be issued from any pending or future patent applications owned by or licensed to us, and moreover, patents that may be issued to us now or in the future may later be found invalid or unenforceable. Further, even if valid and enforceable, our patents may not be sufficiently broad to prevent others from marketing products like ours, despite our patent rights.

The validity of our patent claims depends, in part, on whether prior art references exist that describe or render obvious our inventions as of the filing date of our patent applications. We may not have identified all prior art, such as U.S. and foreign patents or published applications or published scientific literature, that could adversely affect the patentability of our issued patents and pending patent applications. For example, some material references may be in a foreign language and may not be uncovered during examination of our patent applications. Additionally, patent applications in the United States are maintained in confidence for up to 18 months after their filing. In some cases, however, patent applications remain confidential in the U.S. Patent and Trademark Office for the entire time prior to issuance as a U.S. patent. Patent applications filed in countries outside the U.S. are not typically published until at least 18 months from their first filing date. Similarly, publication of discoveries in the scientific or patent literature often lags behind actual discoveries. Therefore, we cannot be certain that we were the first to invent, or the first to file patent applications relating to, our stent technologies. Third parties may initiate adversarial proceedings, known as an inter-partes review (IPR) in the U.S. Patent and Trademark Office to challenge the validity of our patent claims in the United States. It is possible that we may be unsuccessful in the proceedings, resulting in a loss of some portion or all of our patent rights in the United States.

In addition, statutory differences in patentable subject matter among jurisdictions may limit the protection we can obtain on certain of the technologies we develop. The laws of some foreign jurisdictions do not offer the same protection to, or may make it more difficult to effect the enforcement of, proprietary rights as in the United States. This risk may be exacerbated if we move our manufacturing to certain countries in Asia. If we encounter such difficulties or are otherwise precluded from effectively protecting our intellectual property rights in any foreign jurisdictions, our business prospects could be substantially harmed.

Our initiation of litigation to enforce our patent rights may prompt adversaries in such litigation to challenge the validity, scope, ownership, or enforceability of our patents. Third parties can sometimes bring challenges against a patent holder to resolve these issues, as well. If a court decides that any such patents are not valid, not enforceable, not wholly owned by us, or are of a limited scope, we may not have the right to stop others from using our inventions. Also, even if our patent rights are determined by a court to be valid and enforceable, they may not be sufficiently broad to prevent others from marketing products similar to ours or designing around our patents, despite our patent rights, nor do they provide us with freedom to operate unimpeded by the patent and other intellectual property rights of others that may cover our products. We may be forced into litigation to uphold the validity of the claims in our patent portfolio, as well as our ownership rights to such intellectual property, and litigation is often an uncertain and costly process.

We may not be able to protect our trade secrets adequately. Although we rely on non-disclosure and confidentiality agreements with employees, consultants and other parties to protect, in part, trade secrets and other proprietary technology, these agreements may be breached and we may not have adequate remedies for such breach. Moreover, others may independently develop equivalent proprietary information, and third parties may otherwise gain access to our trade secrets and proprietary knowledge. Any disclosure of confidential data into the public domain or to third parties could allow competitors to learn our trade secrets and use the information in competition against us.

Intellectual property rights of third parties could adversely affect our ability to commercialize our products and services, and we might be required to litigate or obtain licenses from third parties in order to develop or market our product candidates. Such litigation or licenses could be costly or not available on commercially reasonable terms.

It is inherently difficult to conclusively assess our freedom to operate without infringing on third-party rights. Our competitive position may be adversely affected if existing patents or patents resulting from patent applications issued to third parties or other third-party intellectual property rights are held to cover our products or services or elements thereof, or our manufacturing or uses relevant to our development plans. In such cases, we may not be in a position to develop or commercialize products or services or our product candidates (and any relevant services) unless we successfully pursue litigation to nullify or invalidate the third-party intellectual property right concerned or enter into a license agreement with the intellectual property right holder, if available on commercially reasonable terms. There may also be pending patent applications that if they result in issued patents, could be alleged to be infringed by our new products or services. If such an infringement claim should be brought and be successful, we may be required to pay substantial damages, be forced to abandon our new products or services or seek a license from any patent holders. No assurances can be given that a license will be available on commercially reasonable terms, if at all.

It is also possible that we have failed to identify relevant third-party patents or applications. For example, U.S. patent applications filed before November 29, 2000, and certain U.S. patent applications filed after that date that will not be filed outside the United States remain confidential until patents issue. Patent applications in the United States and elsewhere are published approximately 18 months after the earliest filing for which priority is claimed, with such earliest filing date being commonly referred to as the priority date. Therefore, patent applications covering our new products or services could have been filed by others without our knowledge. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our services, our new products or the use of our new products. Third-party intellectual property right holders may also actively bring infringement claims against us. We cannot guarantee that we will be able to successfully settle or otherwise resolve such infringement claims. If we are unable to successfully settle future claims on terms acceptable to us, we may be required to engage in or continue costly, unpredictable and time-consuming litigation and may be prevented from or experience substantial delays in pursuing the development of and/or marketing our new products or services. If we fail in any such dispute, in addition to being forced to pay damages, we may be temporarily or permanently prohibited from commercializing our new products or services that are held to be infringing. We might, if possible, also be forced to redesign our new products so that we no longer infringe the third-party intellectual property rights. Any of these events, even if we were ultimately to prevail, could require us to divert substantial financial and management resources that we would otherwise be able to devote to our business.

Patent policy and rule changes could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any issued patents.

Changes in either the patent laws or interpretation of the patent laws in the United States and other countries may diminish the value of any patents that may issue from our patent applications or narrow the scope of our patent protection. The laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. We therefore cannot be certain that we were the first to file the invention claimed in our owned and licensed patent or pending applications, or that we or our licensor were the first to file for patent protection of such inventions. Assuming all other requirements for patentability are met, in the United States prior to March 15, 2013, the first to make the claimed invention without undue delay in filing, is entitled to the patent, while generally outside the United States, the first to file a patent application is entitled to the patent. After March 15, 2013, under the Leahy-Smith America Invents Act, or the Leahy-Smith Act, enacted on September 16, 2011, the United States has moved to a first to file system. The Leahy-Smith Act also includes a number of significant changes that affect the way patent applications will be prosecuted and may also affect patent litigation. In general, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of any issued patents, all of which could have a material adverse effect on our business and financial condition.

We may be involved in lawsuits to protect or enforce our intellectual property, which could be expensive, time consuming, and unsuccessful.

Competitors may infringe our intellectual property. If we were to initiate legal proceedings against a third-party to enforce a patent covering one of our new products or services, the defendant could counterclaim that the patent covering our product candidate is invalid and/or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and/or unenforceability are commonplace. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the United States Patent and Trademark Office, or USPTO, or made a misleading statement, during prosecution. Under the Leahy-Smith Act, the validity of U.S. patents may also be challenged in post-grant proceedings before the USPTO. The outcome following legal assertions of invalidity and unenforceability is unpredictable.

Derivation proceedings initiated by third parties or brought by us may be necessary to determine the priority of inventions and/or their scope with respect to our patent or patent applications or those of our licensors. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Our defense of litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development partnerships that would help us bring our new products or services to market.

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 this type of litigation. There could also be public announcements of the results of hearings, motions, or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our shares of common stock.

Risks Related to Our Business Operations

We face risks associated with litigation and claims.

We have in the past and may, in the future, be involved in one or more lawsuits, claims or other proceedings. These suits could concern issues including contract disputes, employment actions, employee benefits, taxes, environmental, health and safety, fraud and abuse, personal injury and product liability matters.

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

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, research data, our proprietary business information and that of our suppliers, technical information about our products, clinical trial plans and employee records. Similarly, our third-party providers possess certain of our sensitive data and confidential information. The secure maintenance of this information is critical to our operations and business strategy. Despite the implementation of security measures, our internal computer systems, and those of third parties on which we rely, are vulnerable to damage from computer viruses, malware, ransomware, cyber fraud, 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. 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. Any such breach could compromise our networks and the information stored there could be accessed, publicly disclosed, encrypted, lost or stolen. Any such access, inappropriate disclosure of confidential or proprietary information or other loss of information, including our data being breached at third-party providers, could result in legal claims or proceedings, liability or financial loss under laws that protect the privacy of personal information, disruption of our operations or our product development programs and damage to our reputation, which could adversely affect our business. For example, the loss of clinical trial data from completed or ongoing or planned clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data.

The loss of key members of our senior management team or our inability to attract and retain highly skilled scientists and laboratory and field personnel could adversely affect our business.

We depend on the skills, experience and performance of our senior management and research personnel. The efforts of each of these persons will be critical to us as we continue to further develop our products, increase sales and broaden our product offerings. If we were to lose one or more of these key employees, we may experience difficulties in competing effectively, developing our technologies and implementing our business strategies. Our research and development programs and commercial laboratory operations depend on our ability to attract and retain highly skilled scientists and technicians. We may not be able to attract or retain qualified scientists and technicians in the future due to the intense competition for qualified personnel among life science businesses. There can be no assurance that we will be able to attract and retain necessary personnel on acceptable terms given the intense competition among medical device, biotechnology, pharmaceutical and healthcare companies, universities and non-profit research institutions for experienced management, scientists, researchers, sales and marketing and manufacturing personnel. If we are unable to attract, retain and motivate our key personnel to accomplish our business objectives, we may experience constraints that will adversely affect our ability to support our operations, and our results of operations may be materially and adversely affected.

We are an international business, and we are exposed to various global and local risks that could have a material adverse effect on our financial condition and results of operations.

We operate globally and develop and market products in multiple countries. Consequently, we face complex legal and regulatory requirements in multiple jurisdictions, which may expose us to certain financial and other risks. In addition, we are subject to global events beyond our control, including war, public health crises, such as pandemics and epidemics, trade disputes and other international events. Any of these changes could have a material adverse effect on our reputation, business, financial condition or results of operations.

For example, in the past we have been impacted by the COVID-19 pandemic which has caused interruptions or delays of our business plan. In particular, we experienced a significant COVID-19 related impact on our financial condition and results of operations, primarily during the year ended December 31, 2020, which we primarily attribute to the postponement of CGuard EPS procedures (non-emergency procedures), as hospitals shifted resources to patients affected by COVID-19. If there is a renewed outbreak of COVID-19 it may result in restrictions and safety measures that could cause fluctuations in sales of our products, ability to manufacture, as well as potential disruptions to our supply chain.

International sales and operations are subject to a variety of risks, including:

- foreign currency exchange rate fluctuations;
- greater difficulty in staffing and managing foreign operations;
- greater risk of uncollectible accounts;
- longer collection cycles;
- logistical and communications challenges;
- potential adverse changes in laws and regulatory practices, including export license requirements, trade barriers, tariffs and tax laws;
- changes in labor conditions;
- burdens and costs of compliance with a variety of foreign laws;
- political and economic instability;
- the escalation of hostilities in Israel, which could impair our ability to manufacture our products;
- increases in duties and taxation;
- foreign tax laws and potential increased costs associated with overlapping tax structures;
- greater difficulty in protecting intellectual property;
- the risk of third party disputes over ownership of intellectual property and infringement of third party intellectual property by our products; and
- general economic and political conditions in these foreign markets.

International markets are also affected by economic pressure to contain reimbursement levels and healthcare costs. Profitability from international operations may be limited by risks and uncertainties related to regional economic conditions, regulatory and reimbursement approvals, competing products, infrastructure development, intellectual property rights protection and our ability to implement our overall business strategy. We expect these risks will increase as we pursue our strategy to expand operations into new geographic markets. We may not succeed in developing and implementing effective policies and strategies in each location where we conduct business. Any failure to do so may harm our business, results of operations and financial condition.

Environmental, social and corporate governance (ESG) issues, including those related to climate change and sustainability, may have an adverse effect on our business, financial condition and results of operations and damage our reputation.

There is an increasing focus from certain investors, customers, consumers, employees and other stakeholders concerning ESG matters. Additionally, public interest and legislative pressure related to public companies' ESG practices continue to grow. If our ESG practices fail to meet regulatory requirements or investor, customer, consumer, employee or other shareholders' evolving expectations and standards for responsible corporate citizenship in areas including environmental stewardship, support for local communities, Board of Director and employee diversity, human capital management, employee health and safety practices, product quality, supply chain management, corporate governance and transparency, our reputation, brand and employee retention may be negatively impacted, and our customers and suppliers may be unwilling to continue to do business with us.

Customers, consumers, investors and other shareholders are increasingly focusing on environmental issues, including climate change, energy and water use, plastic waste and other sustainability concerns. Concern over climate change may result in new or increased legal and regulatory requirements to reduce or mitigate impacts to the environment. Changing customer and consumer preferences or increased regulatory requirements may result in increased demands or requirements regarding plastics and packaging materials, including single-use and non-recyclable plastic products and packaging, other components of our products and their environmental impact on sustainability, or increased customer and consumer concerns or perceptions (whether accurate or inaccurate) regarding the effects of substances present in certain of our products. Complying with these demands or requirements could cause us to incur additional manufacturing, operating or product development costs.

If we do not adapt to or comply with new regulations, including the SEC's published proposed rules that would require companies to provide significantly expanded climate-related disclosures in their periodic reporting, which may require us to incur significant additional costs to comply and impose increased oversight obligations on our management and board of directors, or fail to meet evolving investor, industry or stakeholder expectations and concerns regarding ESG issues, investors may reconsider their capital investment in our Company, we may become subject to penalties, and customers and consumers may choose to stop purchasing our products, if approved for commercialization, which could have a material adverse effect on our reputation, business or financial condition.

Our business, operating results and growth rates may be adversely affected by current or future unfavorable economic and market conditions and adverse developments with respect to financial institutions and associated liquidity risk.

Our business depends on the economic health of the global economies. If the conditions in the global economies remain uncertain or continue to be volatile, or if they deteriorate, including as a result of the impact of military conflict, such as the war between Russia and Ukraine, terrorism or other geopolitical events, our business, operating results and financial condition may be materially adversely affected. Economic weakness, inflation and increases in interest rates, limited availability of credit, liquidity shortages and constrained capital spending have at times in the past resulted, and may in the future result, in challenging and delayed sales cycles, slower adoption of new technologies and increased price competition, and could negatively affect our ability to forecast future periods, which could result in an inability to satisfy demand for our products and a loss of market share.

In addition, increases in inflation raise our costs for commodities, labor, materials and services and other costs required to grow and operate our business, and failure to secure these on reasonable terms may adversely impact our financial condition. Additionally, increases in inflation, along with the uncertainties surrounding COVID-19, geopolitical developments and global supply chain disruptions, have caused, and may in the future cause, global economic uncertainty and uncertainty about the interest rate environment, which may make it more difficult, costly or dilutive for us to secure additional financing. A failure to adequately respond to these risks could have a material adverse impact on our financial condition, results of operations or cash flows.

More recently, the closures of SVB and Signature Bank and their placement into receivership with the FDIC created bank-specific and broader financial institution liquidity risk and concerns. Although the Department of the Treasury, the Federal Reserve and the FDIC jointly released a statement that depositors at SVB and Signature Bank would have access to their funds, even those in excess of the standard FDIC insurance limits, under a systemic risk exception, future adverse developments with respect to specific financial institutions or the broader financial services industry may lead to market-wide liquidity shortages, impair the ability of companies to access near-term working capital needs, and create additional market and economic uncertainty. There can be no assurance that future credit and financial market instability and a deterioration in confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, liquidity shortages, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, or if adverse developments are experienced by financial institutions, it may cause short-term liquidity risk and also make any necessary debt or equity financing more difficult, more costly, more onerous with respect to financial and operating covenants and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price and could require us to alter our operating plans. In addition, there is a risk that one or more of our service providers, financial institutions, manufacturers, suppliers and other partners may be adversely affected by the foregoing risks, which could directly affect our ability to attain our operating goals on schedule and on budget.

We are subject to financial reporting and other requirements that place significant demands on our resources.

We are subject to reporting and other obligations under the Securities Exchange Act of 1934, as amended, including the requirements of Section 404 of the Sarbanes-Oxley Act of 2002. Section 404 requires us to conduct an annual management assessment of the effectiveness of our internal controls over financial reporting. These reporting and other obligations place significant demands on our management, administrative, operational, internal audit and accounting resources. Any failure to maintain effective internal controls could have a material adverse effect on our business, operating results and stock price. Moreover, effective internal control is necessary for us to provide reliable financial reports and prevent fraud. If we cannot provide reliable financial reports or prevent fraud, we may not be able to manage our business as effectively as we would if an effective control environment existed, and our business and reputation with investors may be harmed.

There are inherent limitations in all control systems, and misstatements due to error or fraud may occur and not be detected.

The ongoing internal control provisions of Section 404 of the Sarbanes-Oxley Act of 2002 require us to identify material weaknesses in internal control over financial reporting, which is a process to provide reasonable assurance regarding the reliability of financial reporting for external purposes in accordance with accounting principles generally accepted in the United States. Our management, including our chief executive officer and chief financial officer, does not expect that our internal controls and disclosure controls will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. In addition, the design of a control system must reflect the fact that there are resource constraints, and the benefit of controls must be relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, in our company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple errors or mistakes. Further, controls can be circumvented by individual acts of some persons, by collusion of two or more persons, or by management override of the controls. The design of any system of controls is also based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, a control may be inadequate because of changes in conditions, such as growth of the company or increased transaction volume, or the degree of compliance with the policies or procedures may deteriorate. Because of inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

In addition, discovery and disclosure of a material weakness, by definition, could have a material adverse impact on our financial statements. Such an occurrence could discourage certain customers or suppliers from doing business with us and adversely affect how our stock trades. This could in turn negatively affect our ability to access equity markets for capital.

Risks Related to Operating in Israel

We anticipate being subject to fluctuations in currency exchange rates because we expect a substantial portion of our revenues will be generated in Euros and U.S. dollars, while a significant portion of our expenses will be incurred in New Israeli Shekels.

We expect a substantial portion of our revenues will be generated in U.S. dollars and Euros, while a significant portion of our expenses, principally salaries and related personnel expenses, is paid in New Israeli Shekels, or NIS. As a result, we are exposed to the risk that the rate of inflation in Israel will exceed the rate of devaluation of the NIS in relation to the Euro or the U.S. dollar, or that the timing of this devaluation will lag behind inflation in Israel. Because inflation has the effect of increasing the dollar and Euro costs of our operations, it would therefore have an adverse effect on our dollar-measured results of operations. The value of the NIS, against the Euro, the U.S. dollar, and other currencies may fluctuate and is affected by, among other things, changes in Israel's political and economic conditions. Any significant revaluation of the NIS may materially and adversely affect our cash flows, revenues and financial condition. Fluctuations in the NIS exchange rate, or even the appearance of instability in such exchange rate, could adversely affect our ability to operate our business.

If there are significant shifts in the political, economic and military conditions in Israel and its neighbors, it could have a material adverse effect on our business relationships and profitability.

Our executive office, sole manufacturing facility and certain of our key personnel are located in Israel. Our business is directly affected by the political, economic and military conditions in Israel and its neighbors. Since the establishment of the State of Israel in 1948, a number of armed conflicts have occurred between Israel and its Arab neighbors.

During June 2021, July and August 2014 and November 2012, Israel was engaged in an armed conflict with Hamas, a militia group and political party which controls the Gaza Strip, and during the summer of 2006, Israel was engaged in an armed conflict with Hezbollah, a Lebanese Islamist Shiite militia group and political party. These conflicts involved missile strikes against civilian targets in various parts of Israel, including areas in which our employees and some of our consultants are located, and negatively affected business conditions in Israel. We cannot predict if or when armed conflict will take place and the duration of each conflict.

Our commercial insurance does not cover losses that may occur as a result of 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 assure you that this government coverage will be maintained or that it will sufficiently cover our 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.

The continued political instability and hostilities between Israel and its neighbors and any future armed conflict, terrorist activity or political instability in the region could adversely affect our operations in Israel and adversely affect the market price of our shares of common stock. In addition, several organizations and countries may restrict doing business with Israel and Israeli companies have been and are today subjected to economic boycotts. The interruption or curtailment of trade between Israel and its present trading partners could adversely affect our business, financial condition and results of operations.

Israel's most recent general elections were held on April 9, 2019, September 17, 2019, March 2, 2020, March 23, 2021 and November 1, 2022. In addition, proposed judicial reform has sparked widespread protests across Israel. Uncertainty surrounding future elections and the outcome of the judicial reform in Israel may continue and the political situation in Israel may further deteriorate. Actual or perceived political instability in Israel or any negative changes in the political environment, may individually or in the aggregate adversely affect the Israeli economy and, in turn, our business, financial condition, results of operations and growth prospects.

Our operations could be disrupted as a result of the obligation of certain of our personnel residing in Israel to perform military service.

Many of our officers and employees reside in Israel and may be required to perform annual military reserve duty. Currently, all male adult citizens and permanent residents of Israel under the age of 40 (or older, depending on their position with the Israeli Defense Forces reserves), unless exempt, are obligated to perform military reserve duty annually and are subject to being called to active duty at any time under emergency circumstances. Our operations could be disrupted by the absence for a significant period of one or more of our key officers and employees due to military service. Any such disruption could have a material adverse effect on our business, results of operations and financial condition.

We may not be able to enforce covenants not-to-compete under current Israeli law.

We have non-competition agreements with most of our employees, many of which are governed by Israeli law. These agreements generally prohibit our employees from competing with us or working for our competitors for a specified period following termination of their employment. However, Israeli courts are reluctant to enforce non-compete undertakings of former employees and tend, if at all, to enforce those provisions for relatively brief periods of time in restricted geographical areas and only when the employee has unique value specific to that employer's business and not just regarding the professional development of the employee. Any such inability to enforce non-compete covenants may cause us to lose any competitive advantage resulting from advantages provided to us by such confidential information.

We may become subject to claims for remuneration or royalties for assigned service invention rights by our employees, which could result in litigation and adversely affect our business.

A significant portion of our intellectual property has been developed by our Israeli employees in the course of their employment for us. Under the Israeli Patent Law, 5727-1967 (the "Israeli Patent Law"), inventions conceived by an employee during the term and as part of the scope of his or her employment with a company are regarded as "service inventions," which belong to the employer, absent a specific agreement between the employee and employer giving the employee service invention rights. The Israeli Patent Law also provides that if there is no such agreement between an employer and an employee, the Israeli Compensation and Royalties Committee (the "C&R Committee"), a body constituted under the Israeli Patent Law, shall determine whether the employee is entitled to remuneration for his inventions. The C&R Committee (decisions of which have been upheld by the Israeli Supreme Court) has held that employees may be entitled to remuneration for their service inventions despite having specifically waived any such rights. We generally enter into intellectual property assignment agreements with our employees pursuant to which such employees assign to us all rights to any inventions created in the scope of their employment or engagement with us. Although our employees have agreed to assign to us service invention rights and have specifically waived their right to receive any special remuneration for such assignment beyond their regular salary and benefits, we may face claims demanding remuneration in consideration for assigned inventions. As a consequence of such claims, we could be required to pay additional remuneration or royalties to our current or former employees, or be forced to litigate such claims, which could negatively affect our business.

It may be difficult for investors in the United States to enforce any judgments obtained against us or some of our directors or officers.

The majority of our assets other than cash are located outside the U.S. In addition, certain of our officers are nationals and/or residents of countries other than the U.S., and all or a substantial portion of such persons' assets are located outside the U.S. As a result, it may be difficult for investors to enforce within the United States any judgments obtained against us or any of our non-U.S. officers, including judgments predicated upon the civil liability provisions of the securities laws of the U.S. or any state thereof. Additionally, it may be difficult to assert U.S. securities law claims in actions originally instituted outside of the U.S. Israeli courts may refuse to hear a U.S. securities law claim because Israeli courts may not be the most appropriate forums in which to bring such a claim. Even if an Israeli court agrees to hear a claim, it may determine that the Israeli law, and not U.S. law, is applicable to the claim. Further, if U.S. law is found to be applicable, certain content of applicable U.S. law must be proved as a fact, which can be a time-consuming and costly process, and certain matters of procedure would still be governed by the Israeli law. Consequently, you may be effectively prevented from pursuing remedies under U.S. federal and state securities laws against us or any of our non-U.S. directors or officers.

The tax benefits that are currently available to us under Israeli law require us to satisfy specified conditions. If we fail to satisfy these conditions, we may be required to pay increased taxes and would likely be denied these benefits in the future.

InspireMD Ltd. has been granted a "Beneficiary Enterprise" status by the Investment Center in the Israeli Ministry of Industry Trade and Labor, and we are therefore eligible for tax benefits under the Israeli Law for the Encouragement of Capital Investments, 1959. The main benefit is a two-year exemption from corporate tax, commencing when we begin to generate net income derived from the beneficiary activities in facilities located in Israel, and a reduced corporate tax rate for an additional five to eight years, depending on the level of foreign investment in each year. In addition, under the January 1, 2011 amendment to the Israeli Law for the Encouragement of Capital Investments, 1959, a uniform corporate tax rate of 16% applies to all qualifying income of "Preferred Enterprise," which we may be able to apply as an alternative tax benefit.

The tax benefits available to a Beneficiary Enterprise or a Preferred Enterprise are dependent upon the fulfillment of conditions stipulated under the Israeli Law for the Encouragement of Capital Investments, 1959 and its regulations, as amended, which include, among other things, maintaining our manufacturing facilities in Israel. If we fail to comply with these conditions, in whole or in part, the tax benefits could be cancelled and we could be required to refund any tax benefits that we received in the past. If we are no longer eligible for these tax benefits, our Israeli taxable income would be subject to regular Israeli corporate tax rates. The standard corporate tax rate for Israeli companies in 2019 and thereafter is 23% of taxable income. The termination or reduction of these tax benefits would increase our tax liability, which would reduce our profits.

In addition to losing eligibility for tax benefits currently available to us under Israeli law, if we do not maintain our manufacturing facilities in Israel, we will not be able to realize certain tax credits and deferred tax assets, if any, including any net operating losses to offset against future profits.

The tax benefits available to Beneficiary Enterprises may be reduced or eliminated in the future. This would likely increase our tax liability.

The Israeli government may reduce or eliminate in the future tax benefits available to Beneficiary Enterprises and Preferred Enterprises. Our Beneficiary Enterprise status and the resulting tax benefits may not continue in the future at their current levels or at any level. The tax benefit period is twelve years from the year of election, which means that after a year of election, the two-year exemption and eight years of reduced tax rate can only be used within the next twelve years. The Company elected the year 2007, as a year of election and 2011 as an additional year of election. The 2011 amendment regarding Preferred Enterprise may not be applicable to us or may not fully compensate us for the change. The termination or reduction of these tax benefits would likely increase our tax liability. The amount, if any, by which our tax liability would increase will depend upon the rate of any tax increase, the amount of any tax benefit reduction, and the amount of any taxable income that we may earn in the future.

Risks Related to Our Common Stock, Preferred Stock and Warrants

The market prices of our common stock are subject to fluctuation and have been and may continue to be volatile, which could result in substantial losses for investors.

The market prices of our common stock have been and are likely to continue to be highly volatile and could fluctuate widely in response to various factors, many of which are beyond our control, including the following:

- technological innovations or new products and services by us or our competitors;
- additions or departures of key personnel;
- our ability to execute our business plan;
- operating results that fall below expectations;
- loss of any strategic relationship;
- industry developments;
- economic, political and other external factors; and
- period-to-period fluctuations in our financial results.

In addition, the securities markets have from time to time experienced significant price and volume fluctuations that are unrelated to the operating performance of particular companies. These market fluctuations may also significantly affect the market prices of our common stock.

Our common stock could be delisted from the Nasdaq Capital Market if we fail to meet the Nasdaq Capital Market's stockholders' equity continued listing standards. Our ability to publicly or privately sell equity securities and the liquidity of our common stock could be adversely affected if we are delisted from the Nasdaq Capital Market.

Our common stock is listed on the Nasdaq Capital Market, and we are therefore subject to its continued listing requirements, including requirements with respect to the market value of publicly-held shares, market value of listed shares, minimum bid price per share, and minimum stockholders' equity, among others, and requirements relating to board and committee independence. If we fail to satisfy one or more of the requirements, we may be delisted from the Nasdaq Capital Market.

Delisting from the Nasdaq Capital Market may adversely affect our ability to raise additional financing through the public or private sale of equity securities, may significantly affect the ability of investors to trade our securities and may negatively affect the value and liquidity of our common stock. Delisting also could have other negative results, including the potential loss of employee confidence, the loss of institutional investors or interest in business development opportunities.

Delaware law and our corporate charter and bylaws contain anti-takeover provisions that could delay or discourage takeover attempts that stockholders may consider favorable.

Our board of directors is authorized to issue shares of preferred stock in one or more series and to fix the voting powers, preferences and other rights and limitations of the preferred stock. Accordingly, we may issue shares of preferred stock with a preference over our common stock with respect to dividends or distributions on liquidation or dissolution, or that may otherwise adversely affect the voting or other rights of the holders of common stock. Issuances of preferred stock, depending upon the rights, preferences and designations of the preferred stock, may have the effect of delaying, deterring or preventing a change of control, even if that change of control might benefit our stockholders. In addition, we are subject to Section 203 of the Delaware General Corporation Law. Section 203 generally prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless (i) prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder; (ii) the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding (a) shares owned by persons who are directors and also officers and (b) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or (iii) on or subsequent to the date of the transaction, the business combination is approved by the board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66, 2/3%, of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 could delay or prohibit mergers or other takeover or change in control attempts with respect to us and, accordingly, may discourage attempts to acquire us even though such a transaction may offer our stockholders the opportunity to sell their stock at a price above the prevailing market price.

We have a staggered board of directors, which could impede an attempt to acquire us or remove our management.

Our board of directors is divided into three classes, each of which serves for a staggered term of three years. This division of our board of directors could have the effect of impeding an attempt to take over our company or change or remove management, since only one class will be elected annually. Thus, only approximately one-third of the existing board of directors could be replaced at any election of directors.

As a former shell company, resales of shares of our restricted common stock in reliance on Rule 144 of the Securities Act are subject to the requirements of Rule 144(i).

We previously were a "shell company" and, as such, sales of our securities pursuant to Rule 144 under the Securities Act of 1933, as amended, cannot be made unless, among other things, at the time of a proposed sale, we are subject to the reporting requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, and have filed all reports and other materials required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 as amended, as applicable, during the preceding 12 months, other than Form 8-K reports. Because, as a former shell company, the reporting requirements of Rule 144(i) will apply regardless of holding period, restrictive legends on certificates for shares of our common stock cannot be removed except in connection with an actual sale that is subject to an effective registration statement under, or an applicable exemption from the registration requirements of, the Securities Act of 1933, as amended. Because our unregistered securities cannot be sold pursuant to Rule 144 unless we continue to meet such requirements, any unregistered securities we issue will have limited liquidity unless we continue to comply with such requirements.

If securities and/or industry analysts fail to continue publishing research about our business, if they change their recommendations adversely or if our results of operations do not meet their expectations, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. In addition, it is likely that in some future period our operating results will be below the expectations of securities analysts or investors. If one or more of the analysts who cover us downgrade our stock, or if our results of operations do not meet their expectations, our stock price could decline.

Aspects of the tax treatment of the securities may be uncertain.

The tax treatment of our preferred stock and our warrants is uncertain and may vary depending upon whether you are an individual or a legal entity and whether or not you are domiciled in the United States. In the event you are a non-U.S. investor, you should consult your tax advisors as to the consequences, under the tax laws of the country where you are resident for tax purposes, of acquiring, holding and disposing of our preferred stock and our warrants.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

Our headquarters are located in Tel Aviv, Israel, where we lease a 1,750 square meter office and manufacturing facility that has the capacity to manufacture and assemble 1,200 stents per month, based upon the production schedule of one shift per day. We believe that our current facility is sufficient to meet anticipated future demand by adding additional shifts to our current production schedule.

Item 3. Legal Proceedings.

From time to time, we may become involved in various lawsuits and legal proceedings, which arise in the ordinary course of business. Litigation is subject to inherent uncertainties, and an adverse result in these or other matters may arise from time to time that may harm our business. There are currently no pending material legal proceedings, and we are currently not aware of any legal proceedings or claims against us or our property that we believe will have any significant effect on our business, financial position or operating results.

Item 4. Mine Safety Disclosures.

Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock has been quoted on the Nasdaq Capital Market ("Nasdaq") since May 21, 2021, under the symbol "NSPR." The last reported sales price of our common stock on the Nasdaq on March 28, 2023, was $1.14 per share.

Record Holders

As of March 28, 2023, we had 266 stockholders of record of our common stock. This figure includes an indeterminate number of stockholders who hold their shares in "street name."

Dividends

In the past, we have not declared or paid cash dividends on our common stock. We do not intend to pay cash dividends in the future; rather, we intend to retain future earnings, if any, to fund the operation and expansion of our business and for general corporate purposes.

The holders of Series C Preferred Stock are not entitled to receive any dividends, unless and until specifically declared by our board of directors. However, holders of our Series C Preferred Stock are entitled to receive dividends on shares of Series C Preferred Stock equal (on an as-if-converted-to-common-stock basis, and without giving effect for such purposes to the 4.99% or 9.99% beneficial ownership limitation, as applicable) to and in the same form as dividends actually paid on shares of the common stock when such dividends are specifically declared by our board of directors. We are not obligated to redeem or repurchase any shares of Series C Preferred Stock. Shares of Series C Preferred Stock are not otherwise entitled to any redemption rights, or mandatory sinking fund or analogous fund provision.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with the accompanying consolidated financial statements and related notes included elsewhere in this Annual Report on Form 10-K.

Overview

We are a medical device company focusing on the development and commercialization of our proprietary MicroNet™ stent platform technology for the treatment of complex vascular and coronary disease. A stent is an expandable "scaffold-like" device, usually constructed of a metallic material, that is inserted into an artery to expand the inside passage and improve blood flow. MicroNet, a micron mesh sleeve, is wrapped over a stent to provide embolic protection in stenting procedures.

Our CGuard™ carotid embolic prevention system ("CGuard EPS") combines MicroNet and a self-expandable nitinol stent in a single device for use in carotid artery applications. Our CGuard EPS originally received CE mark approval in the European Union in March 2013 and was fully launched in Europe in September 2015. Subsequently, we launched CGuard EPS in Russia and certain countries in Latin America and Asia, including India. In September 2020, we launched CGuard EPS in Brazil after receiving regulatory approval in July 2020 and on February 3, 2021, we executed a distribution agreement with Chinese partners for the purpose of expanding our presence in China. Currently, we are seeking strategic partners for a potential launch of CGuard EPS in Japan and other Asian countries.

Our CE mark for CGuard EPS under the MDD expired on November 12, 2022, and we are in the final stages of technical documentation review by the Notified Body auditor to meet the MDR requirements for recertification. In the meantime, on February 14, 2023, we received a derogation per Article 97 paragraph 1 of Regulation 2017/745 from the Agency for Medicines and Health Products (FAMHP) allowing us to continue marketing CGuard EPS in the EU until August 15, 2023, subject to certain procedural requirements. Subsequently, on March 20, 2023, Regulation (EU) 2023/607 was published allowing us to continue marketing CGuard EPS in EU countries under the MDD directive until December 31, 2027. As a result of the foregoing, we may market and sell CGuard EPS in the EU and certain other jurisdictions subject to certain procedural requirements while our MDR CE recertification is pending. We continue to expedite the review process for recertification under the MDR.

On September 8, 2020, we received approval from the U.S. Food and Drug Administration ("FDA") of our Investigation Device Exemption ("IDE"), thereby allowing us to proceed with a pivotal study of our CGuard™ Carotid Stent System, C-Guardians, for prevention of stroke in patients in the United States. C-Guardians is a prospective, multicenter, single-arm, pivotal study to evaluate the safety and efficacy of the CGuard™ Carotid Stent System when used to treat symptomatic and asymptomatic carotid artery stenosis in patients undergoing carotid artery stenting. The trial was designed to enroll approximately 315 subjects in a maximum of 40 study sites located in the United States and Europe. Study sites in Europe may contribute a maximum of approximately 50% of the total enrollees. The primary endpoint of the study will be the composite of incidence of death (all-cause mortality), all stroke, and myocardial infarction (DSMI) through 30-days post-index procedure, based on the clinical events committee (CEC) adjudication and ipsilateral stroke from 31-365 day follow-up, based on Clinical Events Committee (CEC) adjudication. The composite index will be compared to a performance goal based on the observed rate of the two components of the primary endpoint from previous pivotal stent trials which are considered industry standard. The performance goal will be considered met if the upper bound of the two-sided 95% confidence interval calculated from the observed primary endpoint rate is < 11.6% and the p-value is less than 0.025.

On July 23, 2021, we announced the initiation of enrollment and successful completion of the first cases of our C-Guardian trial of CGuard EPS. The first patients, who were under the care of principal investigator, Chris Metzger, M.D., system chair of clinical research at Ballard Health System in Eastern Tennessee, were successfully implanted with the CGuard EPS stent device. These are the first of 315 patients who are expected to be enrolled in the trial and receive CGuard EPS in the treatment of carotid artery stenosis in symptomatic and asymptomatic patients undergoing carotid artery stenting. We are currently continuing with the enrollment phase. In April 2022, we completed our first European recruitment.

Additionally, we intend to continue to invest in current and future potential product and manufacturing enhancements for CGuard EPS that are expected to reduce cost of goods and/or provide the best-in-class performing delivery system, CGuard Prime. In furtherance of our strategy that focuses on establishing CGuard EPS as a viable alternative to vascular surgery, we are exploring adding new delivery systems and accessory solutions for procedural protection to our portfolio such as SwitchGuard.

We consider the current addressable market for our CGuard EPS to be individuals with diagnosed, symptomatic high-grade carotid artery stenosis (HGCS, ≥70% occlusion) for whom intervention is preferable to medical (drug) therapy. This group includes not only carotid artery stenting patients but also individuals undergoing carotid endarterectomy, as the two approaches compete for the same patient population. Assuming full penetration of the intervention caseload by CGuard EPS, we estimate that the addressable market for CGuard EPS will be approximately $666 million in 2022 (source: Health Research International Personal Medical Systems, Inc. September 13, 2021 Results of Update Report on Global Carotid Stenting Procedures and Markets by Major Geography and Addressable Markets). According to this same report, assuming full penetration of the caseload for all individuals diagnosed with high-grade carotid artery stenosis, we estimate that the total available market for CGuard EPS in 2022 will be approximately $5 billion.

Our MGuard™ Prime™ embolic protection system ("MGuard Prime EPS") was marketed for use in patients with acute coronary syndromes, notably acute myocardial infarction (heart attack) and saphenous vein graft coronary interventions, or bypass surgery. MGuard Prime EPS combines MicroNet with a bare-metal cobalt-chromium based stent. MGuard Prime EPS received CE mark approval in the European Union in October 2010 for improving luminal diameter and providing embolic protection. Over the past years there has been a shift in industry preferences away from bare-metal stents, such as MGuard Prime EPS in ST-Elevation Myocardial Infarction ("STEMI") patients. As a result of declining sales of the MGuard Prime EPS, which we believe this is largely driven by the predominant industry preferences favoring drug-eluting, or drug-coated, stents, during the second quarter of 2022 we ceased sales of our MGuard Prime EPS following a phase out period.

We also intend to develop a pipeline of other products and additional applications by leveraging our MicroNet technology to improve peripheral procedures such as the treatment of the superficial femoral artery disease and vascular disease below the knee as well as neurovascular procedures, such as the treatment of acute stroke.

Presently, none of our products may be sold or marketed in the United States, but we do derive revenues from the use of our products in the currently ongoing trials.

We were organized in the State of Delaware on February 29, 2008.

Critical Accounting Policies

We prepared our consolidated financial statements in accordance with U.S. Generally Accepted Accounting Principles ("U.S. GAAP"). U.S. GAAP represents a comprehensive set of accounting and disclosure rules and requirements, and applying these rules and requirements requires management judgments and estimates including, in certain circumstances, choices between acceptable U.S. GAAP alternatives. The following is a discussion of our most critical accounting policies, judgments and uncertainties that are inherent in our application of U.S. GAAP.

Use of estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates using assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of sales and expenses during the reporting periods. Actual results could differ from those estimates.

As applicable to these consolidated financial statements, the most significant estimates and assumptions relate to inventory valuations and assessing the likelihood of exercise of options to extend the lease term.

Concentration of credit risk and allowance for doubtful accounts

Financial instruments that may potentially subject us to a concentration of credit risk consist of cash and cash equivalents, which are deposited in major financially sound institutions in the United States, Israel and Germany, and trade accounts receivable. Our trade accounts receivable is derived from revenues earned from customers from various countries. We perform ongoing credit evaluations of our customers' financial condition and, generally, require no collateral from customers. We also have a credit insurance policy for some customers. We maintain an allowance for doubtful accounts receivable based upon the expected ability to collect the accounts receivable. We review our allowance for doubtful accounts quarterly by assessing individual accounts receivable and all other balances based on historical collection experience and an economic risk assessment. If we determine that a specific customer is unable to meet its financial obligations to us, we provide an allowance for credit losses to reduce the receivable to the amount management reasonably believes will be collected, which is netted against "Accounts receivable — Trade".

Inventory

Inventories are stated at the lower of cost (cost is determined on a "first-in, first-out" basis) or net realizable value. Our inventories generally have a limited shelf life and are subject to impairment as they approach their expiration dates. We regularly evaluate the carrying value of our inventories and when, based on such evaluation, factors indicate that impairment has occurred, we impair the inventories' carrying value. In addition, we write-off fails in production based on actual and estimated.

Leases

Operating leases are included in operating lease right-of-use ("ROU") assets, Accounts payable and accruals - Other, and operating lease liabilities. ROU assets represent Company's right to use an underlying asset for the lease term and lease liabilities represent obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. In determining the present value of lease payments, we use the incremental borrowing rate based on the information available at the lease commencement date as the rate implicit in the lease is not readily determinable. The determination of the incremental borrowing rate requires management judgment based on information available at lease commencement. The lease terms may include periods covered by options to extend the lease when it is reasonably certain that we will exercise such options, and periods covered by options to terminate the lease when it is reasonably certain that we will not exercise such options. Operating lease cost is recognized on a straight-line basis over the lease term. Lease agreements that include lease and non-lease components are accounted for as a single lease component. The Company elected the short-term lease recognition exemption for leases with a lease term of 12 months or less. Our Israeli subsidiary had a lease agreement for a facility in Israel, which expired on December 31, 2022, with an option to extend the agreement for two additional years until December 31, 2024. On May 25, 2022 the Company amended the agreement mentioned above and extended it until December 31, 2026 as well as leasing of additional space in the facility, the additional space amendment was taken in consideration when calculating the operating lease right of use assets and liabilities. The amendment period added approximately $835,000 to the leasing liability.

Revenue recognition

A contract with a customer exists only when: 1) the parties to the contract have approved it and are committed to perform their respective obligations, 2) we can identify each party's rights regarding the distinct goods or services to be transferred ("Performance Obligations"), 3) we can determine the transaction price for the goods or services to be transferred, 4) the contract has commercial substance and 5) it is probable that we will collect the consideration to which it will be entitled in exchange for the goods or services that will be transferred to the customer. Revenues are recorded in the amount of consideration to which we expect to be entitled in exchange for Performance Obligations upon transfer of control to the customer, excluding sales taxes.

Revenue from sales of goods, including sales to distributors, is recognized when the customer obtains control of the product, once we have a present right to payment, legal title, and risk and rewards of ownership are obtained by the customer. This occurs when products are shipped.

We recognize the incremental costs of obtaining contracts as an expense since the amortization period of the assets that we otherwise would have recognized is one year or less. The costs are recorded under selling and marketing expenses.

We recognize revenue net of value added tax (VAT).

Share-based compensation

Employee option awards are classified as equity awards and accounted for using the grant-date fair value method. The fair value of share-based awards is estimated using the Black-Scholes valuation model and expensed over the requisite service period, net of estimated forfeitures. We elected to account for forfeitures as they occur.

We elected to recognize compensation expenses for awards with only service conditions that have graded vesting schedules using the accelerated multiple option approach.

Results of Operations

Twelve months ended December 31, 2022 compared to the twelve months ended December 31, 2021

Revenues. For the twelve months ended December 31, 2022, revenue increased by $676,000, or 15%, to $5,171,000, from $4,495,000 during the twelve months ended December 31, 2021. This increase was predominantly driven by a 18.9% increase in sales volume of CGuard EPS, from $4,309,000 during the twelve months ended December 31, 2021, to $5,123,000 during the twelve months ended December 31, 2022. This sales increase was mainly due to growth in existing and new markets and sales in the United States related to stents used in our C-Guardians FDA study as enrolment accelerated.

With respect to regions, the increase in revenue was primarily attributable to a $269,000 increase in Latin America, a $112,000 increase in Asia, a $94,000 increase in Europe and a $50,000 increase in other geographies. This growth was mainly due to growth in existing and new markets. In addition, there was a $151,000 increase in revenue from North America due to sales in the United States related to stents used in our C-Guardians FDA study.

Gross Profit. For the twelve months ended December 31, 2022, gross profit (revenue less cost of revenues) increased by 48.1%, or $363,000, to $1,117,000, compared to a gross profit of $754,000 for the same period in 2021. This increase in gross profit resulted from a $186,000 increase in revenues (as mentioned above) less the associated related material and labor costs and a decrease of $177,000 in miscellaneous expenses. Gross margin (gross profits as a percentage of revenue) increased to 21.6% during the twelve months ended December 31, 2022 from 16.8% during the twelve months ended December 31, 2021, driven by the reasons mentioned above.

Research and Development Expenses. For the twelve months ended December 31, 2022, research and development expenses increased by 51.4%, or $2,652,000, to $7,810,000, from $5,158,000 during the twelve months ended December 31, 2021. This increase resulted primarily from an increase of $2,431,000 in expenses related to the enrollment in the C-Guardians FDA study which commenced in the second half of 2021 and an increase of $221,000 in miscellaneous expenses.

Selling and Marketing Expenses. For the twelve months ended December 31, 2022, selling and marketing expenses increased by 26.0%, or $757,000, to $3,664,000, from $2,907,000 during the twelve months ended December 31, 2021. This increase resulted primarily from an increase in salary expenses of $297,000, an increase in tradeshows and travel expenses of $288,000 in light of resumed marketing activities following the lifting of restrictions related to COVID-19, and an increase in share-based compensation expenses of $157,000 due to the expense recognition of grants made during the fourth quarter of 2021.

General and Administrative Expenses. For the twelve months ended December 31, 2022, general and administrative expenses increased by 12.8%, or $951,000, to $8,356,000, from $7,405,000 during the twelve months ended December 31, 2021. This increase resulted primarily from an increase in share-based compensation-related expenses of $372,000, mainly due to the expense recognition of grants made during the fourth quarter of 2021, an increase in regulatory expenses of $214,000 related to the implementation of the new European Medical Device Regulation, an increase in patent related expenses of $155,000, an increase in travel expenses of $139,000 in light of resumed activities following governments lifting restrictions related to COVID-19, an increase in directors' and officers' liability insurance expenses of $107,000, due to increased premiums caused by recent trends in the overall insurance industry and an increase of $154,000 in miscellaneous expenses offset, in part, by a decrease in shareholder related expenses of $190,000 mainly due to a special shareholders meeting (which occurred in 2021, but not in 2022) and also due to higher costs of our annual stockholder meeting in 2021 compared to our annual stockholder meeting in 2022.

Financial Income (Expenses). For the twelve months ended December 31, 2022, financial income increased by $407,000, to $250,000 of financial income, from $157,000 of financial expense during the twelve months ended December 31, 2021. The increase in financial income primarily resulted from a $229,000 increase in interest income from short-term bank deposits and an increase of $181,000 in financial income related to changes in exchange rates.

Tax Expenses. For the twelve months ended December 31, 2022, tax decreased by $17,000 compared to the twelve months ended December 31, 2021. Our expenses for income taxes reflect primarily the tax liability due to potential tax exposure.

Net Loss. Our net loss increased by $3,573,000, or 24.0%, to $18,491,000, for the twelve months ended December 31, 2021, from $14,918,000 during the twelve months ended December 31, 2021. The increase in net loss resulted primarily from an increase of $4,360,000 in operating expenses partially offset by an increase of $407,000 in financial income and an increase of $363,000 in gross profit.

Liquidity and Capital Resources

We had an accumulated deficit as of December 31, 2022 of $201 million, as well as a net loss of $18,491,000 and negative operating cash flows. We expect to continue incurring losses and negative cash flows from operations until our product, CGuard EPS, reach commercial profitability. As a result of these expected losses and negative cash flows from operations, along with our current cash position, we believe we have sufficient resources to fund operations until the end of September 2023. Therefore, there is substantial doubt about our ability to continue as a going concern.

Equity Financings

On July 28, 2020, we entered into a Sales Agreement with A.G.P. in connection with the ATM Facility. Any shares to be offered and sold under the Sales Agreement will be issued and sold pursuant to the Company's Registration Statement on Form S-3 (File No. 333-223130), filed with the Securities and Exchange Commission ("SEC") on February 21, 2018 and the prospectus supplement thereto filed with the SEC on July 28, 2020, by methods deemed to be an "at the market offering" as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended, or if specified by us, by any other method permitted by law. On January 11, 2021, we increased the aggregate amount of our shares of common stock that may be sold under the Sales Agreement from $9,300,000 to $10,382,954, and, as a result, utilized and sold the maximum amount allowable under the ATM Facility, which resulted in an aggregate amount of $10,381,958.

On February 8, 2021, we closed an underwritten public offering of 1,935,484 units, with each such unit being comprised of one share of our common stock, par value $0.0001 per share, and one Series G Warrant to purchase one-half of one share of common stock. The offering price to the public was $9.30 per unit. The Series G Warrants were immediately exercisable at a price of $10.23 per share, subject to adjustment in certain circumstances, and expire five years from the date of issuance. We also granted the underwriter of the offering an option to purchase an additional 290,322 shares of common stock and Series G Warrants to purchase 145,161 shares of common stock, which the underwriter exercised in full. In connection with the offering, we granted to the underwriter a compensation warrant to purchase up to 111,290 shares of common stock with an exercise price of $10.23 per share and which are exercisable for five years from February 3, 2021, the date of effectiveness of the registration statement filed in connection with the offering. Our net proceeds from the offering, after giving effect to the exercise of the underwriter's over-allotment option, were approximately $18.9 million, after deducting underwriting discounts and commissions and payment of other estimated expenses associated with the offering, but excluding the proceeds, if any, from the exercise of Series G Warrants sold in the offering.

On February 3, 2021, we entered into a Distribution Agreement with three China-based partners and on the same day, we entered into an investment transaction with QIDI, which included (i) an SPA, pursuant to which QIDI agreed to invest $900,000 in exchange for shares of our common stock at a purchase price of $10.062 per share, and (ii) an IRA, whereby QIDI was provided certain customary registration rights, including a commitment by us to file a registration statement with the SEC on Form S-1 or Form S-3 and have such registration statement become effective not later than 150 days following the closing of the transactions under the SPA. The transaction closed on February 5, 2021.

Twelve months ended December 31, 2022 compared to the twelve months ended December 31, 2021

General. At December 31, 2022, we had cash and cash equivalents of $4,632,000 and Short-term bank deposits of $13,171,000 as compared to $12,004,000 of cash and cash equivalents and $22,036,000 Short-term bank deposits as of December 31, 2021. We have historically met our cash needs through a combination of issuing new shares, borrowing activities and product sales. Our cash requirements are generally for research and development, marketing and sales activities, finance and administrative cost, capital expenditures and general working capital.

For the twelve months ended December 31, 2022, net cash used in our operating activities increased by $2,332,000 to $15,542,000, from $13,210,000 during the same period in 2021. The primary reason for the increase in cash used in our operating activities was an increase of $3,148,000 in payments for third party related expenses and for professional services (primarily due to payments related to our ongoing FDA trial, and production related payments), an increase of $802,000 in salary and bonus payments from $7,756,000 in the twelve months ended December 31, 2021 to $8,558,000 during the same period in 2022 offset, in part, by an increase of $1,618,000 in payments received from customers to $5,333,000 during the twelve months ended December 31, 2022, from $3,715,000 during the same period in 2021.

Cash provided by our investing activities was $8,441,000 during the twelve months ended December 31, 2022, compared to cash used of $22,457,000 during the twelve months ended December 31, 2021. The primary reasons for the increase in cash provided by our investing activities was withdrawal of short-term deposits, net of investments of $9,000,000 during the twelve months ended December 31,2022 , compared to investment in short-term deposits, net of withdrawals of $22,000,000 during the twelve months ended December 31,2021, and due to a decrease in employee funds to $86,000 during the twelve months ended December 31, 2022, compared to employee funds of $113,000 during the same period in 2021, offset, in part, by an increase of $129,000 in net payments made for purchase of property, plant and equipment to $473,000 during the twelve months ended December 31, 2022, from $344,000 during the same period in 2021.

Cash Used by financing activities for the twelve months December 31, 2022, was $140,000, compared to cash provided of $35,034,000 during the same period in 2021. The principal sources of the cash used by financing activities during the twelve months ended December 31, 2022 were due to issuance costs associated with a shelf registration statement on Form S-3 filed with the SEC on June 3, 2022. The principal sources of the cash provided by financing activities during the twelve months ended December 31, 2021 were our February 2021 public offering of common stock and warrants, exercise of Series F and Series G warrants, proceeds from an At-the-market offering as well as proceeds from the issuance of shares to Chinese distributor that resulted in approximately $35,034,000 of aggregate net proceeds.

As of December 31, 2022, our current assets exceeded our current liabilities by a multiple of 4.2. Current assets decreased by $15,768,000 during the period and current liabilities increased by $723,000 during the period. As a result, our working capital decreased by $16,491,000 to $16,256,000 as of December 31, 2022.

Off Balance Sheet Arrangements

We have no off-balance sheet transactions, arrangements, obligations (including contingent obligations), or other relationships with unconsolidated entities or other persons that have, or may have, a material effect on our financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

Recent Accounting Pronouncements

In June 2016, the FASB issued ASU 2016-13, Financial Instruments-Credit Losses (Topic 326)-Measurement of Credit Losses on Financial Instruments. 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 2019, the FASB issued ASU No. 2019-10, Financial Instruments - Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842): Effective Dates ("ASU 2019-10"). The purpose of this amendment is to create a two tier rollout of major updates, staggering the effective dates between larger public companies and all other entities. This granted certain classes of companies, including Smaller Reporting Companies ("SRCs"), additional time to implement major FASB standards, including ASU 2016-13. Larger public companies had an effective date of December 15, 2019, including interim periods within those fiscal years. +All other entities are permitted to defer adoption of ASU 2016-13, and its related amendments, until the earlier of fiscal periods beginning after December 15, 2022. Under the current SEC definitions, we meet the definition of an SRC and are adopting the deferral period for ASU 2016-13. The guidance requires a modified retrospective transition approach through a cumulative-effect adjustment to retained earnings as of the beginning of the period of adoption. We do not believe the adoption of this standard will have a material impact on our consolidated financial statements.

In November 2021, the FASB issued ASU 2021-10 "Government Assistance (Topic 832)", which requires annual disclosures that increase the transparency of transactions involving government grants, including (1) the types of transactions, (2) the accounting for those transactions, and (3) the effect of those transactions on an entity's financial statements. The amendments in this update are effective for financial statements issued for annual periods beginning after December 15, 2021. However, it is not expected to have a material impact on the consolidated financial results of operations, financial position or cash flows.

Factors That May Affect Future Operations

We believe that our future operating results will continue to be subject to quarterly variations based upon a wide variety of factors, including the cyclical nature of the ordering patterns of our distributors, timing of regulatory approvals, the implementation of various phases of our clinical trials and manufacturing efficiencies due to the learning curve of utilizing new materials and equipment. Our operating results could also be impacted by a weakening of the Euro and strengthening of the NIS, both against the U.S. dollar. Lastly, other economic conditions we cannot foresee may affect customer demand, such as individual country reimbursement policies pertaining to our products.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

Not applicable.

Item 8. Financial Statements and Supplementary Data.

The following financial statements are included as part of this Report (See Item 15):

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

Not applicable.

Item 9A. Controls and Procedures.

Management's Conclusions Regarding Effectiveness of Disclosure Controls and Procedures

We conducted an evaluation of the effectiveness of our "disclosure controls and procedures", as defined by Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended, as of December 31, 2022, the end of the period covered by this Annual Report on Form 10-K. The disclosure controls and procedures evaluation was done under the supervision and with the participation of management, including our chief executive officer and chief financial officer. There are inherent limitations to the effectiveness of any system of disclosure controls and procedures. Accordingly, even effective disclosure controls and procedures can only provide reasonable assurance of achieving their control objectives. Based upon this evaluation, our chief executive officer and chief financial officer have concluded that our disclosure controls and procedures were effective at the reasonable assurance level as of December 31, 2022.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended. Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the consolidated financial statements for external reporting purposes in accordance with generally accepted accounting principles.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness of internal control over financial reporting to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate over time.

Management, including our chief executive officer and our chief financial officer, assessed the effectiveness of our internal control over financial reporting as of December 31, 2022. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control—Integrated Framework 2013*. Based on its assessment and those criteria, management has concluded that we maintained effective internal control over financial reporting as of December 31, 2022.

Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting during the fiscal quarter ended December 31, 2022, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Executive Officers and Directors

The following table sets forth information regarding our executive officers and the members of our board of directors.

Name	Age	Position
Marvin Slosman	59	President, Chief Executive Officer and Director
Craig Shore	61	Chief Financial Officer, Chief Administrative Officer, Secretary and Treasurer
Andrea Tommasoli	51	Chief Operating Officer
Shane Gleason	49	General Manager of North America and VP of Global Marketing
Michael Berman[(1)(2)]	65	Director
Paul Stuka[(1)(2)(3)]	68	Chairman of the Board of Directors
Thomas J. Kester[(1)(3)]	76	Director
Gary Roubin, M.D.	74	Director
Kathryn Arnold[(3)]	50	Director

(1) Member of our audit committee

(2) Member of our nominating and corporate governance committee

(3) Member of our compensation committee

Our directors hold office until the earlier of their death, resignation or removal by stockholders or until their successors have been qualified. Our directors are divided into three classes. Paul Stuka and Gary Roubin are our Class 1 directors, with their terms of office expiring at our 2024 annual meeting of stockholders. Michael Berman is our Class 2 director, with his term of office expiring at our 2025 annual meeting of stockholders. Marvin Slosman, Thomas J. Kester and Kathryn Arnold are our Class 3 directors, with their terms of expiring at our 2023 annual meeting of stockholders. At each annual meeting of stockholders, directors elected to succeed those directors whose terms expire shall be elected for a term of office to expire at the third succeeding annual meeting of stockholders after their election, with each director to hold office until his or her successor shall have been duly elected and qualified.

Our officers hold office until the earlier of their death, resignation or removal by our board of directors or until their successors have been selected. They serve at the pleasure of our board of directors.

Marvin Slosman has served as our president, chief executive officer and director since January 1, 2020. Mr. Slosman has served as chief operating officer for MEDCURA Inc. from May 2019 to December 2019. From September 2017 to September 2019, Mr. Slosman served as a Business Consultant, overseeing international commercial strategy and market development, at Integra Life Sciences, a leading innovator in orthopedic extremity surgery, neurosurgery, and reconstructive and general surgery. From 2010 to 2014 Mr. Slosman served as President of Itamar Medical, Inc., a medical technology company focused on cardiovascular and sleep diagnostics. Mr. Slosman also served as chief executive officer of Ovalum Vascular Ltd. from 2008 to 2010. Mr. Slosman's qualifications to serve on the board of directors of the Company include his significant experience in senior management positions of leading medical device companies.

Craig Shore has served as our chief financial officer, secretary and treasurer since March 31, 2011 and as our chief administrative officer since May 3, 2013. In addition, from November 10, 2010 through March 31, 2011, Mr. Shore served as InspireMD Ltd.'s vice president of business development. Mr. Shore has vast experience in financial management in the United States, Europe and Israel for companies such as Pfizer Pharmaceuticals, Bristol Myers Squibb and General Electric. His experience includes raising capital both in the private and public markets. Mr. Shore graduated with honors and received a B.Sc. in Finance from Pennsylvania State University and an M.B.A. from George Washington University.

Andrea Tommasoli has served as our Chief Operating Officer since March 19, 2023. Prior to Mr. Tommasoli's appointment as Chief Operating Officer, he served as our Senior Vice President of Global Sales and Marketing since November 2020 bringing over two decades of life sciences industry experience to the Company. Prior to joining the Company, Mr. Tommasoli held commercial leadership positions at Integra LifeSciences, a medical device manufacturing company that manufactures products for skin regeneration, neurosurgery, reconstructive and general surgery, from 2011 to 2020, serving as the Senior Director of Indirect Markets from January 2017 to October 2020, as Director of Sales for Specialty Surgical Solutions Europe from June 2014 to December 2016 and as Director of Sales for Neurosurgery EMEA from July 2011 to June 2014. Prior to joining Integra, Mr. Tommasoli was a Managing Partner at Alticare, an independent company focusing on start-ups and growth companies in the medtech business from 2009 to 2011 and was the Director of St. Jude Medical Neuromodulation division in France from 2007 to 2009. Mr. Tommasoli has vast experience in commercializing innovative medical technology solutions that improve and advance standard of care. Mr. Tommasoli received his B.A. in nuclear engineering from Bologna University, Italy and his M.B.A. from HEC Paris, France.

Shane Gleason has served as our general manager of North America and vice president of global marketing since March 1, 2023. Prior to joining us, Mr. Gleason served as served as vice president of sales, vascular interventions at Surmodics from 2021. Before that, from 2019 to 2021, he served as senior director, US marketing at Edwards Life Sciences (NYSE: EW), a developer of artificial heart valve and hemodynamic monitoring technologies, and, before that, from 2017 to 2019 as, chief commercial officer at Nuvaira, Inc., a privately held developer of COPD therapies that preserve patient lung health. Earlier in his career, Mr. Gleason held sales and marketing leadership roles at Cordis, a Cardinal Health company (NYSE: CAH) from 2015 to 2016, Trivascular Technologies (part of Endologix) from 2012 to 2015, and Abbott Vascular (NYSE: ABT) from 2007 to 2010, where he launched the second FDA approved carotid stent system. Mr. Gleason received a Bachelor of Science, Engineering Science and Mechanics from Virginia Polytechnic Institute and State University and a Master of Business Administration from the University of Maryland Smith School of Business.

Michael Berman has served as our director since February 7, 2013. Mr. Berman is a medical device entrepreneur who has worked with high-potential development and early-stage commercial companies since 2014. From 2005 to 2012, Mr. Berman was a co-founder and the chairman of BridgePoint Medical, Inc., which developed technology to treat coronary and peripheral vascular chronic total occlusions and which was sold to Boston Scientific. Mr. Berman was also a member of the board of Lutonix, Inc. from 2007 until 2011, when the company was sold to C.R. Bard, Inc. From 2011 to 2018, Mr. Berman served as a co-founder and director of Rebiotix Inc., a company developing an innovative treatment for C Diff colitis. Rebiotix was sold to Ferring Pharmaceuticals in 2018. From 2014 till 2018 Mr. Berman served as a director of Mazor Robotics, a company pioneering Spinal Robotic Surgery. Mazor was sold to Medtronic in 2018. Mr. Berman has served (i) since 2011 as an advisor to, and since 2012 as a director of, Cardiosonic, Inc., a company developing a system for hypertension reduction via renal denervation, (ii) since 2005 as a director of PharmaCentra, LLC, which creates customizable marketing programs that help pharmaceutical companies communicate with physicians and patients, (iii) since 2018 as a Director of STMedical, a medical device company that has developed a temporary stent for the treatment of chronic sinusitis, (iv) since 2019 as a director of CardiacSense Inc, a medical device company that has developed a smart watch vital sign monitor, (v) since 2017 as a Director of Owlytics Healthcare, (vi) since 2013 as a Director of ClearCut Inc., a medical device company that has developed an MRI system for tumor margin assessment, (vii) since 2013 as a director of PulmOne Ltd., a medical device company developing an innovative Pulmonary Function Testing system, (viii) since 2019 as a director of QArt, a medical device company, (ix) since 2014 as a venture partner at RiverVest Ventures. (x) since 2017 as a Director of Truleaf Medical and (xi) since 2022 as a Director of Kedma Solar Ltd. Mr. Berman brings to the board his extensive executive and entrepreneurial experiences in the field of medical devices and vascular intervention, which should assist in strengthening and advancing our strategic focus.

Paul Stuka has served as a director since August 8, 2011 and has served as our chairman since June 2, 2017. Mr. Stuka has served as the managing member of Osiris Partners, LLC, an investment fund, since 2000. Prior to forming Osiris Partners, LLC, Mr. Stuka, with 35 years of experience in the investment industry, was a managing director of Longwood Partners, managing small cap institutional accounts. In 1995, Mr. Stuka joined State Street Research and Management as manager of its Market Neutral and Mid Cap Growth Funds. From 1986 to 1994, Mr. Stuka served as the general partner of Stuka Associates, where he managed a U.S.-based investment partnership. Mr. Stuka began his career in 1980 as an analyst at Fidelity Management and Research. As an analyst, Mr. Stuka followed a wide array of industries including healthcare, energy, transportation, and lodging and gaming. Early in his career he became the assistant portfolio manager for three Fidelity Funds, including the Select Healthcare Fund which was recognized as the top performing fund in the United States for the five-year period ending December 31, 1985. From 2013 to 2022 Mr. Stuka served as a director of Caliber Imaging & Diagnostics, Inc. (formerly Lucid, Inc.). Mr. Stuka's qualifications to serve on the board include his significant strategic and business insight from his years of experience investing in the healthcare industry.

Thomas J. Kester has served as a director since September 6, 2016. Mr. Kester has been serving as the chief financial officer of Kester Search Group, LLC Inc., a private executive search firm specializing in sales force placement for medical, dental and diagnostic device companies, since October 2014. From 2004 to 2010, Mr. Kester served as a director of Orthofix International, NV (NASDAQ: OFIX), a global medical device company. From 2004 till 2019 Mr. Kester served as a director of Conestee Foundation Inc, a not for profit organization that developed a 400 acre Nature Preserve in the center of Greenville County, SC . Mr. Kester has served (i) since 2003 as a director of Upstate forever, a not for profit in Greenville, SC focused on protecting special places in the 10 county upstate region of South Carolina and promoting sustainable development, (ii) since 2021 as a director of South Carolina Environmental Law Project, a not for profit law firm representing clients on environmental issues. Mr. Kester's experience includes 28 years from 1974 until 2002 at KPMG LLP, including 18 years as an audit partner, advising public and private companies in connection with annual audit and financings. Mr. Kester's qualifications to serve on the board include his significant strategic and business insight from his years of experience auditing global companies and serving on the boards of several public and not-for-profit organizations. Mr. Kester received his B.S. in mechanical engineering from Cornell University and an M.B.A. from Harvard University.

Gary Roubin, M.D. has served as a director since October 13, 2020. Dr. Roubin cofounded Essential Medical Inc. in 2010, which has had success in bringing a large bore vascular closure device to world markets and was recently acquired by Teleflex Inc. From 2002 to 2003, Dr. Roubin served as Chief Medical Officer of the Medicines Company during the release of its Angiomax product. From 2003 to 2012, Dr. Roubin served as Department Chairman and Chief of Service of the Lenox Hill Hospital Cardiac and Vascular program in New York. From 1989 to 1997, he served as Chief of Interventional Cardiology at the University of Alabama at Birmingham, to which he joined in 1989 as Professor of Medicine and Radiology and Director of the Cardiac Catheterization Laboratories and Interventional Cardiology Section at the University Hospital. In 2001, Dr. Roubin played a pivotal role in the success of Mednova Inc., which was acquired by Abbott Vascular, resulting in the introduction and marketing in the U.S. of the top selling carotid embolic protection system (NAV6) and stent system (XACT). In 1987, he developed and placed the world's first balloon expandable coronary stent. In 1984, Dr. Roubin joined Andreas Gruentzig at Emory University to continue his post-doctoral research. He is also acknowledged for the development of coronary stenting and the first FDA-approved coronary stent. Dr. Roubin received his M.D. from the University of Queensland medical school and his Ph.D. from Sydney University. Dr. Roubin is qualified to serve on the board given that he is an internationally renowned interventional cardiologist recognized for his pioneering work in carotid stenting and embolic and protection devices. He is also acknowledged for the development of coronary stenting and the first FDA-approved coronary stent.

Kathryn Arnold has served as our director since May 10, 2021. Ms. Arnold is the Founder and CEO of SPRIG Consulting, a strategic marketing consulting firm with over a decade of success in the medical space. Prior to founding SPRIG, Ms. Arnold held sales and marketing management roles with Guidant Corporation (acquired by Abbott Laboratories and Boston Scientific) and Kensey Nash Corporation (acquired by Spectranetics Corporation / Royal Philips). Additionally, Ms. Arnold is an adjunct faculty member at the Kellogg School of Management at Northwestern University where she teaches a course specific to medical product commercialization and financing. Ms. Arnold received a bachelor of arts in environmental science from the University of Vermont and a master's degree from the Kellogg School of Management at Northwestern University.

Board Diversity Matrix

The table below provides certain information regarding the diversity of our board of directors as of the date set forth below.

Board Diversity Matrix (As of March 28, 2023)

Total Number of Directors	**6**			
	Female	**Male**	**Non-Binary**	**Did Not Disclose Gender**
Part I: Gender Identity				
Directors	1	5	#	#
Part II: Demographic Background				
African American or Black	#	#	#	#
Alaskan Native or Native American	#	#	#	#
Asian	#	#	#	#
Hispanic or Latinx	#	#	#	#
Native Hawaiian or Pacific Islander	#	#	#	#
White	1	5	#	#
Two or More Races or Ethnicities	#	#	#	#
LGBTQ+		0		
Did Not Disclose Demographic Background		#		

Family Relationships

We have no family relationships amongst our directors and executive officers.

Board Committees

Our board of directors has established an audit committee, a nominating and corporate governance committee and a compensation committee, each of which has the composition and responsibilities described below.

Audit Committee. Our audit committee is currently comprised of Messrs. Berman, Stuka and Kester, each of whom our board has determined to be financially literate and qualify as an independent director as defined in the Nasdaq Listing Rules and Rule 10A-3 promulgated under the Exchange Act. Mr. Kester is the chairman of our audit committee and qualifies as a financial expert, as defined in Item 407(d)(5)(ii) of Regulation S-K. The audit committee's duties are to recommend to our board of directors the engagement of independent auditors to audit our financial statements and to review our accounting and auditing principles. The audit committee will review the scope, timing and fees for the annual audit and the results of audit examinations performed by the internal auditors and independent public accountants, including their recommendations to improve the system of accounting and internal controls. The audit committee operates under a formal charter adopted by the board of directors that governs its duties and conduct. Copies of the charter can be obtained free of charge from the Company's web site, www.inspiremd.com, by contacting the Company.

Nominating and Corporate Governance Committee. Our nominating and corporate governance committee is currently comprised of Messrs. Berman and Stuka, each of whom qualify as an independent director under as defined in the Nasdaq Listing Rules and Rule 10A-3 promulgated under the Exchange Act. Mr. Berman is the chairman of our nominating and corporate governance committee. The nominating and corporate governance committee identifies and recommends to our board of directors individuals qualified to be director nominees. In addition, the nominating and corporate governance committee recommends to our board of directors the members and chairman of each board committee who will periodically review and assess our code of business conduct and ethics and our corporate governance guidelines. The nominating and corporate governance committee also makes recommendations for changes to our code of business conduct and ethics and our corporate governance guidelines to our board of directors, reviews any other matters related to our corporate governance and oversees the evaluation of our board of directors and our management. The nominating and corporate governance committee operates under a formal charter adopted by the board of directors that governs its duties and conduct. Copies of the charter can be obtained free of charge from the Company's web site, www.inspiremd.com, by contacting the Company.

Compensation Committee. Our compensation committee is currently comprised of Messrs. Stuka and Kester and Ms. Arnold, each of whom qualify as an independent director under as defined in the Nasdaq Listing Rules and Rule 10A-3 promulgated under the Exchange Act. Mr. Stuka is the chairman of our compensation committee. The compensation committee reviews and approves our salary and benefits policies, including compensation of executive officers and directors. The compensation committee also administers our stock option plans and recommends and approves grants of stock options under such plans. The compensation committee operates under a formal charter adopted by the board of directors that governs its duties and conduct. Copies of the charter can be obtained free of charge from the Company's web site, www.inspiremd.com, by contacting the Company.

Code of Ethics

We have adopted a code of ethics and business conduct that applies to our officers, directors and employees, including our principal executive officer, principal financial officer and principal accounting officer, which is posted on our website at *www.inspiremd.com*. We intend to disclose future amendments to certain provisions of the code of ethics, or waivers of such provisions granted to executive officers and directors, on this website within four business days following the date of such amendment or waiver.

Item 11. Executive Compensation.

Summary Compensation Table

The table below sets forth the compensation earned by our named executive officers for the twelve-month period ended December 31, 2022 and 2021.

Name and Principal Position	Year	Salary ($)	Bonus ($)	Stock Awards ($)[1]	Option Awards ($)[1]	All Other Compensation ($)	Total ($)
Marvin Slosman	2022	432,500[3]	233,550[4]	-	-	30,759[5]	696,809
President and Chief Executive Officer	2021	410,000[2]	169,125[4]	603,856	428,803	24,360[5]	1,636,144
Craig Shore	2022	319,524[6]	164,698[4][6]	-	-	141,013[7]	625,234
Chief Financial Officer, Secretary and Treasurer	2021	319,569[6]	164,257[4][6]	300,669	130,499	141,867[7]	1,056,861
Andrea Tommasoli [8]	2022	226,837[9][10]	71,193[4][10][11]	-	-	61,239[12]	359,269
Chief Operating Officer	2021	242,515	46,572[4][10][11]	244,192	72,872	62,337[12]	668,488

(1) For awards of stock, the aggregate grant date fair value is computed in accordance with FASB ASC Topic 718. Fair value is based on the Black-Scholes option pricing model using the fair value of the underlying shares at the measurement date.

(2) Effective as of July 1, 2021, Mr. Slosman's annual base salary was increased to $420,000.

(3) Effective as of July 1, 2022, Mr. Slosman's annual base salary was increased to $445,000.

(4) Cash bonus awards for the 2021 calendar year were approved by the compensation committee in January 2022. Cash bonus awards for the 2022 calendar year were approved by the compensation committee in January 2023.

(5) Mr. Slosman's other compensation for the twelve months ended December 31, 2022 and 2021 consisted of benefits related to health insurance.

(6) Effective as of January 1, 2022, Mr. Shore's annualized base salary was increased to NIS 1,073,280. Compensation amounts received in non-U.S. currency have been converted into U.S. dollars using the average exchange rate for the applicable period, except for bonus amounts which have been converted into U.S. dollars using 3.519 NIS per dollar which was the exchange rate as of December 31, 2022. The average exchange rate for the twelve month period ended December 31, 2022 and 2021 were 3.359 NIS per dollar and 3.229 NIS per dollar, respectively.

(7) Mr. Shore's other compensation consisted solely of benefits in the twelve months ended December 31, 2022 and 2021. In each of the periods reported, Mr. Shore's benefits included our contributions to his severance, pension, vocational studies and disability funds, an annual recreation payment, a company car or car allowance, cell phone and a daily food allowance.

(8) Mr. Tommasoli was appointed Chief Operating Officer in March 2023. Amounts presented are during Mr. Tommasoli's tenure as Senior Vice President of Global Sales and Marketing.

(9) Effective as of January 1, 2022, Mr. Tommasoli' s annualized base salary was increased to Euro 215,256.

(10) Compensation amounts received in non-U.S. currency have been converted into U.S. dollars using the average exchange rate for the applicable period, except for bonus amounts which have been converted into U.S. dollars using 1.073 Euro per dollar which was the exchange rate as of December 31, 2022. The average exchange rate for the twelve-month period ended December 31, 2022 and 2021 were 1.054 Euro per dollar and 1.183 Euro per dollar, respectively.

(11) Amount consists of a cash bonus of $14,546 and sales commissions of $56,647 with respect to 2022 and a cash bonus of $21,599 and sales commissions of $24,973 with respect to 2021.

(12) Mr. Tommasoli's other compensation consisted solely of benefits in the twelve months ended December 31, 2022 and 2021. In each of the periods reported, Mr. Tommasoli' s benefits included our contributions to car allowance, retirement benefits, health insurance, provident fund and other insurances typical in France (excluding social security charges for illness, family allowance and retirement).

Agreements with Named Executive Officers

Marvin Slosman

On December 9, 2019, we entered into an Employment Agreement with Marvin Slosman, which was subsequently amended on December 31, 2019, November 8, 2021 and January 5, 2023 (as amended, the "Slosman Employment Agreement"), pursuant to which Mr. Slosman was appointed as our new chief executive officer and president. Mr. Slosman's term of employment commenced on January 1, 2020, was to remain in effect for three years (the "Initial Employment Term"), unless earlier terminated, and was to be automatically renewed for successive one-year terms after the Initial Employment Term. We subsequently amended Mr. Shore's employment agreement to remove that certain definitive term of his employment such that his employment agreement shall expire if and when terminated by either party pursuant to the terms thereof. Mr. Slosman was also appointed as a Class 3 director, effective January 1, 2020, with a term expiring on the 2020 annual meeting of our stockholders.

As consideration for his services as chief executive officer, Mr. Slosman will be entitled to receive (i) an annual base salary, which as of July 1, 2022 was increased to $445,000, less applicable payroll deductions and tax ("Base Salary"), which will be reviewed by the Board on an annual basis for increase; (ii) reimbursement of up to $50,000 for any reasonable and customary, documented out-of-pocket relocation expenses actually incurred by Mr. Slosman in 2019 or 2020 calendar years, in connection with his relocation to Europe; (iii) annual performance bonuses in an amount up to 60% percent of the Base Salary, as may be in effect from time to time, for each calendar year during his employment with us based on the extent to which performance criteria/financial results for the applicable year have been met; and (iv) equity awards as of the date of the Slosman Employment Agreement that represent, in the aggregate, 5% of the Company's issued and outstanding common stock determined on a fully diluted basis as of the date of grant (the "Equity Awards"), with 75% of the Equity Awards being granted as restricted stock units and with the remaining 25% of the Equity Awards being granted as stock options, all of which Equity Awards shall be outside of the 2013 Long-Term Incentive Plan and subject to terms and conditions of the award agreements entered by Mr. Slosman. In addition, on or before December 31, 2020, Mr. Slosman shall become eligible to receive an additional grant of equity awards under the 2013 Long-Term Incentive Plan and the applicable award agreements up to 5% (including the Equity Awards) of the Company's actual outstanding shares of Common Stock on the date of grant, provided that the actual amount of the grant shall be based on the achievement of certain performance/financial criteria as established by the Board after consultation with Mr. Slosman, in its reasonable discretion.

In January 2022, the Compensation Committee approved a reimbursement of up to $50,000 for any reasonable and customary, documented out-of-pocket relocation expenses actually incurred by Mr. Slosman in the 2022 calendar years, in connection with his relocation to Europe, as well as $62,500 in expenses on an annual basis for expenses relating to commuting expenses, health coverage and corporate and visa status costs.

In the event Mr. Slosman voluntarily resigns without good reason, we may, in our sole discretion, shorten the notice period and determine the date of termination without any obligation to pay Mr. Slosman any additional compensation other than the accrued obligations and without triggering a termination of Mr. Slosman's employment without cause. In the event we terminate Mr. Slosman's employment for cause or Mr. Slosman voluntarily resigns without good reason, we shall have no further liability or obligation to Mr. Slosman under the Slosman Employment Agreement. Notwithstanding the foregoing, in the event that this the Slosman Employment Agreement terminates, we shall, subject to the execution and timely return by Mr. Slosman of a release of claims, pay Mr. Slosman cash payments totalling $100,000 in the aggregate, payable in equal instalments on our regular pay dates that occur during the period commencing on 60th day following his employment termination date and ending on the last day of the Restricted Period (as defined below); provided, however, that if, at any time within the period commencing on the date that is 3 months prior to the termination of his employment agreement , we and a third party execute a definitive, written, and binding agreement (a "Sale Agreement") to enter into certain transactions described therein that, if consummated, would constitute a change in control in us, then Mr. Slosman's termination shall be deemed a termination by us without cause or for good reason, as of the date such Sale Agreement is executed, provided further that any amounts payable to Mr. Slosman pursuant to such termination shall be reduced by any amounts previously paid to him upon expiration of the Slosman Employment Agreement, termination by us for cause or voluntary resignation by Mr. Slosman without good reason.

If Mr. Slosman's employment is terminated (i) by us without cause or (ii) by Mr. Slosman for good reason, then we must pay Mr. Slosman, (a) a severance pay in an amount equal to twelve months of his then-current base salary, (b) his entire performance bonus for any calendar year for which Mr. Slosman has already worked the entire year but the bonus has yet to be paid, (c) a pro-rated performance bonus in an amount equal to the target annual performance bonus to which Mr. Slosman may have been entitled for the year in which the termination occurs that he would have received had his employment not been terminated during such year. In addition, 50% of all unvested stock options, shares of restricted stock, restricted stock units, stock appreciation rights, or similar stock-based rights granted to Mr. Slosman shall vest and, if applicable, be immediately exercisable and any risk of forfeiture included in such restricted or other stock grants previously made to Mr. Slosman shall immediately lapse, and Mr. Slosman may exercise any outstanding stock options or stock appreciation rights until the earlier of (x) the last date on which such stock options or stock appreciation rights could have been exercised pursuant to the terms of the applicable award agreement, irrespective of Mr. Slosman's termination of employment; and (y) the date that is two years following his employment termination date.

Craig Shore

We have been a party to an employment agreement with Craig Shore since November 28, 2010. On May 5, 2014, we entered into an amended and restated employment agreement with Mr. Shore, which was amended on January 5, 2015, July 25, 2016, March 25, 2019, August 14, 2020, November 4, 2021, January 17, 2022 and January 15, 2023 (as amended, the "Shore Employment Agreement"). The Shore Employment Agreement had an initial term that originally was to end on December 31, 2020, and was to automatically renew for additional one-year periods on January 1st thereafter unless either party gave the other party written notice of its election not to extend such employment at least six months prior to the next January 1st renewal date. We subsequently amended the Shore Employment Agreement to remove that certain definitive term of his employment such that his employment agreement shall expire if and when terminated by either party pursuant to the terms thereof.

Under the terms of the Shore Employment Agreement, Mr. Shore is entitled to an annual base salary, which as of January 1, 2023 was increased to no less than NIS 93,912 per month (NIS 1,126,944 on an annualized basis). Such amount may be reduced only as part of an overall cost reduction program that affects all of our senior executives and does not disproportionately affect Mr. Shore, so long as such reduction does not reduce the base salary to a rate that is less than 90% of the amount set forth above (or 90% of the amount to which it has been increased). The base salary will be reviewed annually by our chief executive officer for increase (but not decrease, except as permitted as part of an overall cost reduction program) as part of our annual compensation review. Mr. Shore is also eligible to receive an annual bonus in an amount equal to 60% of his then-annual salary upon the achievement of reasonable target objectives and performance goals, to be determined by the board of directors in consultation with Mr. Shore. Mr. Shore is eligible to receive the percentage of his annual bonus corresponding to the percentage of his achievement of such target objectives and performance goals. The annual bonus will be reviewed annually by our chief executive officer for increase in the amount of the percentage of his then-base salary (but not decrease), as well as the criteria and the goals, as part of our annual compensation review. In addition, Mr. Shore is eligible to receive such additional bonus or incentive compensation as the board may establish from time to time in its sole discretion. Mr. Shore will also be considered for grants of equity awards each year as part of the board's annual compensation review, which will be made at the sole discretion of the board of directors. Each grant will, with respect to any awards that are options, have an exercise price equal to the fair market value of our common stock as of the date of grant, and will be subject to a three-year vesting period subject to Mr. Shore's continued service with us, with one-third of each additional grant vesting equally on the first, second, and third anniversary of the date of grant for such awards.

If Mr. Shore's employment is terminated upon his death or disability, by us without cause (as such term is defined in the Shore Employment Agreement), or upon his resignation for "good reason" (as such term is defined in the Shore Employment Agreement), Mr. Shore will be entitled to receive, in addition to any amounts he is entitled to receive under the manager's insurance policy: (i) any unpaid base salary and accrued unpaid vacation or earned incentive compensation and the pro rata amount of any bonus plan incentive compensation for the fiscal year of such termination (based on the number of business days he was actually employed by us during the fiscal year of such termination and based on the percentage of the goals that he actually achieved under the bonus plan) that he would have received had his employment not been terminated; (ii) a one-time lump sum severance payment equal to 100% of his base salary, provided that he executes a release relating to employment matters and the circumstances surrounding his termination in favor of us, our subsidiaries and our officers, directors and related parties and agents, in a form reasonably acceptable to us at the time of such termination; (iii) vesting of all unvested stock options, stock appreciation rights or similar stock-based rights granted to him and immediate lapse of any risk of forfeiture included in restricted or other stock grants previously made to Mr. Shore; (iv) an extension of the exercise period of all vested stock options granted to Mr. Shore until the earlier of (a) two years from the date of termination or (b) the latest date that each stock option would otherwise expire by its original terms; (v) to the fullest extent permitted by our then-current benefit plans, continuation of health, dental, vision and life insurance coverage for the lesser of 12 months after termination or until Mr. Shore obtains coverage from a new employer; and (vi) reimbursement of up to $30,000 for executive outplacement services, subject to certain restrictions. The severance payment described in (ii) of the foregoing sentence upon Mr. Shore's death or disability will be reduced by any payments received by Mr. Shore pursuant to any of our employee welfare benefit plans providing for payments in the event of death or disability. If the Shore Employment Agreement is terminated by us for cause or by Mr. Shore voluntarily, Mr. Shore will only be entitled to unpaid amounts owed to him (e.g., base salary, accrued vacation and earned incentive compensation through the date of such termination) and whatever rights, if any, are available to him pursuant to our stock-based compensation plan or any award documents related to any stock-based compensation.

Mr. Shore may terminate his employment for good reason by delivering a notice of termination to us 30 days in advance of the date of termination; provided, however, that Mr. Shore agreed to not terminate his employment for good reason until he has given us at least 30 days' notice from which to cure the circumstances set forth in the notice of termination constituting good reason, and if such circumstances are not cured by the 30th day, Mr. Shore's employment shall terminate on such date.

Pursuant to terms contained in Mr. Shore's stock option and restricted stock award agreements, in the event of a change of control of our company, the stock options and restricted stock granted to Mr. Shore that were unvested will vest immediately upon such change of control, in the case of stock options, if such stock options are not assumed or substituted by the surviving company.

If we terminate Mr. Shore's employment without cause, Mr. Shore will be entitled, under Israeli law, to severance payments equal to his last month's salary multiplied by the number of years Mr. Shore has been employed with us. In order to finance this obligation, we make monthly contributions equal to 8.33% of Mr. Shore's salary to a severance payment fund. The total amount accumulated in Mr. Shore's severance payment fund as of December 31, 2022 was $254,000, as adjusted for conversion from New Israeli Shekels to U.S. Dollars. However, if Mr. Shore's employment is terminated without cause, on account of a disability or upon his death, as of December 31, 2022, Mr. Shore would have been entitled to receive $308,000 in severance under Israeli law, thereby requiring us to pay Mr. Shore $54,000, in addition to releasing the $254,000 in Mr. Shore's severance payment fund. On the other hand, pursuant to the Shore Employment Agreement, Mr. Shore is entitled to the total amount contributed to and accumulated in his severance payment fund in the event of the termination of his employment as a result of his voluntary resignation. In addition, Mr. Shore would be entitled to receive his full severance payment under Israeli law, including the total amount contributed to and accumulated in his severance payment fund, if he retires from our company at or after age 67.

We are entitled to terminate Mr. Shore's employment immediately at any time for "cause" (as such term is defined in the agreement and the Israeli Severance Payment Act 1963), upon which, after meeting certain requirements under the applicable law and recent Israeli Labor court requirements, we believe we will have no further obligation to compensate Mr. Shore.

Also, upon termination of Mr. Shore's employment for any reason, we will compensate him for all unused or previously uncompensated vacation days accrued.

The employment agreement also contains certain standard noncompetition, non-solicitation, confidentiality, and assignment of inventions requirements for Mr. Shore.

Mr. Shore is also entitled to participate in or receive benefits under our social insurance and benefits plans, including but not limited to our manager's insurance policy and education fund, which are customary benefits provided to executive employees in Israel. A management insurance policy is a combination of severance savings (in accordance with Israeli law), defined contribution tax-qualified pension savings and disability pension payments. An education fund is a savings fund of pre-tax contributions to be used after a specified period of time for advanced educational training and other permitted purposes, as set forth in the by-laws of the education fund. We will make periodic contributions to these insurance and social benefits plans based on certain percentages of Mr. Shore's base salary, including (i) 7.5% to the education fund and (ii) 15.83% to the manager's insurance policy, of which 8.33% will be allocated to severance pay, 5.5% to pension fund payments and up to 2.5% to disability pension payments. Upon the termination of Mr. Shore's employment for any reason other than for cause, Mr. Shore will be entitled to receive the total amount contributed to and accumulated in his manager insurance policy fund.

Andrea Tommasoli

We have been a party to an employment agreement with Mr. Andrea Tommasoli since November 2, 2020 (the "Tommasoli Agreement"). Mr. Tommasoli served as the Company's Senior Vice President of Global Sales and Marketing since November 2020 until his promotion to Chief Operating Officer, effective as of March 19, 2023. Following his promotion Mr. Tommasoli receives an annual base salary of 240,000 Euros (approximately $260,000) and is entitled to a yearly gross bonus of 35% of his base salary, which will be based on the Board's assessment of Mr. Tommasoli's individual performance and the overall performance of the Company. Mr. Tommasoli's remuneration is subject to deduction of the employee's share of social contributions, and CSG and CRDS. The Tommasoli Agreement was entered into for an indefinite period, and it may be terminated at any time by either the Company or Mr. Tommasoli with a six months' notice period; however, no notice period applies in case of serious or gross misconduct. The Tommasoli Agreement further provides for standard benefits, such as reimbursement of business expenses, professional vehicle expenses and participation in the Company's employee benefit plans and programs. The Tommasoli Agreement also contains certain standard confidentiality requirements.

Change of Control Agreements

Pursuant to our forms of our restricted stock award agreement, stock option agreement, or restricted stock unit award agreement pursuant to our, in the event of a change of control, any unvested awards shall become immediately vested.

We do not currently have any plans providing for the payment of retirement benefits to our named executive officers or directors, other than as described above and under "Agreements with Executive Officers" above.

We do not currently have any change-of-control or severance agreements with any of our named executive officers or directors, other than as described under "Agreements with Executive Officers" above. In the event of the termination of employment of the named executive officers, any and all unexercised stock options shall expire and no longer be exercisable after a specified time following the date of the termination, other than as described under "Agreements with Executive Officers" above.

Outstanding Equity Awards at December 31, 2022

The following table shows information concerning unexercised options and unvested shares of restricted stock outstanding as of December 31, 2022 for each of our named executive officers.

	Option Awards				Stock Awards	
Name	Number of securities underlying unexercised options (#) exercisable	Number of securities underlying unexercised options (#) unexercisable	Option exercise price ($)	Option expiration date	Number of shares of stock that have not vested (#)	Market value of shares of stock that have not vested ($)
Marvin Slosman	2,702	1,351(1)	16.50	1/2/2030		
					4,053(2)	3,486
	17,412	8,706(3)	5.85	8/31/2030		
					26,117(4)	22,461
	13,333	26,667(5)	6.90	4/19/2031		
	16,285	32,570(6)	4.12	10/13/2031		
					97,711(7)	84,032
Craig Shore	1	-	124,687.50	07/25/2026		
	10,057	5,029(3)	5.85	8/31/2030		
					15,085(8)	12,973
	2,222	4,445(5)	6.90	4/19/2031		
	8,109	16,217(9)	4.09	11/10/2031		
					48,652(10)	41,841
Andrea Tommasoli	4,023	2,012(11)	5.25	11/2/2030		
					6,034(12)	5,190
	6,585	13,171(6)	4.12	10/13/2031		
					39,513(13)	33,981

(1) These options vest annually, with one vesting remaining on January 2, 2023.

(2) These restricted stock units (RSUs) vest annually, with one vesting remaining on January 2, 2023.In case of the holders termination of services for any reason other than by the Company for cause, the Company shall convert the vested RSUs into the number of whole shares of Common Stock equal to the number of vested RSUs and shall deliver them to the holder.

(3) These options vest annually, with one vesting remaining on August 31, 2023.

(4) These RSUs vest annually, with one vesting remaining on August 31, 2023.

(5) These options vest annually, with one-half vesting on each of April 19, 2023, and April 19, 2024.

(6) These options vest annually, with one-half vesting on each of October 13, 2023, and October 13, 2024.

(7) These RSUs vest annually, with one-half vesting on each of October 13, 2023, and October 13, 2024.

(8) These shares of restricted stock vest annually, with one vesting remaining on August 31, 2023.

(9) These options vest annually, with one-half vesting on each of November 10, 2023, and November 10, 2024.

(10) These shares of restricted stock vest annually, with one-half vesting on each of November 10, 2023, and November 10, 2024.

(11) These options vest annually, with one vesting remaining on November 2, 2023.

(12) These shares of restricted stock vest annually, with one vesting remaining November 2, 2023.

(13) These shares of restricted stock vest annually, with one-half vesting on each of October 3, 2023, and October 3, 2024.

Option Exercises and Stock Vested

There were no stock options exercised by our named executive officers during the twelve months ended December 31, 2022.

2011 UMBRELLA Option Plan

On March 28, 2011, our board of directors and stockholders adopted and approved the InspireMD, Inc. 2011 UMBRELLA Option Plan, which was subsequently amended on October 31, 2011 and December 21, 2012. Under the InspireMD, Inc. 2011 UMBRELLA Option Plan, we have reserved 13 shares of our common stock as awards to the employees, consultants, and service providers to InspireMD, Inc. and its subsidiaries and affiliates worldwide. The InspireMD, Inc. 2011 UMBRELLA Option Plan is administered by our compensation committee. The InspireMD, Inc. 2011 UMBRELLA Option Plan has expired on March 27, 2021. We have no shares of common stock available for future issuance under our 2011 UMBRELLA Option Plan.

2013 Long-Term Incentive Plan

On December 16, 2013, our stockholders approved the InspireMD, Inc. 2013 Long-Term Incentive Plan, which was adopted by our board of directors on October 25, 2013.

The purpose of the InspireMD, Inc. 2013 Long-Term Incentive Plan is to provide an incentive to attract and retain employees, officers, consultants, directors, and service providers whose services are considered valuable, to encourage a sense of proprietorship and to stimulate an active interest of such persons in our development and financial success. The InspireMD, Inc. 2013 Long-Term Incentive Plan provides for the granting of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock, restricted stock units, performance awards, dividend equivalent rights, and other awards, which may be granted singly, in combination, or in tandem. The InspireMD, Inc. 2013 Long-Term Incentive Plan is administered by our compensation committee.

The InspireMD, Inc. 2013 Long-Term Incentive Plan is intended to serve as an "umbrella" plan for us and our subsidiaries worldwide. Therefore, if so required, appendices may be added to the InspireMD, Inc. 2013 Long-Term Incentive Plan in order to accommodate local regulations that do not correspond to the scope of the InspireMD, Inc. 2013 Long-Term Incentive Plan. Attached as Appendix A to the InspireMD, Inc. 2013 Long-Term Incentive Plan is the InspireMD, Inc. 2013 Employee Stock Incentive Plan, for the purpose of making grants of stock options, restricted stock, and other stock incentive awards pursuant to Sections 102 and 3(i) of the Israeli Income Tax Ordinance (New Version), 1961 to Israeli employees and officers and any other service providers or control holders of us who are subject to Israeli Income Tax.

When the InspireMD, Inc. 2013 Long-Term Incentive Plan was adopted, a total of 11 shares of common stock were reserved for awards under the InspireMD, Inc. 2013 Long-Term Incentive Plan.

On September 9, 2015, our stockholders approved an amendment to the InspireMD, Inc. 2013 Long-Term Incentive Plan to increase the number of shares of common stock available for issuance pursuant to awards under the InspireMD, Inc. 2013 Long-Term Incentive Plan by 11 shares of common stock, to a total of 22 shares of common stock.

On May 24, 2016, our stockholders approved the second amendment to the InspireMD, Inc. 2013 Long-Term Incentive Plan to increase the number of shares of common stock available for issuance pursuant to awards under the InspireMD, Inc. 2013 Long-Term Incentive Plan by 229 shares of common stock, to a total of 251 shares of common stock.

On September 28, 2016, our stockholders approved the third amendment to the InspireMD, Inc. 2013 Long-Term Incentive Plan to increase the number of shares of common stock available for issuance pursuant to awards under the InspireMD, Inc. 2013 Long-Term Incentive Plan by 144 shares of common stock, to a total of 395 shares of common stock.

On October 24, 2018, our stockholders approved the fourth amendment to the InspireMD, Inc. 2013 Long-Term Incentive Plan to (i) increase the number of shares of common stock available for issuance pursuant to awards under such InspireMD, Inc. 2013 Long-Term Incentive Plan by 178,000 shares, to a total of 178,395 shares of common stock, and (ii) remove the cap on the number of shares of common stock with respect to which stock options or stock appreciation rights may be granted to certain executive officers of the Company during any calendar year.

On March 21, 2019, our stockholders approved the fifth amendment to the InspireMD, Inc. 2013 Long-Term Incentive Plan to increase the total number of shares of common stock issuable under the InspireMD, Inc. 2013 Long-Term Incentive Plan by 500,000 shares to a total of 678,395 shares of common stock

On August 31, 2020, our stockholders approved the sixth amendment to the InspireMD, Inc. 2013 Long-Term Incentive Plan to increase the total number of shares of common stock issuable under the InspireMD, Inc. 2013 Long-Term Incentive Plan by 6,500,000 shares to a total of 7,178,395 shares of common stock.

As of December 31, 2022, we had 73,175 shares of common stock available for future issuance under our 2013 Long-Term Incentive Plan.

As of March 28, 2023, we had 74,195 shares of common stock available for future issuance under our 2013 Long-Term Incentive Plan.

2021 Equity Incentive Plan

On September 30, 2021, at our 2021 annual meeting of stockholders, our stockholders approved our 2021 Equity Incentive Plan.

The purpose of the InspireMD, Inc. 2021 Equity Incentive Plan is to provide an incentive to attract and retain employees, officers, consultants, directors, and service providers whose services are considered valuable, to encourage a sense of proprietorship and to stimulate an active interest of such persons in our development and financial success. The InspireMD, Inc. 2021 Equity Incentive Plan provides for the granting of incentive stock options, nonqualified stock options, stock appreciation rights, restricted stock, restricted stock units, performance awards, dividend equivalent rights, and other awards, which may be granted singly, in combination, or in tandem. The InspireMD, Inc. 2021 Equity Incentive Plan is administered by our compensation committee.

As of December 31, 2022, we had 739,826 shares of common stock available for future issuance under our 2021 Equity Incentive Plan.

As of March 28, 2023, we had 700,039 shares of common stock available for future issuance under our 2021 Equity Incentive Plan.

Director Compensation

The following table provides certain information concerning the compensation for services rendered in all capacities by each non-employee director serving on our board during the year ended December 31, 2022, other than Mr. Slosman, our Chief Executive Officer, who did not receive additional compensation for his services as director and whose compensation is set forth in the Summary Compensation Table found elsewhere in this Item 11.

Name	Fees Earned or Paid in Cash ($)	Stock Awards ($)	Option Awards ($)	All Other Compensation ($)	Total ($)
Paul Stuka	62,000	-	-	-	62,000
Michael Berman	41,000	-	-	-	41,000
Campbell Rogers, M.D.(1)	21,333	-	-	-	21,333
Thomas Kester	46,000	-	-	-	46,000
Gary Roubin, M.D.	35,000	-	-	-	35,000
Kathryn Arnold	36,000	-	-	-	36,000

(1) Dr. Rogers' term as a director ended on August 31, 2022

For the 2022 calendar year, our board approved the following compensation for our independent directors: (i) a $48,000 stipend, payable quarterly to the chairman of the board; (ii) a $30,000 stipend, payable quarterly to the other directors; (iii) annual committee chair compensation of $12,000 for the chairman of the audit committee, $8,000 for the chairman of the compensation committee and $5,000 for the chairmen of the nominating and corporate governance committee and the research and development committee; and (iv) annual committee membership compensation of $4,000 for members of the audit committee and the compensation committee and $2,000 for members of the nominating and corporate governance committee and the research and development committee.

Beginning on January 1, 2023, directors may elect to receive all or a portion of their cash retainer amount in shares of our common stock under the 2021 Equity Incentive Plan. If a director makes that election, a stock award under the 2021 Plan will be paid quarterly on the first day of each quarter ("Grant Dates") and will become fully vested on the Grant Dates. The stock award will be determined by dividing (x) the product of the cash retainer amount and percentage of the cash retainer amount elected to be taken in shares by (y) the "Fair Market Value" (as defined in the 2021 Equity Incentive Plan of a share on the Grant Dates. If a director's service on the board terminates for any reasons prior to a Grant Date, he/she will receive a pro rata portion of shares or cash based on the number of days served on the board during the relevant quarter.

Directors' and Officers' Liability Insurance

We currently have directors' and officers' liability insurance insuring our directors and officers against liability for acts or omissions in their capacities as directors or officers, subject to certain exclusions. Such insurance also insures us against losses which we may incur in indemnifying our officers and directors. In addition, we have entered into indemnification agreements with key officers and directors and such persons shall also have indemnification rights under applicable laws, and our certificate of incorporation and bylaws.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The following table sets forth information with respect to the beneficial ownership of our common stock as of March 28, 2023 by:

- each person known by us to beneficially own more than 5.0% of our common stock;
- each of our directors;
- each of the named executive officers; and
- all of our directors and executive officers as a group.

The percentages of common stock beneficially owned are reported on the basis of regulations of the the SEC governing the determination of beneficial ownership of securities. Under the rules of the SEC, 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.

Except as indicated in the footnotes to this table, each beneficial owner named in the table below has sole voting and sole investment power with respect to all shares beneficially owned and each person's address is c/o InspireMD, Inc., 4 Menorat Hamaor St., Tel Aviv, Israel 6744832. As of March 28, 2023, we had 8,326,648 shares outstanding.

Name of Beneficial Owner	Number of Shares Beneficially Owned[(1)]	Percentage Beneficially Owned[(1)]
5% Owners		
Officers and Directors		
Marvin Slosman	189,106[(2)]	2.22%
Craig Shore	362,749[(3)]	4.25%
Michael Berman	12,329[(4)]	*
Paul Stuka	122,280[(5)]	1.47%
Thomas Kester	47,647[(6)]	*
Gary Roubin, M.D.	195,864[(7)]	2.34%
Kathryn Arnold	32,042[(8)]	*
Shane Gleason	-	*
Andrea Tommasoli	87,982[(9)]	1.06%
All directors and executive officers as a group (9 persons)	1,049,997	11.94%

* Represents ownership of less than one percent.

(1) Shares of common stock beneficially owned and the respective percentages of beneficial ownership of common stock assumes the exercise of all options, warrants and other securities convertible into common stock beneficially owned by such person or entity currently exercisable or exercisable within 60 days of March 30, 2023. Shares issuable pursuant to the exercise of stock options and warrants exercisable within 60 days are deemed outstanding and held by the holder of such options or warrants for computing the percentage of outstanding common stock beneficially owned by such person but are not deemed outstanding for computing the percentage of outstanding common stock beneficially owned by any other person.

(2) Consists of (i) 6,392 shares of common stock, (ii) 12,159 Restricted Stock Units granted outside the plan that are currently exercisable or exercisable within 60 days of March 30, 2023, (iii) 52,235 Restricted Stock Units granted under the 2013 Equity Incentive Plan, (iv) 48,856 Restricted Stock Units granted under the 2021 Equity Incentive Plan, (v) options to purchase 64,417 shares of common stock that are currently exercisable or exercisable within 60 days of March 30, 2023, and (vi) 5,048 warrants to purchase shares of common stock that are currently exercisable.

(3) Consists of (i) 54,902 shares of common stock, (ii) options to purchase 22,612 shares of common stock that are currently exercisable or exercisable within 60 days of March 30, 2023, (iii) 15,085 shares of restricted stock granted under the Israeli Appendix of the InspireMD, Inc. 2013 Long-Term Incentive Plan, (iv) 48,652 shares of restricted stock granted under the 2021 Equity Incentive Plan, and (v) 224,219 shares of restricted stock granted to employees under the Israeli Appendix of the InspireMD, Inc. 2013 Long-Term Incentive Plan held in trust, and with respect to which Mr. Shore was granted a proxy with the right to vote such shares at his discretion.

(4) Consists of (i) 5,378 shares of common stock, (ii) warrants to purchase 2,688 shares of common stock that are currently exercisable or exercisable within 60 days of March 30, 2023, and (iii) options to purchase 4,263 shares of common stock that are currently exercisable or exercisable within 60 days of March 30, 2023. Excludes 10,710 shares of restricted stock granted under the Israeli Appendix of InspireMD, Inc. 2013 Long-Term Incentive Plan and 17,248 shares of restricted stock granted under the 2021 Equity Incentive Plan held in trust, with respect to which the trustee has a proxy with the right to vote such shares at his discretion.

(5) Paul Stuka is the principal and managing member of Osiris Investment Partners, L.P., and, as such, has beneficial ownership of (A) 73,534 shares of common stock (B) personally holding (i) options to purchase 6,443 shares of common stock that are currently exercisable or exercisable within 60 days of March 30, 2023, (ii) 5,310 shares of restricted stock granted under the InspireMD, Inc. 2013 Long-Term Incentive Plan, (iii) 17,386 shares of restricted stock granted under the 2021 Equity Incentive Plan, and (iv) 19,607 shares of common stock.

(6) Consists of (i) 19,077 shares of common stock, (ii) 8,780 shares of restricted stock granted under the InspireMD, Inc. 2013 Long-Term Incentive Plan, (iii) 11,499 shares of restricted stock granted under the 2021 Equity Incentive Plan, (iv) 4,032 warrants to purchase shares of common stock that are currently exercisable, and (v) options to purchase 4,260 shares of common stock that are currently exercisable or exercisable within 60 days of March 28, 2023.

(7) Consists of (i) 147,385 shares of common stock, (ii) 5,310 shares of restricted stock granted under the InspireMD, Inc. 2013 Long-Term Incentive Plan, (ii) 11,499 shares of restricted stock granted under the 2021 Equity Incentive Plan, and (iii) 22,880 warrants to purchase shares of common stock that are currently exercisable and (iv) options to purchase 8,790 shares of common stock that are currently exercisable or exercisable within 60 days of March 28, 2023.

(8) Consists of (i) 9,261 shares of common stock, (ii) 7,024 shares of restricted stock granted under the InspireMD, Inc. 2013 Long-Term Incentive Plan, (iii) 11,499 shares of restricted stock granted under the 2021 Equity Incentive Plan, and (iv) options to purchase 4,258 shares of common stock that are currently exercisable or exercisable within 60 days of March 28, 2023.

(9) Consists of (i) 31,825 shares of common stock, (ii) 6,034 shares of restricted stock granted under the InspireMD, Inc. 2013 Long-Term Incentive Plan, (iii) 39,513 shares of restricted stock granted under the 2021 Equity Incentive Plan, and (iv) options to purchase 10,609 shares of common stock that are currently exercisable or exercisable within 60 days of March 28, 2023.

Equity Compensation Plan Information

The following table provides certain information as of December 31, 2022, with respect to our equity compensation plans under which our equity securities are authorized for issuance:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders	451,293	4.43	813,001
Equity compensation plans not approved by security holders	10,088[1]	9.77	-
Total	461,381	4.55	813,001

(1) Comprised of awards made to individuals outside the InspireMD, Inc. 2011 UMBRELLA Option Plan, 2013 Long Term Incentive Plan and 2021 Equity Incentive Plan, as described below:

- On January, 2020, we issued to Mr. Marvin Slosman, our Chief Executive Officer, President and Director, 12,159 shares of restricted stock and 4,053 shares of common stock, as inducement awards outside the Company's 2013 Long-Term Incentive Plan.

- On November 3, 2020, we issued to Mr. Andrea Tommasoli, our Senior Vice President of Global Sales and Marketing, options to purchase 6,035 shares of our common stock, as inducement awards outside the Company's 2013 Long-Term Incentive Plan.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

In accordance with our audit committee charter, the audit committee is required to approve all related party transactions. In general, the audit committee will review any proposed transaction that has been identified as a related party transaction under Item 404 of Regulation S-K. A related party includes (i) a director, director nominee or executive officer of us, (ii) a security holder known to be an owner of more than 5% of our voting securities, (iii) an immediate family member of the foregoing or (iv) a corporation or other entity in which any of the foregoing persons is an executive, principal or similar control person or in which such person has a 5% or greater beneficial ownership interest.

There were no related party transactions that are required to be disclosed pursuant to Regulation S-K promulgated under the Securities Act of 1933, as amended.

Director Independence

The board of directors has determined that Dr. Roubin, Messrs. Stuka, Berman and Kester, and Ms. Arnold satisfy the requirement for independence set out in Nasdaq Listing Rules and Rule 10A-3 promulgated under the Exchange Act. In making its independence determinations, the board of directors sought to identify and analyze all of the facts and circumstances relating to any relationship between a director, his or her immediate family or affiliates and our company and our affiliates and did not rely on categorical standards other than those contained in the rules referenced above.

Item 14. Principal Accountant Fees and Services.

The fees billed for professional services provided to us by Kesselman & Kesselman, Certified Public Accountants ("Kesselman"), a member of PricewaterhouseCoopers International Limited, for the years ended December 31, 2022 and 2021 are described below.

Fee category	2022	2021
Audit Fees [(1)]	$ 188,000	$ 176,000
Audit – related fees	25,900	$ 49,900
Tax fees	40,282	$ 38,675
All other fees	-	$ -
Total fees	$ 254,182	$ 264,575

Audit Fees

Kesselman billed us audit fees in the aggregate amount of $188,000 and $176,000 for the years ended December 31, 2022 and 2021, respectively. These fees relate to the audit of our annual financial statements and the review of our interim quarterly financial statements.

Audit-Related Fees

Kesselman billed us audit-related fees in the aggregate amount of $25,900 and $49,900 for the year ended December 31, 2022 and 2021, respectively. The fees for the year ended December 31, 2022 mostly related to registration statement on Form S-3 filed with the SEC in June 2022.

The fees for the year ended December 31, 2021 mostly related to registration statement on Form S-1 filed with the SEC in February 2021 and to registration statement on Form S-3 filed with the SEC in April 2021.

Tax Fees

Kesselman billed us tax fees in the aggregate amount of $40,282 and $38,675 for the year ended December 31, 2022 and 2021, respectively. These fees relate to professional services rendered for tax compliance, tax advice and tax planning.

All Other Fees

Kesselman did not bill us for any other fees for the year ended December 31, 2022 and 2021.

Our audit committee pre-approves all auditing services, internal control-related services and permitted non-audit services (including the fees and terms thereof) to be performed for us by our independent auditor, except for de minimis non-audit services that are approved by the audit committee prior to the completion of the audit. The audit committee may form and delegate authority to subcommittees consisting of one or more members when appropriate, including the authority to grant pre-approvals of audit and permitted non-audit services, provided that decisions of such subcommittee to grant pre-approvals is presented to the full audit committee at its next scheduled meeting. The Audit Committee pre-approved all of the fees set forth above.

PART IV

Item 15. Exhibits and Financial Statement Schedules.

Documents filed as part of report:

1. Financial Statements

The following financial statements are included herein:

2. Financial Statement Schedules

None

3. Exhibits

See Index to Exhibits

Item 16. Form 10-K Summary

Not applicable.

Index to Exhibits

Exhibit No.	Description
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 to Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on November 9, 2015)
3.2	Amended and Restated Bylaws (incorporated by reference to Exhibit 3.2 to Current Report on Form 8-K filed with the Securities and Exchange Commission on June 29, 2021).
3.3	Certificate of Amendment to Amended and Restated Certificate of Incorporation of InspireMD, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on May 25, 2016)
3.4	Certificate of Amendment to Amended and Restated Certificate of Incorporation of InspireMD, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on September 29, 2016)
3.5	Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on March 15, 2017)
3.6	Certificate of Amendment to Certificate of Designation of Preferences, Rights and Limitation of Series C Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on November 29, 2017)
3.7	Certificate of Amendment to Certificate of Designation of Preferences, Rights and Limitation of Series B Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on December 12, 2017)
3.8	Certificate of Amendment to Amended and Restated Certificate of Incorporation of InspireMD, Inc. (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on February 7, 2018)
3.9	Certificate of Amendment to Certificate of Designation of Preferences, Rights and Limitation of Series D Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on March 1, 2018)
3.10	Certificate of Amendment to Certificate of Designation of Preferences, Rights and Limitation of Series D Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on April 3, 2018)
3.11	Certificate of Amendment to Amended and Restated Certificate of Incorporation of InspireMD, Inc., dated March 27, 2019 (incorporated by reference to Exhibit 3.1 to the Current Report on Form 8-K filed on March 28, 2019)
3.12	Certificate of Amendment to Amended and Restated Certificate of Incorporation of InspireMD, Inc., dated April 14, 2021 (incorporated by reference to Exhibit 3.1 to Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 10, 2021)
3.13	Form of Common Stock Certificate (incorporated by reference to Exhibit 4.1 to Amendment No. 3 to Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 5, 2013)
3.15	Form of Series B Warrant Agent Agreement and Form of Series B Warrant (incorporated by reference to Exhibit 4.3 to Amendment No.3 to Registration Statement on Form S-1 filed with the Securities and Exchange Commission on March 6, 2017)
4.1*	Description of Securities
10.2+	Form of Indemnity Agreement between InspireMD, Inc. and each of the directors and executive officers thereof (incorporated by reference to Exhibit 10.22 to Amendment No. 1 to Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 26, 2011)
10.3	Agreement by and between InspireMD Ltd. and MeKo Laser Material Processing, dated as of April 15, 2010 (incorporated by reference to Exhibit 10.26 to Amendment No. 1 to Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 26, 2011)
10.4	Agreement by and between InspireMD Ltd. and Natec Medical Ltd, dated as of September 23, 2009 (incorporated by reference to Exhibit 10.27 to Amendment No. 1 to Registration Statement on Form S-1 filed with the Securities and Exchange Commission on August 26, 2011)
10.5+	InspireMD, Inc. 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on December 20, 2013)
10.6+	Amended and Restated Employment Agreement, dated May 5, 2014, by and between InspireMD, Inc. and Craig Shore (incorporated by reference to Exhibit 10.2 to Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 7, 2014)

10.7+	First Amendment to the InspireMD, Inc. Amended and Restated 2011 UMBRELLA Option Plan (incorporated by reference to Exhibit 10.3 to Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission on May 7, 2014)
10.8+	Form of Incentive Stock Option Award Agreement under the InspireMD, Inc. 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 99.2 to Registration Statement on Form S-8 filed with the Securities and Exchange Commission on June 5, 2014)
10.9+	Form of Nonqualified Stock Option Award Agreement under the InspireMD, Inc. 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 99.3 to Registration Statement on Form S-8 filed with the Securities and Exchange Commission on June 5, 2014)
10.10+	Form of Restricted Stock Award Agreement under the InspireMD, Inc. 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 99.4 to Registration Statement on Form S-8 filed with the Securities and Exchange Commission on June 5, 2014)
10.11+	Form of Restricted Stock Unit Award Agreement under the InspireMD, Inc. 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 99.5 to Registration Statement on Form S-8 filed with the Securities and Exchange Commission on June 5, 2014)
10.12+	Form of Section 3(i) Stock Option Award Agreement under the InspireMD, Inc. 2013 Long-Term Incentive Plan (Israeli) (incorporated by reference to Exhibit 99.6 to Registration Statement on Form S-8 filed with the Securities and Exchange Commission on June 5, 2014)
10.13+	Form of Section 102 Capital Gain Stock Option Award Agreement under the InspireMD, Inc. 2013 Long-Term Incentive Plan (Israeli) (incorporated by reference to Exhibit 99.7 to Registration Statement on Form S-8 filed with the Securities and Exchange Commission on June 5, 2014)
10.14+	Form of Section 102 Capital Gain Restricted Stock Award Agreement under the InspireMD, Inc. 2013 Long-Term Incentive Plan (Israeli) (incorporated by reference to Exhibit 99.8 to Registration Statement on Form S-8 filed with the Securities and Exchange Commission on June 5, 2014)
10.15+	Form of Stock Option Award Agreement under the InspireMD, Inc. 2013 Long-Term Incentive Plan (European) (incorporated by reference to Exhibit 99.9 to Registration Statement on Form S-8 filed with the Securities and Exchange Commission on June 5, 2014)
10.16+	Form of Restricted Stock Award Agreement under the InspireMD, Inc. 2013 Long-Term Incentive Plan (European) (incorporated by reference to Exhibit 99.10 to Registration Statement on Form S-8 filed with the Securities and Exchange Commission on June 5, 2014)
10.17+	Form of Stock Option Award Agreement outside the InspireMD, Inc. 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 99.11 to Registration Statement on Form S-8 filed with the Securities and Exchange Commission on June 5, 2014)
10.18+	First Amendment to Amended and Restated Employment Agreement, dated January 5, 2015, by and between InspireMD, Inc. and Craig Shore (incorporated by reference to Exhibit 10.3 to Current Report on Form 8-K filed with the Securities and Exchange Commission on January 6, 2015)
10.19+	First Amendment to the InspireMD, Inc. 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on September 9, 2015)
10.20+	Second Amendment to the InspireMD, Inc. 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on May 25, 2016)
10.21+	Second Amendment to Amended and Restated Employment Agreement, dated July 25, 2016, by and between InspireMD, Inc. and Craig Shore agent (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on July 29, 2016)

10.22+	Third Amendment to the InspireMD, Inc. 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on September 29, 2016)
10.23+	Director Offer Letter, between InspireMD, Inc. and Thomas J. Kester, dated September 6, 2016
10.29	Form of Underwriter Warrant, dated April 2, 2018 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on April 3, 2018)
10.31	Form of Series D Warrant (incorporated by reference to Exhibit A to Exhibit 4.3 to the Company's Registration Statement on Form S-1, Amendment No. 2, filed with the SEC on June 26, 2018 (File No. 333-225680))
10.32	Form of Underwriter Warrant (incorporated by reference to Exhibit 4.5 to the Company's Registration Statement on Form S-1, Amendment No. 2, filed with the SEC on June 26, 2018 (File No. 333-225680))
10.33+	Fourth Amendment to the InspireMD, Inc. 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on October 26, 2018)
10.34+	Fifth Amendment to the InspireMD, Inc. 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on March 21, 2019)
10.35+	Third Amendment to Amended and Restated Employment Agreement, dated March 25, 2019, by and between InspireMD, Inc. and Craig Shore (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on March 28, 2019)
10.36	Form of Underwriter Warrant, dated April 8, 2019 (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on April 8, 2019)
10.37	Form of Series E Warrant (incorporated by reference to Exhibit 4.3 to the Company's Registration Statement on Form S-1, Amendment No. 1, filed with the SEC on September 13, 2019 (File No. 333-233432)).
10.38	Form of Underwriter Warrant (incorporated by reference to Exhibit 4.5 to the Company's Registration Statement on Form S-1, Amendment No. 1, filed with the SEC on September 13, 2019 (File No. 333-233432)).
10.39+	Employment Agreement, dated December 9, 2019, by and between the Company and Marvin Slosman (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on December 10, 2019).
10.40+	First Amendment to Employment Agreement, dated December 31, 2019, by and between the Company and Marvin Slosman (incorporated by reference to Exhibit 10.2 to the Current Report on Form 8-K filed on January 6, 2020).
10.41+	Nonqualified Stock Option Agreement, by and between the Company and Marvin Slosman (incorporated by reference to Exhibit 10.60 to the Annual Report on Form 10-K filed on March 10, 2020)
10.42+	Restricted Stock Unit Award agreement, by and between the Company and Marvin Slosman (incorporated by reference to Exhibit 10.61 to the Annual Report on Form 10-K filed on March 10, 2020)

10.43	Form of Series F Warrant (incorporated by reference to Exhibit 4.5 to the Company's Registration Statement on Form S-1, Amendment No. 1, filed with the SEC on June 1, 2020 (File No. 333-238247)).
10.44	Form of Underwriter Warrant (incorporated by reference to Exhibit 1.1 to the Company's Registration Statement on Form S-1, Amendment No. 1, filed with the SEC on June 1, 2020 (File No. 333-238247))
10.45	Form of Series G Warrant (incorporated by reference to Exhibit 4.5 to the Company's Registration Statement on Form S-1, Amendment No. 1, filed with the SEC on February 3, 2021 (File No. 333-238247))
10.46	Form of Underwriter Warrant (incorporated by reference to Exhibit 4.6 to the Company's Registration Statement on Form S-1, Amendment No. 1, filed with the SEC on February 3, 2021 (File No. 333-238247))
10.47+	Sixth Amendment to the InspireMD, Inc. 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K filed on August 31, 2020)
10.48+	Seventh Amendment to the InspireMD, Inc. 2013 Long-Term Incentive Plan (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q filed on August 9, 2021)
10.49+	First Amendment to Employment Agreement, dated November 8, 2021, by and between InspireMD, Inc. and Marvin Slosman (incorporated by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q filed on November 8, 2021).
10.50+	Fifth Amendment to Employment Agreement, dated November 4, 2021, by and between InspireMD, Inc. and Craig Shore (incorporated by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q filed on November 8, 2021).
10.51+	Sixth Amendment to Employment Agreement, dated January 17, 2022, by and between InspireMD, Inc. and Craig Shore (incorporated by reference to Exhibit 10.51 to the Annual Report on Form 10-K filed on March 7, 2022)
10.52+	2021 Equity Compensation Plan (incorporated by reference to Annex A to the registrant's Proxy Statement on Schedule 14A filed with the Commission on August 12, 2021).
10.53+	Form of Nonqualified Stock Option Agreement for U.S. employees under the 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.53 to the Annual Report on Form 10-K filed on March 7, 2022)
10.54+	Form of Nonqualified Stock Option Agreement for European employees under the 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.54 to the Annual Report on Form 10-K filed on March 7, 2022)
10.55+	Form of Nonqualified Stock Option Agreement for consultants under the 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.55 to the Annual Report on Form 10-K filed on March 7, 2022)
10.56+	Form of Nonqualified Stock Option Agreement for Israeli employees under the 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.56 to the Annual Report on Form 10-K filed on March 7, 2022)
10.57+	Form of Nonqualified Stock Option Agreement for U.S. directors under the 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.57 to the Annual Report on Form 10-K filed on March 7, 2022)
10.58+	Form of Restricted Stock Award Agreement for U.S. employees under the 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.58 to the Annual Report on Form 10-K filed on March 7, 2022)

10.59+	Form of Restricted Stock Award Agreement for U.S. directors under the 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.59 to the Annual Report on Form 10-K filed on March 7, 2022)
10.60+	Form of Restricted Stock Award Agreement for Israeli employees under the 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.60 to the Annual Report on Form 10-K filed on March 7, 2022)
10.61+	Form of Restricted Stock Award Agreement for European employees under the 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.61 to the Annual Report on Form 10-K filed on March 7, 2022)
10.62+	Form of Restricted Stock Unit Award Agreement under the 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.62 to the Annual Report on Form 10-K filed on March 7, 2022)
10.63	Sales Agreement by and between InspireMD, Inc. and A.G.P./Alliance Global Partners, dated June 3, 2022 (incorporated by reference to Exhibit 1.2 of the Registration Statement on Form S-3 as filed on June 3, 2022).
10.64+*	Third Amendment to Employment Agreement, dated January 5, 2023, by and between InspireMD, Inc. and Marvin Slosman
10.65+*	Seventh Amendment to Employment Agreement, dated January 18, 2023, by and between InspireMD, Inc. and Craig Shore
10.66+*^	Employment Agreement, dated November 2, 2020, by and between the Company and Andrea Tommasoli
21.1	List of Subsidiaries (incorporated by reference to Exhibit 21.1 to Current Report on Form 8-K filed with the Securities and Exchange Commission on April 6, 2011)
23.1*	Consent of Kesselman & Kesselman, Certified Public Accountants
31.1*	Certification of Chief Executive Officer Pursuant to Section 302 of Sarbanes-Oxley Act of 2002
31.2*	Certification of Chief Financial Officer Pursuant to Section 302 of Sarbanes-Oxley Act of 2002
32.1*	Certification of Chief Executive Officer Pursuant to Section 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2*	Certification of Chief Financial Officer Pursuant to Section 18 U.S.C. Section 1350, as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS*	Inline XBRL Instance Document (the Instance Document does not appear in the interactive data file because its XBRL tags are embedded within the Inline XBRL document)
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Labels Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* Filed herewith.

+ Management contract or compensatory plan or arrangement.

^ Portions of this exhibit (indicated by asterisks) have been omitted under rules of the U.S. Securities and Exchange Commission permitting the confidential treatment of select information.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

INSPIREMD, INC.

Date: March 30, 2023

By: */s/ Marvin Slosman*
Marvin Slosman
President and Chief Executive Officer

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Marvin Slosman Marvin Slosman	President, Chief Executive Officer and Director (principal executive officer)	March 30, 2023
/s/ Craig Shore Craig Shore	Chief Financial Officer, Chief Administrative Officer, Secretary and Treasurer (principal financial and accounting officer)	March 30, 2023
/s/ Paul Stuka Paul Stuka	Chairman of the Board of Directors	March 30, 2023
/s/ Michael Berman Michael Berman	Director	March 30, 2023
/s/ Thomas J. Kester Thomas J. Kester	Director	March 30, 2023
/s/ Gary Roubin Gary Roubin	Director	March 30, 2023
/s/ Kathryn Arnold Kathryn Arnold	Director	March 30, 2023

INSPIREMD, INC.
CONSOLIDATED FINANCIAL STATEMENTS
AS OF AND FOR THE YEAR ENDED DECEMBER 31, 2022

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Report of Independent Registered Public Accounting Firm

To the board of directors and shareholders of InspireMD Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of InspireMD Inc. and its subsidiaries (the "Company") as of December 31, 2022 and 2021, and the related consolidated statements of operations, changes in equity and cash flows for the years then ended, 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, 2022 and 2021, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt About the Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1b to the consolidated financial statements, the Company has suffered recurring losses from operations and cash outflows from operating activities that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1b. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that (i) relate to accounts or disclosures that are material to the consolidated financial statements and (ii) involved our especially challenging, subjective, or complex judgments. We determined there are no critical audit matters.

/s/ Kesselman&Kesselman
Certified Public Accountants (Isr.)
A member of PricewaterhouseCoopers International Limited

Tel-Aviv, Israel
March 30, 2023

We have served as the Company's auditor since 2010.

INSPIREMD, INC.
CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands)

	December 31,	
	2022	**2021**
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 4,632	$ 12,004
Short-term bank deposits	13,171	22,036
Accounts receivable:		
Trade, net	1,034	1,224
Other	213	165
Prepaid expenses	655	522
Inventory	1,621	1,143
TOTAL CURRENT ASSETS	21,326	37,094
NON-CURRENT ASSETS:		
Property, plant and equipment, net	917	632
Operating lease right of use assets	1,554	1,081
Fund in respect of employee rights upon retirement	856	905
TOTAL NON-CURRENT ASSETS	3,327	2,618
TOTAL ASSETS	$ 24,653	$ 39,712
LIABILITIES AND EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	659	893
Other	4,411	3,454
TOTAL CURRENT LIABILITIES	5,070	4,347
LONG-TERM LIABILITIES:		
Operating lease liabilities	1,195	781
Liability for employee rights upon retirement	995	1,052
TOTAL LONG-TERM LIABILITIES	2,190	1,833
COMMITMENTS AND CONTINGENT LIABILITIES (Note 6)		
TOTAL LIABILITIES	7,260	6,180
EQUITY:		
Common stock, par value $0.0001 per share; 150,000,000 shares authorized at December 31, 2022 and 2021; 8,330,918 and 8,296,256 shares issued and outstanding at December 31, 2022 and 2021, respectively	1	1
Preferred C shares, par value $0.0001 per share; 1,172,000 shares authorized at December 31, 2022 and 2021; 1,718 shares issued and outstanding at December 31, 2022 and 2021;	*	*
Additional paid-in capital	218,977	216,625
Accumulated deficit	(201,585)	(183,094)
Total equity	17,393	33,532
Total liabilities and equity	$ 24,653	$ 39,712

*Represents an amount less than $1

The accompanying notes are an integral part of the consolidated financial statements.

INSPIREMD, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(U.S. dollars in thousands, except per share data)

	Year Ended December 31,	
	2022	**2021**
REVENUES	$ 5,171	$ 4,495
COST OF REVENUES	4,054	3,741
GROSS PROFIT	1,117	754
OPERATING EXPENSES:		
Research and development	7,810	5,158
Selling and marketing	3,664	2,907
General and administrative	8,356	7,405
Total operating expenses	19,830	15,470
LOSS FROM OPERATIONS	(18,713)	(14,716)
FINANCIAL INCOME (EXPENSES), net:	250	(157)
LOSS BEFORE TAX EXPENSES	(18,463)	(14,873)
TAX EXPENSES	28	45
NET LOSS	$ (18,491)	$ (14,918)
NET LOSS PER SHARE - basic and diluted	(2.35)	(2.03)
WEIGHTED AVERAGE NUMBER OF ORDINARY SHARES USED IN COMPUTING NET LOSS PER SHARE - basic and diluted	7,871,814	7,346,022

The accompanying notes are an integral part of the consolidated financial statements.

INSPIREMD, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY
(U.S. dollars in thousands, except share data)

	Common stock		Series B Convertible Preferred Stock		Series C Convertible Preferred Stock		Additional paid-in capital	Accumulated deficit	Total equity
	Shares	Amount	Shares	Amount	Shares	Amount			
BALANCE as of January 1, 2021	**3,284,322**	*	**17,303**	*	**2,343**	*	**$ 180,339**	**$ (168,176)**	**$ 12,163**
Net loss								**(14,918)**	**(14,918)**
Issuance of common shares, including at the market offering net of $2,024 issuance costs	**3,133,775**	**1**					**25,241**		**25,242**
Exercise of Warrants F	**1,093,536**	*					**8,120**		**8,120**
Exercise of Warrants G	**131,876**	*					**1,349**		**1,349**
Conversion of Series B Convertible Preferred Stock to common shares	**207,528**	*	**(17,303)**	*					*
Conversion of Series C Convertible Preferred Stock to common shares	**831**	*			**(625)**	*			*
Share-based compensation related to restricted stock, restricted stock units and stock options award, net of forfeitures of 20,822 shares	**399,120**						**1,576**		**1,576**
Round up of shares due to reverse stock split effectuated on April 26, 2021	**45,268**	*	-	-	-	-	-	-	*
BALANCE as of December 31, 2021	**8,296,256**	**1**	**-**	**-**	**1,718**	*	**216,625**	**(183,094)**	**33,532**

***** Represents an amount less than $1

INSPIREMD, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN EQUITY
(U.S. dollars in thousands, except share data)

	Common stock		Series C Convertible Preferred Stock		Additional paid-in capital	Accumulated deficit	Total equity
	Shares	Amount	Shares	Amount			
BALANCE as of December 31, 2021	**8,296,256**	**1**	1,718	*	216,625	(183,094)	**33,532**
Net loss						(18,491)	**(18,491)**
Share-based compensation related to restricted stock, restricted stock units and stock options award, net of forfeitures of 10,832 shares	**34,662**				2,352		**2,352**
BALANCE as of December 31, 2022	**8,330,918**	**1**	1,718	*	218,977	(201,585)	**17,393**

***** Represents an amount less than $1

INSPIREMD, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(U.S. dollars in thousands)

	Year ended December 31,	
	2022	**2021**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (18,491)	$ (14,918)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	188	161
Gain from sale of property, plant and equipment	-	(1)
Change in liability for employees rights upon retirement	(57)	142
Other financial expense	131	8
Change in operating right of use asset and operating leasing liability	(60)	(14)
Increase in interest receivable on short term deposits	(135)	(36)
Share-based compensation expenses	2,352	1,576
Loss (gain) on amounts funded in respect of employee rights upon retirement, net	135	(67)
Changes in operating asset and liability items:		
Decrease (Increase) in prepaid expenses	7	(188)
Decrease (increase) in trade receivables	190	(748)
Increase in other receivables	(48)	(19)
Decrease (increase) in inventory	(478)	272
Increase (decrease) in trade payables	(234)	657
Increase (decrease) in other payables	958	(35)
Net cash used in operating activities	(15,542)	(13,210)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment	(473)	(344)
Investment in short-term bank deposits	(19,000)	(24,000)
Withdrawal from short-term bank deposits	28,000	2,000
Amounts funded in respect of employee rights upon retirement	(86)	(113)
Net cash provided by (used in) investing activities	8,441	(22,457)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Issuance costs of At The Market offering	(140)	-
Proceeds from issuance of shares and warrants and exercise of Pre-Funded Warrants and unit purchase option, net of $2,024 issuance costs	-	35,034
Net cash provided by (used in) financing activities	(140)	35,034
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	(131)	(8)
DECREASE IN CASH AND CASH EQUIVALENTS	(7,372)	(641)
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR	12,004	12,645
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF YEAR	$ 4,632	$ 12,004
SUPPLEMENTAL NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Acquisition of right-of-use assets by means of lease liabilities	835	91

The accompanying notes are an integral part of the consolidated financial statements.

NOTE 1 - DESCRIPTION OF BUSINESS

a. General

InspireMD, Inc., a Delaware corporation (the "Company"), together with its subsidiaries, is a medical device Company focusing on the development and commercialization of its proprietary MicroNet™ stent platform technology for the treatment of complex vascular and coronary disease. MicroNet, a micron mesh sleeve, is wrapped over a stent to provide embolic protection in stenting procedures.

The Company's carotid product (CGuard™ EPS) combines MicroNet and a self-expandable nitinol stent in a single device to treat carotid artery disease.

The Company's MGuard™ Prime™ embolic protection system ("MGuard Prime EPS") was marketed for use in patients with acute coronary syndromes, notably acute myocardial infarction (heart attack) and saphenous vein graft coronary interventions, or bypass surgery. MGuard Prime EPS combines MicroNet with a bare-metal cobalt-chromium based stent. MGuard Prime EPS received CE mark approval in the European Union in October 2010 for improving luminal diameter and providing embolic protection. Over the past years, there has been a shift in industry preferences away from bare-metal stents, such as MGuard Prime EPS in ST-Elevation Myocardial Infarction ("STEMI") patients. As a result of declining sales of the MGuard Prime EPS, which the Company believes is largely driven by the predominant industry preferences favoring drug-eluting, or drug-coated, stents, during the second quarter of 2022, the Company ceased sales of the Company's MGuard Prime EPS following a phase out period.

The Company markets its products through distributors in international markets, mainly in Europe.

b. Liquidity

The Company has an accumulated deficit as of December 31, 2022, as well as a history of net losses and negative operating cash flows in recent years. The Company expects to continue incurring losses and negative cash flows from operations until its product, CGuard™ EPS, reaches commercial profitability. As a result of these expected losses and negative cash flows from operations, along with the Company's current cash position, the Company has sufficient resources to fund operations until the end of September 2023. Therefore, there is substantial doubt about the Company's ability to continue as a going concern. These financial statements have been prepared assuming that the Company will continue as a going concern and do not include any adjustments that might result from the outcome of this uncertainty.

Management's plans include the continued commercialization of the Company's product and raising capital through the sale of additional equity securities, debt or capital inflows from strategic partnerships. There are no assurances however, that the Company will be successful in obtaining the level of financing needed for its operations. If the Company is unsuccessful in commercializing its products and raising capital, it may need to reduce activities, curtail or cease operations.

NOTE 1 - DESCRIPTION OF BUSINESS (continued):

c. Failure to satisfy regulatory requirements of the new European Medical Device Regulation could prevent the Company from marketing CGuard EPS in countries requiring the CE Mark.

For the European Union nations, medical devices must obtain a CE mark before they may be placed on the market. In order to obtain and maintain the CE mark, the Company must comply with EU law on medical devices, which, until May 26, 2021 was governed by the Medical Device Directive 93/42/EEC ("MDD"), by presenting comprehensive technical files for its products demonstrating safety and efficacy of the product to be placed on the market and passing initial and annual quality management system audit as per ISO 13485 standard by a European Notified Body.

The Company has obtained ISO 13485 quality system certification and CGuard EPS that the Company currently distributes into the European Union, displays the required CE mark. In order to maintain certification, the Company is required to pass an annual surveillance audit conducted by Notified Body auditors.

The European Union replaced the MDD with the new European Medical Device Regulation, or MDR (MDR 2017/745). The MDR entered into force after a transitional period of three years and a one year extension of that transition period due to the COVID-19 pandemic on May 26, 2021 and which changes several aspects of the regulatory framework in the European Union. Manufacturers had the duration of the transition period to update their technical documentation and processes to meet the new requirements in order to obtain a CE Mark.

In the Company's specific case, the Company's' CE mark for CGuard EPS under the MDD expired on November 12, 2022 and it is in the final stages of technical documentation review by the Notified Body auditor to meet the Medical Device Regulation ("MDR") (MDR 2017/745) requirements (which replaced the MDD) for recertification. In the meantime, on February 14, 2023, the Company received a derogation per Article 97 paragraph 1 of Regulation 2017/745 from the Agency for Medicines and Health Products (FAMHP) allowing it to continue marketing CGuard EPS in the European Union until August 15, 2023 subject to certain procedural requirements. Subsequently, on March 20, 2023, Regulation (EU) 2023/607 was published allowing us to continue marketing CGuard EPS in EU countries under the MDD directive until December 31, 2027. This allows the Company to market and sell CGuard EPS in the EU and certain other jurisdictions subject to certain procedural requirements while the Company's MDR CE recertification is pending.

NOTE 1 - DESCRIPTION OF BUSINESS (continued):

d. Risks Related to the Geopolitical and Military Tensions Between Russia and Ukraine in Europe

In February 2022, Russia launched a military invasion into Ukraine. The Company derived approximately 9.9% of total sales in Russia and Belarus in 2021 while during 2022 the Company's sales to Russia and Belarus were 12.1%. The escalation of geopolitical instability in Russia and Ukraine as well as currency fluctuations in the Russian Ruble could negatively impact the Company's operations, sales, and future growth prospects in that region.

As a result of the crisis in Ukraine, the United States and the EU have implemented sanctions against certain Russian individuals and entities and have made it more difficult for us to collect on outstanding accounts receivable from customers in this region. The Company's global operations expose the Company to risks that could adversely affect the Company's business, financial condition, results of operations, cash flows or the market price of the Company's securities, including the potential for increased tensions between the United States and Russia resulting from the current situation involving Russia and Ukraine, tariffs, economic sanctions and import-export restrictions imposed by either nation, and retaliatory actions by the other nation, as well as the potential negative impact on the Company's business and sales in Russia, and Belarus. Current geopolitical instability in Russia and Ukraine and related sanctions by the U.S. government against certain companies and individuals may hinder the Company's ability to conduct business with potential or existing customers and vendors in these countries.

The U.S. government has imposed sanctions through several executive orders restricting U.S. companies from conducting business with specified Russian individuals and companies. While the Company believes that the executive orders currently do not preclude the Company from conducting business with the Company's current customers or vendors in Russia, and Belarus, the sanctions imposed by the U.S. government may be expanded in the future to restrict the Company from engaging with them. If the Company is unable to conduct business with new or existing customers or vendors or pursue business opportunities in Russia, or Belarus, the Company's business, including revenue, profitability and cash flows, and operations could be adversely affected. The Company cannot provide assurance that current sanctions or potential future changes in sanctions will not have a material impact on the Company's operations in Russia, and Belarus or on the Company's financial results.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES

a. Use of estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates using assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting periods. Actual results could differ from those estimates.

As applicable to these consolidated financial statements, the most significant estimates and assumptions relate to inventory valuations and assessing the likelihood of exercise of options to extend the lease term.

b. Functional currency

The currency of the primary economic environment in which the operations of the Company and its subsidiaries are conducted is the U.S. dollar ("$" or "dollar"). Accordingly, the functional currency of the Company and its subsidiaries is the U.S. dollar.

The dollar figures are determined as follows: transactions and balances originally denominated in dollars are presented in their original amounts. Balances in foreign currencies are translated into dollars using historical and current exchange rates for non-monetary and monetary balances, respectively. The resulting translation gains or losses are recorded as financial income or expense, as appropriate. For transactions reflected in the statements of operations in foreign currencies, the exchange rates at transaction dates are used. Depreciation and changes in inventories and other changes deriving from non-monetary items are based on historical exchange rates.

c. Principles of consolidation

The consolidated financial statements include the accounts of the Company and of its subsidiaries. Intercompany transactions and balances have been eliminated upon consolidation.

d. Cash and cash equivalents

The Company considers all highly liquid investments, which include short-term bank deposits (up to three months from date of deposit), that are not restricted as to withdrawal or use, to be cash equivalents.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

e. Short-term bank deposits

Bank deposits with original maturities of more than three months but less than one year are presented as part of short-term bank deposits. Deposits are presented at their cost which approximates market values including accrued interest. Interest on deposits is recorded as financial income.

f. Concentration of credit risk and allowance for doubtful accounts

Financial instruments that may potentially subject the Company to a concentration of credit risk consist of cash and cash equivalents and short-term bank deposits, which are deposited in major financially sound institutions in the U.S, Israel and Germany, and trade accounts receivable. The Company's trade accounts receivable is derived from revenues earned from customers from various countries. The Company performs ongoing credit evaluations of its customers' financial condition and, requires no collateral from its customers. The Company also has a credit insurance policy for some of its customers. The Company maintains an allowance for doubtful accounts receivable based upon the expected ability to collect the accounts receivable. The Company reviews its allowance for doubtful accounts quarterly by assessing individual accounts receivable and all other balances based on historical collection experience and an economic risk assessment. If the Company determines that a specific customer is unable to meet its financial obligations to the Company, the Company provides an allowance for credit losses to reduce the receivable to the amount management reasonably believes will be collected, which is netted against "Accounts receivable - Trade".

g. Inventory

Inventories are stated at the lower of cost (cost is determined on a "first-in, first-out" basis) or net realizable value. The Company's inventories generally have a limited shelf life and are subject to impairment as they approach their expiration dates. The Company regularly evaluates the carrying value of its inventory and when, based on such evaluation, factors indicate that impairment has occurred, the Company impairs the inventories' carrying value.

h. Leases

Operating leases are included in operating lease right-of-use ("ROU") assets. Short-term balances regarding lease liabilities are included in accounts payable and accruals - Other and long-term balances regarding lease liabilities are included in operating lease liabilities. ROU assets represent Company's right to use an underlying asset for the lease term and lease liabilities represent obligation to make lease payments arising from the lease. Operating lease ROU assets and liabilities are recognized at the lease commencement date based on the present value of lease payments over the lease term. In determining the present value of lease payments, the Company uses the incremental borrowing rate based on the information available at the lease commencement date as the rate implicit in the lease is not readily determinable. The determination of the incremental borrowing rate requires management judgment based on information available at lease commencement. The lease terms may include periods covered by options to extend the lease when it is reasonably certain that the Company will exercise such options, and periods covered by options to terminate the lease when it is reasonably certain that the Company will not exercise such options. Operating lease cost is recognized on a straight-line basis over the lease term. Lease agreements that include lease and non-lease components are accounted for as a single lease component. The Company elected the short-term lease recognition exemption for leases with a lease term of 12 months or less.

i. Property, plant and equipment

Property, plant and equipment are stated at cost, net of accumulated depreciation and amortization. Depreciation is calculated using the straight-line method over the estimated useful lives of the related assets: over three years for computers and other electronic equipment, and seven to fifteen years for office furniture and equipment and machinery and equipment (mainly seven years). Leasehold improvements are amortized on a straight-line basis over the term of the lease, which is shorter than the estimated life of the improvements.

j. Impairment in value of long-lived assets

The Company tests long-lived tangible assets for impairment whenever events or circumstances present an indication of impairment. If the sum of expected future cash flows (undiscounted and without interest charges) of the long-lived assets is less than the carrying amount of such assets, an impairment would be recognized, and the assets would be written down to their estimated fair values, based on expected future discounted cash flows.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

k. Revenue recognition

A contract with a customer exists only when: 1) the parties to the contract have approved it and are committed to perform their respective obligations, 2) the Company can identify each party's rights regarding the distinct goods or services to be transferred ("Performance Obligations"), 3) the Company can determine the transaction price for the goods or services to be transferred, 4) the contract has commercial substance and 5) it is probable that the Company will collect the consideration to which it will be entitled in exchange for the goods or services that will be transferred to the customer. Revenues are recorded in the amount of consideration to which the Company expects to be entitled in exchange for Performance Obligations upon transfer of control to the customer, excluding sales taxes.

Revenue from sales of goods, including sales to distributors, is recognized when the customer obtains control of the product, once the Company has a present right to payment and the customer has legal title, and risk and rewards of ownership are obtained by the customer. Generally, this occurs when products are shipped. In few cases when products are directly sold to medical centers on consignment basis, revenue is recognized when the product is consumed.

The Company recognizes the incremental costs of obtaining contracts as an expense since the amortization period of the assets that the Company otherwise would have recognized is one year or less. The costs are recorded under selling and marketing expenses. Disaggregated revenue is disclosed in Note 11.

The Company recognizes revenue net of value added tax (VAT).

l. Research and development costs

Research and development costs, including the costs of the Company's US based clinical trial costs of approximately $4,468,000 and $2,037,000 for the years ended December 31, 2022 and 2021, respectively, and are charged to the statement of operations as incurred.

m. Share-based compensation

The Company has equity incentive plans under which the Company grants equity awards, including stock options, restricted stock and restricted stock units ("RSUs") to employees and service providers. Employee equity awards are classified as equity awards and accounted for using the grant-date fair value method. The Company determines compensation expense associated with restricted stock and RSUs based on the fair value of our common stock on the date of grant. The fair value of option awards is estimated using the Black-Scholes valuation model and expensed over the requisite service period. The Company elected to account for forfeitures as they occur.

The Company elected to recognize compensation expenses for awards to employees with only service conditions that have graded vesting schedules using the accelerated multiple option approach.

n. Uncertain tax positions

The Company follows a two-step approach to recognizing and measuring uncertain tax positions. The first step is to evaluate the tax position for recognition by determining if the weight of available evidence indicates that it is more likely than not that the position will be sustained on audit. If under the first step a tax position is assessed to be more likely than not of being sustained on audit, the second step is performed, under which the tax benefit is measured as the largest amount that is more than 50% likely to be realized upon ultimate settlement. Such liabilities are classified as long-term, unless the liability is expected to be resolved within twelve months from the balance sheet date. The Company's policy is to include interest related to unrecognized tax benefits within "Financial expenses - net".

o. Deferred income taxes

Deferred taxes are determined utilizing the "asset and liability" method based on the estimated future tax effects of differences between the financial accounting and tax bases of assets and liabilities under the applicable tax laws, and on tax rates anticipated to be in effect when the deferred taxes are expected to be paid or realized. The Company assesses realization of deferred income tax assets and, based on all available evidence, concludes whether it is more likely than not that the net deferred income tax assets will be realized. A valuation allowance is provided for the amount of deferred income tax assets not considered to be realizable.

The Company may incur an additional tax liability in the event of intercompany dividend distributions by its subsidiaries. Such additional tax liability in respect of these foreign subsidiaries has not been provided for in these financial statements as it is the Company's policy to permanently reinvest the subsidiaries' earnings and to consider distributing dividends only in connection with a specific tax opportunity that may arise.

Taxes that would apply in the event of disposal of investments in a foreign subsidiary have not been taken into account in computing the deferred taxes, as it is the Company's intention to hold, and not to realize, these investments.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

p. Advertising

Costs related to advertising and promotion of products are charged to sales and marketing expense as incurred. Advertising expenses were approximately $359,000 and $290,000 for the years ended December 31, 2022 and 2021, respectively.

q. Net loss per share

Basic and diluted net loss per share is computed by dividing the net loss for the period attributable to common stock by the weighted average number of shares of common stock outstanding during the period, including 0 and 11,696 weighted average shares of common stock issuable to holders of Series B Convertible Preferred Stock for the years ended December 31, 2022 and 2021, respectively. The total number of shares of common stock related to outstanding options, warrants, restricted stock, RSUs and Series C Convertible Preferred Stock excluded from the calculations of diluted loss per share were 2,741,355 and 2,840,179 for the years ended December 31, 2022 and 2021, respectively.

r. Segment reporting

The Company has one operating and reportable segment.

s. Fair value measurement

The Company measures fair value and discloses fair value measurements for financial assets and liabilities. Fair value is based on the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date.

The accounting standard establishes a fair value hierarchy that prioritizes observable and unobservable inputs used to measure fair value into three broad levels, which are described below:

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 has no financial instruments measured carried at fair value in each reporting period. The fair value of the Company’s financial instruments approximates their carrying values.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

t. Issued accounting pronouncements effective in future periods

Financial Instruments - Credit Losses

In June 2016, the FASB issued ASU 2016-13, Financial Instruments-Credit Losses (Topic 326)-Measurement of Credit Losses on Financial Instruments. 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 2019, the FASB issued ASU No. 2019-10, Financial Instruments - Credit Losses (Topic 326), Derivatives and Hedging (Topic 815), and Leases (Topic 842): Effective Dates ("ASU 2019-10"). The purpose of this amendment is to create a two-tier rollout of major updates, staggering the effective dates between larger public companies and all other entities. This granted certain classes of companies, including Smaller Reporting Companies ("SRCs"), additional time to implement major FASB standards, including ASU 2016-13. Larger public companies had an effective date for fiscal years beginning after December 15, 2019, including interim periods within those fiscal years. All other entities are permitted to defer adoption of ASU 2016-13, and its related amendments, until the earlier of fiscal periods beginning after December 15, 2022. Under the current SEC definitions, the Company meets the definition of an SRC and is adopting the deferral period for ASU 2016-13. The guidance requires a modified retrospective transition approach through a cumulative-effect adjustment to retained earnings as of the beginning of the period of adoption. The Company does not believe the adoption of this standard will have a material impact on its consolidated financial statements.

NOTE 3 - PROPERTY, PLANT AND EQUIPMENT

a. Composition of assets, grouped by major classifications, is as follows:

	December 31,	
	2022	**2021**
	($ in thousands)	
Cost:		
Computer equipment	$ 396	$ 361
Office furniture and equipment	231	157
Machinery and equipment	1,704	1,599
Leasehold improvements	494	243
	2,825	2,360
Less - accumulated depreciation and amortization	(1,908)	(1,728)
Net carrying amount	$ 917	$ 632

b. Depreciation and amortization expenses totaled approximately $188,000 and $161,000 for the years ended December 31, 2022 and 2021, respectively.

NOTE 4 - LIABILITY FOR EMPLOYEES RIGHT UPON RETIREMENT

Israeli labor law generally requires payment of severance pay upon dismissal of an employee or upon termination of employment in certain other circumstances.

Pursuant to section 14 of the Israeli Severance Compensation Act, 1963, most of the Company's employees are entitled to have monthly deposits, at a rate of 8.33% of their monthly salary, made in their name with insurance companies. Payments in accordance with section 14 relieve the Company from any future severance payments to these employees. The severance pay expenses for such employees were approximately $241,000 and $199,000 for the years ended December 31, 2022 and 2021, respectively.

The severance pay liability of the Company for the rest of its Israeli employees, which reflects the undiscounted amount of the liability, is based upon the number of years of service and the latest monthly salary. The severance pay liability is partly covered by insurance policies and by regular deposits with recognized severance payment funds. The Company may only withdraw funds previously deposited for savings in connection with the payment of severance. The severance pay expenses for such employees were approximately $68,000 and $103,000 for the years ended December 31, 2022 and 2021, respectively.

NOTE 5 – LEASE AGREEMENTS

1) The Company's Israeli subsidiary had a lease agreement for a facility in Israel, which expired on December 31, 2022 with an option to extend the agreement for two additional years until December 31, 2024. On May 25, 2022 the Company amended the agreement mentioned above and extended it until December 31, 2026 as well as leasing of additional space in the facility, the additional space amendment was taken in consideration when calculating the operating lease right of use assets and liabilities.

2) Operating lease cost for the years ended December 31, 2022 and 2021 was $442,000 and $476,000 respectively.

Supplemental information related to leases are as follows:

	December 31 2022 ($ in thousands)	December 31 2021 ($ in thousands)
Operating lease right-of-use assets	1,554	1,081
Current Operating lease liabilities	(419)	(420)
Non-current operating lease liabilities	(1,195)	(781)

Other information:

Operating cash flows from operating leases (cash paid in thousands)	(436)	(437)
Weighted Average Remaining Lease Term	4	3
Weighted Average Discount Rate	8.69%	8.38%

Maturities of lease liabilities are as follows:

	Amount ($ in thousands)
2023	432
2024	472
2025	472
2026	513
Total lease payments	1,889
Less imputed interest	(275)
Total	1,614

NOTE 6 - COMMITMENTS AND CONTINGENT LIABILITIES:

Distribution Agreement with Chinese Partner

On February 3, 2021, the Company entered into a distribution agreement (the "Distribution Agreement") with three China-based partners, pursuant to which the Chinese partners will be responsible for conducting the necessary registration trials for commercial approval of the Company's products in China, followed by an eight-year exclusive distribution right to sell the Company's products in China with the term of the agreement continuing on a year-to-year basis unless terminated. Under the Distribution Agreement, the China-based partners will be subject to minimum purchase obligations. The Distribution Agreement may be terminated for cause upon failure to meet minimum purchase obligations, failure to obtain regulatory approvals or for other material breaches.

In addition, the agreement stipulates that if the Distributor fails to obtain the Regulatory Approvals by the time stipulated in the agreement due to the failure of the clinical trials, and this Agreement was terminated as a result of such failure to obtain Regulatory Approvals, InspireMD shall reimburse Distributor in an amount which is 50% of Distributor's direct out of pocket costs to 3rd parties for conducting the clinical trials, which reimbursement will not exceed USD 1,000,000. The financial statements include a liability, based on 50% of the Distributor costs incurred up to December 31, 2022. The liability at December 31, 2022. is immaterial.

See Note 7 for details regarding an investment transaction with one of the Chinese parties to the Distribution Agreement.

NOTE 7 - EQUITY

a. Share capital

The Company's shares that previously traded on the NYSE American were approved for listing on the Nasdaq Capital Market ("Nasdaq") and such shares began trading on Nasdaq on May 21, 2021 under the symbol, "NSPR."

On April 19, 2021, the Company filed with the Secretary of State of Delaware a Certificate of Amendment to the Company's Amended and Restated Certificate of Incorporation to effect a one-for-fifteen reverse stock split of its common stock, par value $0.0001 per share, effective as of April 26, 2021.

NOTE 7 – EQUITY (continued):

Public Offering

On February 8, 2021, the Company closed an underwritten public offering (the "Offering") of 1,935,484 units ("Units"), with each Unit being comprised of one share of the Company's common stock, par value $0.0001 per share, and one Series G warrant (the "Series G Warrants") to purchase one-half of one share of common stock. In connection with this public offering, the underwriter exercised its over-allotment option in full and purchased an additional 290,322 shares of common stock and 145,161 Series G Warrants. The offering price to the public was $9.30 per Unit. The Series G Warrants are immediately exercisable at a price of $10.23 per and expire five years from the date of issuance.

The Company granted the underwriter compensation warrants to purchase up to 111,290 shares of common stock. The underwriter warrants have an exercise price of $10.23 per share and are exercisable immediately and for five years from the date of effectiveness of the registration statement in connection with the Offering.

The net proceeds to the Company from the Offering, after giving effect to the exercise of the underwriter's over-allotment option, were approximately $18.9 million, after deducting underwriting discounts and commissions and payment of other expenses associated with the Offering, but excluding the proceeds, if any, from the exercise of Series G Warrants sold in the Offering.

On February 3, 2021, the Company entered into a Distribution Agreement with three China-based partners, See Note 6b. for details about the Distribution Agreement.

In addition, and on the same day, the Company entered into an investment transaction with one of the Chinese parties to the Distribution Agreement, which included a securities purchase agreement pursuant to which investor agreed to invest $900,000 in exchange for 89,445 shares of the Company's common stock at a purchase price of $10.062 per share.

During the year ended December 31, 2021, Series F and Series G warrants to purchase shares of common stock were exercised by investors at an exercise price of $7.425 and $10.23 per share, resulting in the issuance of 1,225,412 shares of common stock for proceeds of approximately $9,469,000.

ATM Offering

During the year ended December 31, 2021, the Company sold 818,523 shares of its common stock pursuant to its at-the-market (ATM) issuance sales agreement with a sales agent. These sales resulted aggregate net proceeds to the Company of approximately $5,453,000.

On July 7, 2016, the Company issued 442,424 shares of Series B Preferred Stock in a public offering. During the year ended December 31, 2021, all the remaining 17,303 shares of Series B Convertible Preferred Stock were converted into 207,528 shares of common stock.

NOTE 7 – EQUITY (continued):

On March 14, 2017, the Company issued 1,069,822 shares of Series C Preferred Stock in a public offering.

During the year ended December 31, 2021, an amount of 625 shares of Series C Convertible Preferred Stock were converted into 831 shares of common stock. As of December 31, 2021 and 2022, there were 1,718 shares of Series C Preferred Stock outstanding with a total stated value of $10,997 which convertible into an aggregate of 2,284 shares of our common stock reflecting a conversion price equal to $ 4.815.

As of December 31, 2022, the Company has outstanding warrants to purchase an aggregate of 1,793,815 shares of common stock as follows:

	Number of underlying common stock		Weighted average exercise price
Series E Warrants	198,159	$	27.000
Series F Warrants	433,878	$	7.425
Series G Warrants	1,092,344	$	10.230
Underwriter Warrants	18,277	$	7.425
Other warrants	51,157	$	225.000 and above
Total Warrants	1,793,815	$	

As of December 31, 2022, the Company has 155,000,000 authorized shares of capital stock, par value $0.0001 per share, of which 150,000,000 are shares of common stock and 5,000,000 are shares of “blank check” preferred stock.

NOTE 7 – EQUITY (continued):

b. Share-Based Compensation

1) Pursuant to the current Section 102 of the Israeli Tax Ordinance, which came into effect on January 1, 2003, options may be granted through a trustee (i.e., Approved 102 Options) or not through a trustee (i.e., Unapproved 102 Options). As a result of an election made by the Company under Section 102 of the Income Tax Ordinance, the Company will not be allowed to claim as an expense for tax purposes in Israel the amounts credited to the employee as capital gains to the grantees, although it will generally be entitled to do so in respect of the salary income component (if any) of such awards when the related tax is paid by the employee.

2) During the years ended December 31, 2022 and 2021, the Company granted stock options to the CEO, employees, consultants and directors to purchase a total of 154,508 and 225,225, respectively, shares of the Company's common stock. The options have exercise prices ranging from $2.61-$2.97 and $3.89-$10.05 per share, respectively, which were the fair market value of the company's common stock on the date of each respective grant. The fair value of the above options, using the Black-Scholes pricing models, was approximately $360,356 and $1,026,000, respectively. Of the 154,508 options granted during the year ended December 31, 2022, 109,839 options are subject to a three-year vesting period, with one-third of such awards vesting each year and 44,669 options with performance conditions, mainly related to clinical activities.

3) During the years ended December 31, 2022 and 2021, the Company granted to the employees and directors 45,494 and 419,943 restricted stock, respectively. The fair value of these restricted stock was approximately $109,886 and $1,781,981, respectively. The restricted stock are subject to a three-year vesting period, with one-third of such awards vesting each year.

4) During the year ended December 31, 2021, the Company granted to the CEO 146,567 RSUs. The fair value of these restricted stock units was approximately $603,856. The RSUs granted during the year ended December 31, 2021, are subject to a three-year vesting period, with one-third of such awards vesting each year.

NOTE 7 – EQUITY (continued):

5) The following table summarizes information about stock options granted to employees:

	Year ended December 31			
	2022		2021	
	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price
Outstanding - beginning of period	289,408	5.29	91,692	$ 6.20
Granted	7,841	2.61	205,223	4.90
Forfeited	(2,537)	5.70	(7,507)	5.69
Outstanding- end of period	294,712	5.21	289,408	$ 5.29
Exercisable at the end of the period	123,115	5.51	28,360	6.26

6) The following table summarizes information about stock options granted to non-employees:

	Year ended December 31			
	2022		2021	
	Number of options	Weighted average exercise price	Number of options	Weighted average exercise price
Outstanding - beginning of period	20,002	6.90	-	-
Granted	146,667	2.89	20,002	6.90
Forfeited	-	-	-	-
Exercised	-	-	-	-
Outstanding - end of period	166,669	3.37	20,002	6.90
Exercisable at the end of the period	35,667	3.61	-	-

7) The following table summarizes information about restricted stock granted to employees:

	Year ended December 31	
	2022	2021
	Number of restricted stock	
Outstanding - beginning of period	527,668	185,725
Reverse Split Adjustments	-	59
Granted	45,494	419,943
Forfeited	(10,832)	(20,822)
Vested	(206,379)	(57,237)
Outstanding - end of period	355,951	527,668

NOTE 7 – EQUITY (continued):

8) The following table summarizes information about RSUs granted to employees:

	Year ended December 31	
	2022	2021
	Number of RSUs	
Outstanding - beginning of period	237,078	90,511
Granted	-	146,567
Forfeited	-	-
Vested	-	-
Outstanding - end of period	237,078	237,078

9) The following table provides additional information about all options outstanding and exercisable:

		Outstanding as of December 31, 2022		
Exercise price		Options outstanding	Weighted average remaining contractual life (years)	Options exercisable
$	2.61-2.97	154,508	9.25	29,000
$	3.89-4.12	146,347	8.81	48,782
$	4.95-10.05	156,473	8.00	78,298
$	16.50	4,053	7.01	2,702
		461,381	8.67	158,782

The weighted average of the remaining contractual life of total vested and exercisable options as of December 31, 2022 was 8.41 years.

The aggregate intrinsic value of the total exercisable options as of December 31, 2022 was approximately $0.

The weighted average fair value of options granted was $2.56 for the year ended December 31, 2022. The weighted average fair value of options granted was estimated using the Black-Scholes option-pricing model.

10) The following table sets forth the assumptions that were used in determining the fair value of options granted to employees for the year December 31, 2022 and 2021:

	Year ended December 31	
	2022	2021
Expected life	5.125-6.5 years	5.5-6.5 years
Risk-free interest rates	1.79%-2.88%-	0.59%-1.40%
Volatility	127.43%-130.93%	129.11%-136.78%
Dividend yield	-	-

NOTE 7 – EQUITY (continued):

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 annual risk-free rates are based on the yield rates of zero coupon non-index linked U.S. Federal Reserve treasury bonds as both the exercise price and the share price are in dollar terms. The Company's expected volatility is derived from its historical data.

11) As of December 31, 2022, the total unrecognized compensation cost on employee and non-employee stock options, restricted stock and RSUs, related to unvested stock-based compensation, amounted to approximately $1.30 million. This cost is expected to be recognized over a weighted-average period of approximately 0.85 years. This expected cost does not include the impact of any future stock-based compensation awards.

12) The following table summarizes the allocation of total share-based compensation expense in the consolidated statements of operations:

	Year ended December 31	
	2022	2021
	($ in thousands)	
Cost of revenues	$ 72	$ 49
Research and development	582	64
Sales and marketing	318	182
General and administrative	1,380	1,281
	$ 2,352	$ 1,576

NOTE 8 – RELATED PARTIES TRANSACTIONS

On May 10, 2021, the board of directors of the Company appointed a new member. During the twelve months ended December 31, 2022 and 2021, a consulting company whose founder and CEO is our new board member provided certain marketing services in the amount of $9,645 and $33,775, respectively.

NOTE 9 - TAXES ON INCOME:

a. Tax laws applicable to the Company and its subsidiaries

Taxation in the United States

InspireMD, Inc. is taxed under U.S. tax laws. Accordingly, the applicable federal corporate tax rate in 2022 is 21%. State tax may also apply.

Taxation in Israel

InspiredMD, Ltd is taxed under Israeli tax laws. Accordingly, the applicable corporate tax rate in 2022 is 23%.

Taxation in Germany

InspireMD GmbH is taxed according to the tax laws in Germany. Accordingly, the applicable tax rates are corporate tax rate of 15.825% and trade tax rate of 17.15%.

b. Tax benefits under the Law for the Encouragement of Capital Investments, 1959 (the "Law"):

InspireMD Ltd. has been granted a "Beneficiary Enterprises" status under the Investment Law including Amendment No. 60 thereof, which became effective in April 2005. The tax benefits derived from any such Beneficiary Enterprise relate only to taxable profits attributable to the specific program of investment to which the status was granted.

The main benefit, to which InspireMD Ltd. is entitled, conditional upon the fulfilling of certain conditions stipulated by the above law, is a two-year exemption and five to eight years of a reduced tax rate of 10% to 23% from tax on income derived from beneficiary activities in facilities in Israel. The two-year exemption starts only when the Company starts to pay taxes after using all tax offsetting losses. The tax benefit period is twelve years from the year of election, which means that after a year of election, the two-year exemption and eight years of reduced tax rate can only be used within the next twelve years. The Company elected the year 2011 as a year of election and accordingly 2022 is the last year that would have entitled the Company tax benefits under this law.

NOTE 9 - TAXES ON INCOME (continued):

In the event of a distribution of tax-exempt income attributable to "Beneficiary Enterprises" as a cash dividend, the Company will be required to pay tax at a rate of 10% to 23% on the amount distributed, subject to certain conditions. In addition, dividends originating from income attributable to the "Beneficiary Enterprises" will be subject to a 20% withholding tax.

Should InspireMD Ltd. derive income from sources other than the "Beneficiary Enterprises" during the period of benefits, such income shall be taxable at the regular corporate tax rate.

1) Conditions for entitlement to the benefits

The entitlement to the above benefits is conditional upon InspireMD Ltd. fulfilling the conditions stipulated by the law, regulations published thereunder and the instruments of approval for the specific investments in approved assets. In the event of failure to comply with these conditions, the benefits may be cancelled, and InspireMD Ltd. may be required to refund the amount of the benefits, in whole or in part, with the addition of interest and linkage.

The Company opted not to apply for Preferred Enterprise status (as defined in the Amendment of the Law for the Encouragement of Capital Investments, 1959).

c. Carry forward tax losses

As of December 31, 2022, the Company had a net carry forward tax loss of approximately $51 million, of which approximately $35 million (arising before January 1, 2018), expires until 2037, and approximately $16 million, which does not expire, but is limited to offset 80% of the net income in the year it is utilized.

Under the U.S. tax laws, for net operating losses (NOLs) arising after December 31, 2017, the Tax Cuts and Jobs Act enacted on December 22, 2017 (the "2017 Act") limits a taxpayer's ability to utilize NOL carryforwards to 80% of taxable income.

In addition, NOLs arising after 2017 can be carried forward indefinitely, but carryback is generally prohibited. NOLs generated in tax years beginning before January 1, 2018, will not be subject to the foregoing taxable income limitation and will continue to have a two-year carryback and twenty-year carryforward period.

As of December 31, 2022, InspireMD Ltd., an Israeli subsidiary, had a net carry forward tax loss of approximately $107 million. Under Israeli tax laws, the carry forward tax losses can be utilized indefinitely.

The Israeli subsidiary is taxed in the New Israeli Shekel ("NIS"), which is different from its functional currency (U.S. Dollar). The change in the Israeli subsidiary NOL's for tax purposes is partly resulted by such rate differences.

d. Loss before income taxes

The components of loss before income taxes are as follows:

	Year ended December 31	
	2022	2021
	($ in thousands)	
Loss before taxes on income:		
InspireMD, Inc.	$ (4,773)	$ (4,452)
Subsidiaries	(13,690)	(10,421)
	$ (18,463)	$ (14,873)

NOTE 9 - TAXES ON INCOME (continued):

e. Current taxes on income

The main 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.

The changes in the valuation allowance for the year ended December 31, 2022 and 2021 were as follows:

	Year ended December 31	
	2022	2021
	($ in thousands)	
Balance at the beginning of the year	$ 39,212	$ 35,145
Changes during the year:		
Losses during the year (including foreign exchange rate effect)	859	4,067
Balance at the end of the year	$ 40,071	$ 39,212

f. Accounting for Uncertain Tax position

The following is a reconciliation of the total amounts of the Company's uncertain tax positions during the year ended December 31, 2022 and 2021 were as follows:

	Year ended December 31,	
	2022	2021
	($ in thousands)	
Balance at beginning of period	$ 89	$ 52
Increase in uncertain tax positions because of tax positions taken during the year	17	37
Balance at end of period	$ 106	$ 89

A summary of open tax years by major jurisdiction is presented below:

Jurisdiction	Years
U.S.	2019-2022
Israel	2018-2022
Germany	2019-2022

NOTE 9 - TAXES ON INCOME (continued):

g. Deferred income tax:

	December 31,	
	2022	**2021**
	($ in thousands)	
Long-term:		
Provision for vacation and recreation pay	45	53
R&D expenses	1,452	1,000
Operating lease right of use assets	(357)	(248)
Operating lease liabilities	371	276
Share-based compensation	3,021	2,849
Carry forward tax losses	35,507	35,248
Accrued severance pay, net	32	34
	40,071	39,212
Less-valuation allowance	(40,071)	(39,212)
	-	-

NOTE 10 - SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION:

Balance sheets:

Inventory:

	December 31,	
	2022	**2021**
	($ in thousands)	
Finished goods	$ 179	$ 92
Work in process	510	436
Raw materials and supplies	932	615
	$ 1,621	$ 1,143

NOTE 10 - SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION (continued):

a. Accounts payable and accruals-other:

	December 31,	
	2022	**2021**
	($ in thousands)	
Employees and employee institutions	$ 1,853	$ 1,510
Accrued vacation and recreation pay	197	233
Accrued expenses	554	632
Clinical trial accrual	1,258	504
Current Operating lease liabilities	419	420
Other	130	155
	$ 4,411	$ 3,454

NOTE 11 – DISAGGREGATED REVENUE AND ENTITY WIDE DISCLOSURES:

Revenues are attributed to geographic areas based on the location of the customers. The following is a summary of revenues:

	Year ended December 31,	
	2022	**2021**
	($ in thousands)	
Germany	$ 866	$ 948
Italy	970	981
Other	3,335	2,566
	$ 5,171	$ 4,495

By product:

	Year ended December 31,	
	2022	**2021**
	($ in thousands)	
CGuard™ EPS	$ 5,123	$ 4,309
MGuard Prime™ EPS	48	186
	$ 5,171	$ 4,495

By principal customers:

	Year ended December 31,	
	2022	**2021**
Customer A	17%	20%
Customer B	10%	13%

All tangible long lived assets are located in Israel.

NOTE 12 - SUBSEQUENT EVENTS:

Election to Receive Shares of Common Stock in lieu of Cash Compensation

Beginning on January 1, 2023, non-employee directors may elect to receive all or a portion of their cash retainer amount in shares of the Company's common stock under the 2021 Equity Incentive Plan. If a director makes that election, a stock award under the 2021 Equity Incentive Plan will be paid quarterly on the first day of each quarter ("Grant Dates") and will become fully vested on the Grant Dates. The stock award will be determined by dividing (x) the product of the cash retainer amount and percentage of the cash retainer amount elected to be taken in shares by (y) the "Fair Market Value" (as defined in the 2021 Equity Incentive Plan) of a share on the Grant Dates. If a director's service on the board terminates for any reasons prior to a Grant Date, he/she will receive a pro rata portion of shares or cash based on the number of days served on the board during the relevant quarter.

Exhibit 4.1

DESCRIPTION OF SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

As of March 30*, 2023, InspireMD, Inc., a Delaware corporation ("we," "our" and the "Company") has one class of security registered under Section 12 of the Securities Exchange Act of 1934, as amended: common stock, par value $0.0001 per share. The following description of such security is intended as a summary of the terms of such security as currently in effect and is qualified in its entirety by the provisions of our amended and restated certificate of incorporation, as amended (the "Certificate of Incorporation") and the bylaws are filed as exhibits to this Annual Report on Form 10-K and are incorporated by reference herein. We encourage you to read our amended and restated Certificate of Incorporation and amendments thereto, our bylaws and the applicable provisions of the Delaware General Corporation Law, as amended (the "DGCL"), for additional information.*

Authorized Capital Stock

Pursuant to our Certificate of Incorporation, we have authorized 155,000,000 shares of capital stock, par value $0.0001 per share, of which 150,000,000 are shares of common stock and 5,000,000 are shares of "blank check" preferred stock. The authorized and unissued shares of common stock and the authorized and undesignated shares of preferred stock are available for issuance without further action by our stockholders, unless such action is required by applicable law or the rules of any stock exchange on which our securities may be listed. Unless approval of our stockholders is so required, our board of directors does not intend to seek stockholder approval for the issuance and sale of our common stock or preferred stock.

Common Stock

The holders of our common stock are entitled to one vote per share. Our Certificate of Incorporation does not provide for cumulative voting. Our directors are divided into three classes. At each annual meeting of stockholders, directors elected to succeed those directors whose terms expire are elected for a term of office to expire at the third succeeding annual meeting of stockholders after their election. The holders of our common stock are entitled to receive ratably such dividends, if any, as may be declared by our board of directors out of legally available funds; however, the current policy of our board of directors is to retain earnings, if any, for operations and growth. Upon liquidation, dissolution or winding-up, the holders of our common stock are entitled to share ratably in all assets that are legally available for distribution. The holders of our common stock have no preemptive, subscription, redemption or conversion rights. The rights, preferences and privileges of holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of any series of preferred stock, which may be designated solely by action of our board of directors and issued in the future.

On April 26, 2021, Company effectuated a reverse stock split of its common stock at a ratio of 1-for-15.

The transfer agent and registrar for our common stock is Securities Transfer Corporation. The transfer agent's address is 2901 Dallas Parkway, Suite 380, Plano, Texas 75093.

Our common stock is listed on the Nasdaq Capital Market ("Nasdaq") under the symbol "NSPR."

Preferred Stock

The board of directors is authorized, subject to any limitations prescribed by law, without further vote or action by the stockholders, to issue from time to time shares of preferred stock in one or more series. Each such series of preferred stock shall have such number of shares, designations, preferences, voting powers, qualifications, and special or relative rights or privileges as shall be determined by the board of directors, which may include, among others, dividend rights, voting rights, liquidation preferences, conversion rights and preemptive rights. Issuance of preferred stock by our board of directors may result in such shares having dividend and/or liquidation preferences senior to the rights of the holders of our common stock and could dilute the voting rights of the holders of our common stock.

Prior to the issuance of shares of each series of preferred stock, the board of directors is required by the Delaware General Corporation Law and our Certificate of Incorporation to adopt resolutions and file a certificate of designation with the Secretary of State of the State of Delaware. The certificate of designation fixes for each class or series the designations, powers, preferences, rights, qualifications, limitations and restrictions, including, but not limited to, some or all of the following:

- the number of shares constituting that series and the distinctive designation of that series, which number may be increased or decreased (but not below the number of shares then outstanding) from time to time by action of the board of directors;
- the dividend rate and the manner and frequency of payment of dividends on the shares of that series, whether dividends will be cumulative, and, if so, from which date;
- whether that series will have voting rights, in addition to any voting rights provided by law, and, if so, the terms of such voting rights;
- whether that series will have conversion privileges, and, if so, the terms and conditions of such conversion, including provision for adjustment of the conversion rate in such events as the board of directors may determine;
- whether or not the shares of that series will be redeemable, and, if so, the terms and conditions of such redemption;
- whether that series will have a sinking fund for the redemption or purchase of shares of that series, and, if so, the terms and amount of such sinking fund;
- whether or not the shares of the series will have priority over or be on a parity with or be junior to the shares of any other series or class in any respect;
- the rights of the shares of that series in the event of voluntary or involuntary liquidation, dissolution or winding up of the corporation, and the relative rights or priority, if any, of payment of shares of that series; and
- any other relative rights, preferences and limitations of that series.

Once designated by our board of directors, each series of preferred stock may have specific financial and other terms.

Series C Convertible Preferred Stock (the "Series C Preferred Stock")

As of March 30, 2023, there were 1,718 shares of Series C Preferred Stock outstanding, convertible into an aggregate of 2,284 shares of our common stock.

On March 14, 2017, we issued 1,069,822 shares of Series C Preferred Stock in a public offering. Our Series C Preferred Stock has a stated value of $6.40, and each share of Series C Preferred Stock was initially convertible into 0.00015267 of a share of common stock at an initial conversion price equal to $42,000 per share of common stock. Series C Preferred Stock, to the extent that it has not been converted previously, is subject to full ratchet anti-dilution price protection upon the issuance of equity or equity-linked securities at an effective common stock purchase price of less than the conversion price then in effect, subject to adjustment as provided in the certificate of designation. In accordance with the anti-dilution price protection contained in the certificate of designation for the Series C Preferred Stock as further described below, we reduced the Series C Preferred Stock conversion price to $2250.00 per share in connection with the underwritten public offering that closed on March 1, 2018, to $1312.50 per share in connection with the underwritten public offering that closed on April 2, 2018, to $225.00 per share in connection with the underwritten public offering that closed on July 3, 2018, to $75.00 per share in connection with the underwritten public offering that closed on April 8, 2019, then to $27 per share in connection with the underwritten public offering that closed on September 24, 2019, to $6.75 per share in connection with the underwritten public offering that closed on June 5, 2020, and to $4.815 per share in connection with the utilization of the ATM Facility.

The Series C Preferred Stock is convertible at any time at any time at the option of the holder, provided that the holder will be prohibited from converting Series C Preferred Stock into shares of our common stock if, as a result of such conversion, the holder, together with its affiliates, would own more than 4.99% of the total number of shares of our common stock then issued and outstanding. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99%, provided that any increase in such percentage shall not be effective until 61 days after such notice to us.

In the event of our liquidation, dissolution, or winding up, holders of our Series C Preferred Stock will be entitled to receive the amount of cash, securities or other property to which such holder would be entitled to receive with respect to such shares of Series C Preferred Stock if such shares had been converted to common stock immediately prior to such event (without giving effect for such purposes to the 4.99% or 9.99% beneficial ownership limitation, as applicable) subject to the preferential rights of holders of any class or series of our capital stock specifically ranking by its terms senior to the Series C Preferred Stock as to distributions of assets upon such event, whether voluntarily or involuntarily.

Shares of Series C Preferred Stock are not entitled to receive any dividends, unless and until specifically declared by our board of directors. However, holders of our Series C Preferred Stock are entitled to receive dividends on shares of Series C Preferred Stock equal (on an as-if-converted-to-common-stock basis, and without giving effect for such purposes to the 4.99% or 9.99% beneficial ownership limitation, as applicable) to and in the same form as dividends actually paid on shares of the common stock when such dividends are specifically declared by our board of directors. We are not obligated to redeem or repurchase any shares of Series C Preferred Stock. Shares of Series C Preferred Stock are not otherwise entitled to any redemption rights, or mandatory sinking fund or analogous fund provision.

The holders of the Series C Preferred Stock have no voting rights, except as required by law. Any amendment to our Certificate of Incorporation, bylaws or certificate of designation that adversely affects the powers, preferences and rights of the Series C Preferred Stock requires the approval of the holders of a majority of the shares of Series C Preferred Stock then outstanding.

Pursuant to the anti-dilution provisions contained in the certification of designation for our Series C Preferred Stock, in the event that, while any of our Series C Preferred Stock is outstanding, we issue equity or equity-linked securities at an effective common stock purchase price of less than the Series C Preferred Stock conversion price then in effect, we are required, subject to certain limitations and adjustments as provided in the certificate of designation, to reduce the Series C Preferred Stock conversion price to equal the effective common stock purchase price. This reduction in the Series C Preferred Stock conversion price will result in a greater number of shares of common stock becoming issuable upon conversion of the Series C Preferred Stock for no additional consideration.

We have not listed, and we do not plan on making an application to list, the Series C Preferred Stock on Nasdaq, any other national securities exchange or any other nationally recognized trading system.

Shares of Series C Preferred Stock were issued in book-entry form under a transfer agency and service agreement between Action Stock Transfer Corp., as transfer agent, and us, and are represented by one or more book-entry certificates deposited with DTC and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC.

The transfer agent and registrar for our Series C Preferred Stock is Securities Transfer Corporation. The transfer agent's address is 2901 Dallas Parkway, Suite 380, Plano, Texas 75093.

You should review the certificate of designation of the Series C Preferred Stock, and a subsequent amendment, which are filed as an exhibit to this Annual Report on Form 10-K, for a complete description of the terms and conditions of the Series C Preferred Stock.

Delaware Anti-Takeover Law, Provisions of our Certificate of Incorporation and Bylaws

Delaware Anti-Takeover Law

We are subject to Section 203 of the Delaware General Corporation Law. Section 203 generally prohibits a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless:

- prior to the date of the transaction, the board of directors of the corporation approved either the business combination or the transaction which resulted in the stockholder becoming an interested stockholder;
- the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding (i) shares owned by persons who are directors and also officers and (ii) shares owned by employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or
- on or subsequent to the date of the transaction, the business combination is approved by the board and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

Section 203 defines a business combination to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, transfer, pledge or other disposition involving the interested stockholder of 10% or more of the assets of the corporation;
- subject to exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder; or
- the receipt by the interested stockholder of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, Section 203 defines an interested stockholder as any entity or person beneficially owning 15% or more of the outstanding voting stock of the corporation and any entity or person affiliated with, or controlling, or controlled by, the entity or person. The term "owner" is broadly defined to include any person that, individually, with or through that person's affiliates or associates, among other things, beneficially owns the stock, or has the right to acquire the stock, whether or not the right is immediately exercisable, under any agreement or understanding or upon the exercise of warrants or options or otherwise or has the right to vote the stock under any agreement or understanding, or has an agreement or understanding with the beneficial owner of the stock for the purpose of acquiring, holding, voting or disposing of the stock.

The restrictions in Section 203 do not apply to corporations that have elected, in the manner provided in Section 203, not to be subject to Section 203 of the Delaware General Corporation Law or, with certain exceptions, which do not have a class of voting stock that is listed on a national securities exchange or held of record by more than 2,000 stockholders. Our Certificate of Incorporation and bylaws do not opt out of Section 203.

Section 203 could delay or prohibit mergers or other takeover or change in control attempts with respect to us and, accordingly, may discourage attempts to acquire us even though such a transaction may offer our stockholders the opportunity to sell their stock at a price above the prevailing market price.

Certificate of Incorporation and Bylaws

Provisions of our Certificate of Incorporation and bylaws may delay or discourage transactions involving an actual or potential change in our control or change in our management, including transactions in which stockholders might otherwise receive a premium for their shares, or transactions that our stockholders might otherwise deem to be in their best interests. Therefore, these provisions could adversely affect the price of our common stock. Among other things, our Certificate of Incorporation and bylaws:

- permit our board of directors to issue up to 5,000,000 shares of preferred stock, without further action by the stockholders, with any rights, preferences and privileges as they may designate, including the right to approve an acquisition or other change in control;

- provide that the authorized number of directors may be changed only by resolution of the board of directors;
- provide that all vacancies, including newly created directorships, may, except as otherwise required by law, be filled by the affirmative vote of a majority of directors then in office, even if less than a quorum;
- divide our board of directors into three classes, with each class serving staggered three-year terms;
- do not provide for cumulative voting rights (therefore allowing the holders of a majority of the shares of common stock entitled to vote in any election of directors to elect all of the directors standing for election, if they should so choose);
- provide that special meetings of our stockholders may be called only by our board of directors; and
- set forth an advance notice procedure with regard to the nomination, other than by or at the direction of our board of directors, of candidates for election as directors and with regard to business to be brought before a meeting of stockholders.

Exhibit 10.64

THIRD AMENDMENT TO EMPLOYMENT AGREEMENT

This THIRD AMENDMENT TO EMPLOYMENT AGREEMENT (this "***Amendment***"), dated as of January 5, 2023 by and between Marvin Slosman (the "***Executive***") and InspireMD, Inc. (the "***Company***").

WHEREAS, the Company and Executive are parties to an Employment Agreement dated as of December 9, 2019, as amended by those amendments dated as of December 31, 2019 and November 8, 2021 (the "***Agreement***"); and

WHEREAS, on January 5, 2023, the Compensation Committee determined to increase the target amount of Executive's Performance Bonus as further set forth herein;

NOW, THEREFORE, pursuant to Article V, Section G of the Agreement, and for good and valuable consideration, the sufficiency of which is hereby acknowledged, the Company and the Executive agree as follows:

1. Performance Bonus. The first sentence of Article II, Section C of the Agreement is hereby replaced by the following:

The Executive shall be entitled to receive annual bonuses in an amount up to 60% percent of the Base Salary, less applicable payroll deductions and tax withholdings (each, a "Performance Bonus") as may be in effect from time to time, for calendar year 2022 and for each calendar year thereafter during his employment with the Company based on the extent to which performance criteria/financial results for the applicable year have been met, which bonuses are expected to be paid on or before March 15 of the calendar year following the calendar year to which the Performance Bonus relates.

2. Except as expressly amended by this Amendment, the Agreement shall continue in full force and effect in accordance with the provisions thereof

3. In the event of a conflict between the Agreement and this Amendment, this Amendment shall govern.

[*Remainder of Page Intentionally Left Blank;*
Signature Page Follows.]

IN WITNESS WHEREOF, the Parties have executed this Amendment to Employment Agreement as of the date first set forth above.

THE COMPANY:

INSPIREMD, INC.

By: */s/ Paul Stuka*
Name: Paul Stuka
Title: Chairman of the Board

THE EXECUTIVE:

/s/ Marvin Slosman
Marvin Slosman

Exhibit 10.65

SEVENTH AMENDMENT TO AMENDED AND RESTATED EMPLOYMENT AGREEMENT

This SEVENTH AMENDMENT TO AMENDED AND RESTATED EMPLOYMENT AGREEMENT (this "***Amendment***") is made and entered as of this 18th day of January 2023 (the "***Amendment Effective Date***") by and between InspireMD, Inc., a Delaware corporation (the "***Company***"), and Craig Shore (the "***Executive***"; together with the Company, the ***"Parties"***) for purposes of amending that certain Amended and Restated Employment Agreement dated as of May 5, 2014, as amended on January 5, 2015, July 25, 2016, March 25, 2019, August 14, 2020, November 4, 2021 and January 17, 2022, by and between the Company and the Executive (the "***Agreement***"). Terms used in this Amendment with initial capital letters that are not otherwise defined herein shall have the meanings ascribed to such terms in the Agreement.

WHEREAS, Section 7.5 of the Agreement provides that the parties to the Agreement may amend the Agreement in a writing signed by the parties; and

WHEREAS, the Parties desire to amend the Agreement in certain respects.

NOW THEREFORE, pursuant to Section 7.5 of the Agreement, and for good and valuable consideration, the sufficiency of which is hereby acknowledged, the Company and the Executive agree as follows:

1. Section 2.2 of the Agreement, paragraph (a), is hereby amended as of the Amended Effective Date by deleting said paragraph in its entirety and substituting in lieu thereof the following new Section 2.2, paragraph (a):

> (a) The Executive shall be paid a base salary of no less than NIS 93,912 effective January 1, 2023, per month (NIS 1,126,944 on an annualized basis) during the Term; provided, however, that nothing shall prohibit the Company, to the extent permitted by law, from reducing the base salary as part of an overall cost reduction program that affects all senior executives of the Company Group and does not disproportionately affect the Executive, so long as such reductions do not reduce the base salary to a rate that is less than 90% of the minimum base salary amount set forth above (or, if the minimum base salary amount has been increased during the Term, 90% of such increased amount). The Executive's base salary shall be reviewed annually by the Chief Executive Officer for increase (but not decrease, except as permitted above) as part of the Company's annual compensation review.

2. Except as expressly amended by this Amendment, the Agreement shall continue in full force and effect in accordance with the provisions thereof.

3. In the event of a conflict between the Agreement and the Amendment, this Amendment shall govern.

[Signature Page Follows]

IN WITNESS WHEREOF, the parties have executed this Agreement as of the Effective Date.

INSPIREMD, INC.	EXECUTIVE
/s/ Marvin Slosman [signature]	*/s/ Craig Shore* [signature]
By: Marvin Slosman	Craig Shore, an individual
Its: Chief Executive Officer	

Certain confidential information contained in this document, marked by [***], has been omitted because it is not material and is the type that the registrant treats as private and confidential.

EMPLOYMENT CONTRACT

Between:

InspireMD, an Israeli company registered at the Paris Registry of Companies under the number _____, whose registered office is located at Menorat Hamaor 4, 3th Floor, Tel Aviv, 67448 Israel,

Represented for the purposes hereof by Mr. Craig Shore, CFO,

(hereafter referred to as the "**Company**")

And:

Mr. Andrea Tommasoli
[***]

(hereafter referred to as the "**Employee**")

CONTRAT DE TRAVAIL

Entre :

InspireMD, société Israélienne, immatriculée au Registre du Commerce et des Sociétés de Paris sous le numéro _____, et dont le siège social est situé Menorat Hamaor 4, 3th Floor, Tel Aviv, 67448 Israël,

Représentée aux fins des présentes par Mr. Craig Shore, CFO,

(ci-après dénommée la « **Société** »)

Et :

Mr. Andrea Tommasoli
[***]

(ci-après dénommé le «**Salarié** »)

IT HAS BEEN AGREED AS FOLLOWS:

ARTICLE 1 – HIRING

1.1 The Employee is hired the November 2, 2020. He reminds having formally stated that, at the time of his hiring, he will have left his previous employer free from any commitments whatsoever, and that he was not subject to any non-competition clause which would prevent him from working for the Company.

1.2 For information purposes, the collective bargaining agreement, which is applied by the Company at the date of the signature of the present contract, is the Collective Bargaining Agreement for medical equipment's trade.

This reference to the Collective Bargaining Agreement is not considered as an essential condition of this employment contract and may change in case of evolution of the Company's activity.

ARTICLE 2 – FUNCTION - DUTIES

2.1 The Employee shall be employed by the Company in the position of Senior V.P. Global Sales and Marketing, Executive status, job classification V.

In this capacity, the Employee will have the duties listed in appendix n°1.

The Employee understands that these duties will necessarily evolve in accordance with the development of the business. The Employee therefore accepts that his duties may be changed as the Company judges necessary and that these modifications may not be considered as a modification to his contract as long as they respect his qualifications.

2.2 In respect of his professional activity, the Employee will report to the CEO, or to any person who may validly replace him.

IL A ETE CONVENU ET ARRETE CE QUI SUIT :

ARTICLE 1 - ENGAGEMENT

1.1 Le Salarié est engagé le 2 Novembre 2020. Il rappelle avoir formellement déclaré qu'au moment de son embauche, il ne sera plus lié à aucune autre entreprise, qu'il avait quitté son précédent employeur libre de tout engagement de quelque nature qu'il soit et qu'il n'était soumis à aucune clause de non-concurrence qui aurait pu l'empêcher d'être employé par la Société.

1.2 A titre d'information, la Convention Collective appliquée par la Société à la date de signature du présent contrat est la Convention Collective Nationale Médico-techniques (IDCC 1982).

La référence à cette Convention Collective ne constitue pas un élément essentiel du présent contrat de travail et est susceptible de modification en fonction de l'évolution de l'activité de la Société.

ARTICLE 2 - FONCTION - ATTRIBUTIONS

2.1 Le Salarié est engagé par la Société en qualité de Senior V.P. Global Sales and Marketing statut Cadre, niveau V.

En cette qualité, le Salarié aura notamment les attributions listées en annexe °1.

Les attributions du Salarié sont nécessairement évolutives et pourront faire l'objet de toutes modifications ou précisions jugées utiles par la Société, sous réserve de respecter ses qualifications et sans que cette modification ne constitue une modification du présent contrat.

2.2 Le Salarié devra rendre compte de son activité professionnelle au CEO ou à toute personne qui pourrait lui être substituée.

ARTICLE 3 – DURATION OF CONTRACT

This contract is concluded for an indefinite period. Each of the parties being entitled to terminate the contract at any time in accordance with the legal and contractual provisions in force.

ARTICLE 3 - DUREE DU CONTRAT

Le présent contrat est conclu pour une durée indéterminée, chacune des parties pouvant y mettre fin à tout moment en respectant les dispositions légales et conventionnelles en vigueur.

ARTICLE 4 – REMUNERATION

4.1 As remuneration for his activity, the Employee shall receive a gross annual salary of 205,000.00 € paid in twelve (12) equal installments.

4.2 The Employee is entitled to a yearly gross bonus (the "Bonus") of 35% of his base salary per 12-month period subject to the Company bonus plan and his successful achievement of 100% of the targets determined between the Parties. The Bonus is paid on a yearly basis. During the year 2020 the bonus will be prorated per the months actually worked in 2020. For each year, the actual payout is subject to the compensation committee's discretion and final approval

4.3 All the elements of remuneration mentioned above shall be subject to deduction of the employee's share of social contributions, and CSG and CRDS.

4.4 Incentive plan

The Employee will be entitled to a remuneration of 271,534 "Restricted stock" (under American law) and 90,511 "stock options" (under American law), after a vesting period of 3 years.

The terms and conditions of these stock options and restricted stock will be specified in the award agreements.

The grants are subject to Compensation Committee approval and the execution of the award agreements.

ARTICLE 4 – REMUNERATION

4.1 En rémunération de son activité, le Salarié recevra un salaire annuel brut de 205.000,00 € payé en douze (12) mensualités égales.

4.2 Le Salarié est éligible à un bonus annuel brut (le «Bonus») de 35% de son salaire de base par période de 12 mois sous réserve du plan de bonus de la Société et de l'accomplissement à 100% des objectifs fixés entre les parties. Le Bonus est payé sur une base annuelle. Au cours de l'année 2020, le Bonus sera calculé au prorata des mois effectivement travaillés en 2020. Pour chaque année, le versement effectif du Bonus est soumis à la discrétion et à l'approbation finale du comité de rémunération.

4.3 L'ensemble des éléments de rémunération tels que définis ci-dessus sera soumis à déduction des charges sociales salariales ainsi qu'à la CSG et à la CRDS.

4.4 Plan d'incentive

Le Salarié aura droit à l'attribution de 271.534 « Restricted stock » (« SRA » de droit américain) et 90.511 « stock-options » (de droit américain) après une période de « vesting » de 3 ans.

Les modalités et conditions d'attributions seront précisées dans le document d'attribution.

Ces attributions sont soumises à l'approbation du Comité des rémunérations et au respect des conditions d'attribution.

ARTICLE 5 – WORKING TIME DURATION

ARTICLE 5 – DUREE DU TRAVAIL

As a top executive ("cadre dirigeant") and considering the scope of his responsibilities, the large autonomy he enjoys in the management of his working time, his ability to make decisions and the amount of his remuneration, the Employee is not bound by legal and regulatory provisions on working time, pursuant to article L. 3111-2 of French Labor Code.

En sa qualité de Cadre dirigeant et compte tenu de l'étendue de ses responsabilités, de la grande autonomie dont il bénéficie dans l'organisation de son emploi du temps, de sa capacité à prendre des décisions et du montant de sa rémunération, le Salarié n'est pas soumis aux dispositions législatives et réglementaires relatives à la durée du travail, en application de l'article L. 3111-2 du Code du travail.

ARTICLE 6 – WORKPLACE

The Employee will perform his duties at his home place in Lyon.

This remote work will not give rise to any compensation. The fixed salary of the Employee taking into account this situation of remote work at home.

Considering the Employee's functions, he agrees that his workplace could be transferred to any other place in metropolitan France as the Company may reasonably require. This transfer will not be considered as a modification of the employment contract.

Besides, the Employee agrees that he may be requested to go frequently on specific business trips, either in France or abroad, within the scope of missions entrusted to him by the Company.

ARTICLE 6 - LIEU DE TRAVAIL

Le Salarié exercera ses fonctions à son domicile à Lyon.

Ce télétravail ne donnera lieu à aucune indemnité, le salaire forfaitaire du Salarié prenant en compte cette situation de télétravail à domicile.

Eu égard à la nature de ses fonctions, le Salarié reconnaît que son lieu de travail pourra être transféré dans tout autre lieu en France Métropolitaine, si la Société en éprouvait la nécessité, sans que ce transfert constitue une modification de son contrat de travail.

Par ailleurs, le Salarié accepte que, dans le cadre de ses fonctions, il puisse être amené à effectuer des déplacements professionnels réguliers, tant en France qu'à l'étranger.

ARTICLE 7 – REIMBURSEMENT OF EXPENSES

The travel and hotel expenses, as well as any professional expenses incurred in the Company's interest and which fall within the scope of the Company's business expense management policy shall be borne by the Company, upon presentation of an expense report and receipts by the Employee.

Professional's vehicle expenses are covered up to a limit of € 1,000 per month upon presentation of an expense report and receipts by the Employee.

ARTICLE 7 - REMBOURSEMENT DE FRAIS

Les dépenses de voyage, frais d'hôtels, ainsi que toutes les dépenses d'ordre professionnel engagées dans l'intérêt de la Société et entrant dans le cadre de la politique de gestion des frais professionnels de la Société, seront prises en charge par la Société, sur présentation par le Salarié d'une note de frais accompagnée des documents justificatifs.

Les frais de véhicules effectués pour les besoins professionnels sont pris en charges sur justificatifs dans la limite de 1.000 € par mois.

ARTICLE 8 – PAID HOLIDAYS

The Employee shall benefit from the number of worked days of paid holidays following the applicable rules. For the time being, the number is 25 worked days.

ARTICLE 8 - CONGES PAYES

Le Salarié bénéficiera des droits à congés payés selon les dispositions en vigueur applicables qui se montent actuellement à 25 jours ouvrés.

The dates of the Employee's paid vacation shall be set in agreement with the Company which shall take into account the Employee's wishes as far as possible. The requirements linked to the organization of the Company shall take precedence.

Paid holidays accrued for a reference year (June 1st to May 31) may not be taken or carried over to beyond the end of the following reference year, without prior consent of the Company.

ARTICLE 9 – ABSENCE/SICK DAYS

In the event of circumstances preventing the Employee from performing his activity due to accident or sickness, the latter shall advise the Company as soon as possible, and by the latest within a period of 24 hours, of the motivation and the possible length of his absence. This information shall be confirmed by the Employee within a period of two (2) days by submitting a medical certificate indicating the probable length of absence.

ARTICLE 10 – PROVIDENCE AND RETIREMENT SCHEMES

The Employee will benefit from the providence and complementary retirement schemes as well as from any other collective contract which may concluded by the Company.

In this respect, the Employee expressly accepts that the employee's contributions relating to the said schemes will be deducted from his monthly gross salary.

ARTICLE 11 – EXCLUSIVITY AND CONFIDENTIALITY

11.1 The Employee undertakes to devote all his work time and effort for the exclusive benefit of the Company and he may therefore not exercise any other professional activity throughout the duration of this contract without the prior written express approval of a legal representative of the Company.

11.2 Whether during his employment in the Company or at any other time after the termination of his employment contract, whatever the cause may be, the Employee may not disclose to any third party whomsoever any confidential information concerning the Company, the parent company,

Les dates des congés payés du Salarié seront fixées avec l'accord de la Société, laquelle tiendra compte, dans la mesure du possible, des souhaits de l'intéressé. Les impératifs liés à l'organisation de la Société primeront en la matière.

Les congés acquis au titre d'une période de référence (1er juin au 31 mai) ne pourront être pris ou reportés au-delà du terme de l'année de référence suivante sans l'accord préalable de la Société.

ARTICLE 9 - ABSENCE/MALADIE

En cas d'empêchement d'exercer son activité par suite de maladie ou d'accident, le Salarié doit aviser la Société dès que possible, et au plus tard dans les 24 heures, du motif et de la durée probable de son absence. Cet avis doit être confirmé par le Salarié au plus tard dans les deux (2) jours en produisant un certificat médical faisant connaître la durée probable de l'interruption de travail.

ARTICLE 10 - REGIMES DE PREVOYANCE ET DE RETRAITE

Le Salarié bénéficiera des régimes de prévoyance et de retraite complémentaire, ainsi que de tout autre contrat collectif qui pourrait être souscrit par la Société.

A cet égard, le Salarié accepte expressément que les cotisations salariales relatives aux régimes susvisés seront déduites de son salaire mensuel brut.

ARTICLE 11 - EXCLUSIVITE ET CONFIDENTIALITE

11.1 Le Salarié s'engage à consacrer tout son temps et ses efforts au service exclusif de la Société et à ne pas exercer d'autre activité professionnelle pendant la durée de son contrat sans l'accord préalable écrit du représentant légal de la Société.

its subsidiaries, and/or the companies of the Group and/or concerning any of their subcontractors, suppliers, clients, agents, employees or representatives, except if the disclosure of such information (i) is required for the proper execution of the Employee's duties towards the Company under the terms of the Contract or (ii) is authorized by the Company.

For the purposes of this Contract, the term "confidential information" means, without limitation, know-how, trade secrets, client listings, operating methods, financial and accountancy information, company and marketing schemes, confidential information concerning company personnel and all other information considered confidential by the Company.

Confidential information consists of, without limitation, all information concerning the Company and all companies of the Group that the Employee may have knowledge of during his employment.

11.2 Que ce soit pendant la durée de son emploi dans la Société ou à tout moment après la rupture de son contrat de travail, quelle qu'en soit la cause, le Salarié ne pourra divulguer à aucun tiers quel qu'il soit des informations confidentielles sur la Société, sa société mère, ses filiales et/ou sur l'un quelconque de leurs sous-traitants, fournisseurs, clients, concessionnaires de licence, employés ou agents, sauf si et dans la mesure où (i) une telle divulgation est nécessaire à l'exécution de ses obligations envers la Société aux termes du présent contrat ou (ii) est autorisée par la Société.

Aux fins du présent contrat, le terme « informations confidentielles » comprend notamment sans que cette énumération soit limitative, le savoir-faire, les secrets commerciaux, fichiers clients, méthodes d'exploitation, informations financières et comptables, plans d'entreprise, plans de marketing, informations confidentielles sur le personnel et toutes autres informations considérées comme confidentielles par la Société.

Les informations confidentielles comprennent en outre, mais sans que cette énumération soit limitative, les informations se rapportant à la société et aux sociétés du groupe que le Salarié serait amenées à connaître pendant la durée de son emploi.

ARTICLE 12 – USE OF THE COMPANY'S EQUIPMENTS AND COMMUNICATION TOOLS

The Employee undertakes not to use for private purposes, save for a reasonable and limited use, the Company's equipment and communication tools put at his disposal in the framework of his professional activity. The said equipment and tools are notably the following, without limitation: computer, mobile phone, etc.

The Employee expressly acknowledges and accepts that the Company may monitor and/or record the Employee's use of the Company's equipment and communication tools above mentioned, subject to compliance with the legal provisions. This way, the Company could prevent or detect any possible unauthorized use, but ensure the effective operation of

ARTICLE 12 - UTILISATION DES EQUIPEMENTS ET OUTILS DE COMMUNICATION DE LA SOCIETE

Le Salarié s'interdit d'utiliser à des fins personnelles, sauf usage limité et raisonnable, les équipements et outils de communication de la Société mis à sa disposition dans le cadre de son activité professionnelle. Lesdits équipements et outils sont notamment, sans que cette liste soit limitative : téléphone portable, ordinateur etc.

Le Salarié reconnaît et accepte expressément que la Société peut contrôler et/ou enregistrer l'utilisation faite des équipements et outils de communication ci-dessus mentionnés, dans le respect des dispositions légales. De cette façon, la Société est en mesure de prévenir ou détecter les éventuels usages non autorisés, mais également de s'assurer du fonctionnement effectif des équipements et outils mis à la disposition du Salarié.

the equipment and tools put at the Employee's disposal.

ARTICLE 13 – RESTITUTION

Upon termination of the employment for whatsoever reason, the Employee shall return to the Company upon his leaving, irrespective of the legal term of the contract, any documents, reports, studies, research, listings, files and correspondence, as well as any equipment such as a laptop or any other devices belonging to the Company.

ARTICLE 14 – TERMINATION

This employment contract may be terminated at any time by either the Company or the Employee, it is subjected to a 6 months' notice period in case of a dismissal. However, no notice period applies in case of serious or gross misconduct.

The notice period duration in case of a resignation is provided in the applicable collective bargaining agreement.

ARTICLE 15 – DATA PROTECTION

The Employee acknowledges and agrees that, for the purposes of human resources management and the performance of the current employment contract, personal data relating to the Employee are collected, stored and processed by the Company during the performance of the employment contract.

The Employee accepts that these personal data be disclosed and transferred to other employees of the Company or to any other persons as may be reasonably necessary and as otherwise required by law.

In accordance with the provisions of the Law n°78-17 of 6 January 1978 and the GDPR, the Employee is entitled to a right to access and modification regarding the personal data relating to him towards the Management, also competent to answer any questions relating to the data processing implemented within the Company on the basis of the personal data relating to the Employee.

ARTICLE 13 - RESTITUTION

Au terme de son contrat de travail pour quelque raison que ce soit, le Salarié remettra à la Société, lors de son départ effectif tous documents, rapports, études, recherches, listes, fichiers et correspondances, ainsi que tout matériel tel que l'ordinateur portable ou tout autre matériel appartenant à la Société.

ARTICLE 14 – RUPTURE DU CONTRAT DE TRAVAIL

Ce contrat peut être résilié à tout moment par la Société ou le Salarié, à condition de respecter un préavis dont la durée sera de 6 mois en cas de licenciement. Toutefois, en cas de faute grave ou lourde, aucun préavis ne sera applicable.

La durée du préavis en cas de démission du Salarié est déterminée par la convention collective applicable.

ARTICLE 15 - DONNEES PERSONNELLES

Le Salarié reconnaît et accepte que la Société, pour les besoins de la gestion de ses ressources humaines et de l'exécution du présent contrat, procède à la mise en œuvre de traitements automatisés des données personnelles le concernant, collectées et stockées au cours de l'exécution du présent contrat.

Le Salarié accepte que ces données personnelles puissent être divulguées ou transférées à d'autres salariés de la Société ou à tout autre personne, si la Société en éprouvait la nécessité ou si la loi l'exigeait.

Conformément aux dispositions de la Loi n° 78-17 du 6 janvier 1978 et du RGPD, le Salarié dispose d'un droit d'accès et de rectification des données personnelles le concernant auprès de la Direction, également compétente pour répondre aux questions concernant les traitements automatisés mis en œuvre au sein de la Société à partir des données personnelles concernant le Salarié.

ARTICLE 16 – APPLICABLE LAW – JURISDICTION

This contract is governed by French law, both for the purposes of its performance and its termination. The French courts shall have exclusive jurisdiction concerning any dispute related hereto.

ARTICLE 17 – TRANSLATION

In the event of a conflict between the French and English version hereof, the French text shall prevail in all circumstances.

Signed in Lyon
On
In duplicate[1]

/s/ Craig Shore */s/ Marvin Slosman*

For InspireMD
Mr. Craig Shore, CFO

Read and approved - good for agreement

/s/ Andrea Tommasoli

Mr. Andrea Tommasoli[1]

ARTICLE 16 - LOI APPLICABLE - TRIBUNAUX COMPETENTS

Le présent contrat est soumis à la loi française, tant pour son exécution que pour sa résiliation, et tout litige s'y rapportant sera de la compétence exclusive des tribunaux français.

ARTICLE 17 - TRADUCTION

En cas de conflit entre les versions en langue française et anglaise du présent contrat de travail, le texte en français prévaudra en toute circonstance.

Fait à Lyon
Le
En double exemplaire [1]

/s/ Craig Shore */s/ Marvin Slosman*

Pour InspireMD
Mr. Craig Shore, CFO

Lu et approuvé – bon pour accord

/s/ Andrea Tommasoli

Mr. Andrea Tommasoli[1]

[1] Each page must be initialed and the signature shall be preceded by the handwritten notation « *lu et approuvé – bon pour accord* » (= "read and approved – good for agreement").

Appendix 1

Job Description

Job Description
Identify potential markets
Negotiations with potential distributors
Responsible for regional sales people
Responsible for Sales
Identify and define particular market needs
Train distributor and sales representatives
Responsible for managing the approved budget within department
Serves as a member in the executive team
Responsible for marketing strategy

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements on Form S-1 (Nos. 333-238247, 333-233432, 333-225680 and 333-215682), Form S-3 (Nos. 333-223530, 333-255038 and 333-265409) and Form S-8 (Nos. 333-248837, 333-249320, 333-232348, 333-218499, 333-196533, 333-188839 and 333-260216), of InspireMD, Inc. of our report dated March 30, 2023 relating to the financial statements, which appears in this Form 10-K.

Tel-Aviv, Israel
March 30, 2023

/s/ Kesselman & Kesselman
Certified Public Accountants (Isr.)
A member of PricewaterhouseCoopers International Limited

Exhibit 31.1

CERTIFICATION OF CHIEF EXECUTIVE OFFICER PURSUANT TO RULE 13a-14(a)

I, Marvin Slosman, certify that:

1. I have reviewed this Annual Report on Form 10-K of InspireMD, Inc. (the "registrant");

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 registrant as of, and for, the periods presented in this report;

4. The registrant'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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant 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 registrant, 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant'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 registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant'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 registrant'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 registrant's internal control over financial reporting.

Date: March 30, 2023

By: */s/ Marvin Slosman*
Name: Marvin Slosman
President and Chief Executive Officer (Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF CHIEF FINANCIAL OFFICER PURSUANT TO RULE 13a-14(a)

I, Craig Shore, certify that:

1. I have reviewed this Annual Report on Form 10-K of InspireMD, Inc. (the "registrant");

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 registrant as of, and for, the periods presented in this report;

4. The registrant'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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant 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 registrant, 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant'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 registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant'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 registrant'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 registrant's internal control over financial reporting.

Date: March 30, 2023

By: */s/ Craig Shore*
Name: Craig Shore
Title: Chief Financial Officer (Principal Financial Officer)

Exhibit 32.1

CERTIFICATION FURNISHED PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

This certification is furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350) and accompanies the Annual Report on Form 10-K (the "Form 10-K") for the fiscal year ended December 31, 2022 of InspireMD, Inc. (the "Company"). I, Marvin Slosman, the Chief Executive Officer of the Company, certify that, based on my knowledge:

(1) The Form 10-K fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company as of and for the periods covered in this report.

Date: March 30, 2023

By: */s/ Marvin Slosman*
Name: Marvin Slosman
Title: President and Chief Executive Officer (Principal Executive Officer)

The foregoing certification is being furnished as an exhibit to the Form 10-K pursuant to Item 601(b)(32) of Regulation S-K and Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code) and, accordingly, is not being filed as part of the Form 10-K for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.

Exhibit 32.2

CERTIFICATION FURNISHED PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

This certification is furnished solely pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 (18 U.S.C. 1350) and accompanies the Annual Report on Form 10-K (the "Form 10-K") for the fiscal year ended December 31, 2022 of InspireMD, Inc. (the "Company"). I, Craig Shore, the Chief Financial Officer of the Company, certify that, based on my knowledge:

(1) The Form 10-K fully complies with the requirements of Section 13(a) or Section 15(d) of the Securities Exchange Act of 1934; and

(2) The information contained in the Form 10-K fairly presents, in all material respects, the financial condition and results of operations of the Company as of and for the periods covered in this report.

Date: March 30, 2023

By: */s/ Craig Shore*
Name: Craig Shore
Title: Chief Financial Officer (Principal Financial Officer)

The foregoing certification is being furnished as an exhibit to the Form 10-K pursuant to Item 601(b)(32) of Regulation S-K and Section 906 of the Sarbanes-Oxley Act of 2002 (subsections (a) and (b) of Section 1350, Chapter 63 of Title 18, United States Code) and, accordingly, is not being filed as part of the Form 10-K for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing.