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, 2025

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)

6303 Waterford District Drive
Suite 215
Miami, Florida 33126
(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, 2025, based on the price at which the common equity was last sold on such date, was $60,925,742. 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 18, 2026
Common Stock, $0.0001 par value	46,801,561

Documents incorporated by reference:

Portions of the Registrant's definitive proxy statement for its 2026 Annual Meeting of Stockholders, which the Registrant intends to file pursuant to Regulation 14A with the Securities and Exchange Commission not later than 120 days after December 31, 2025, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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INTRODUCTION

"InspireMD," the "InspireMD" logo, "CGuard," "CGuard Prime," "MicroNet," "SwitchGuard," and our other registered or common law trade names, trademarks or service marks appearing in this Annual Report on Form 10-K are our property. Trade names, trademarks and service marks of other companies appearing in this Annual Report on Form 10-K are the property of their respective owners. We do not intend our use or display of other companies' trade names, trademarks or service marks to imply a relationship with, or endorsement or sponsorship of us by, these other companies unless otherwise stated. Solely for convenience, the trademarks and tradenames referred to in this Annual Report on Form 10-K appear without the ® and ™ symbols, but those references are not intended to indicate, in any way, that we will not assert, to the fullest extent under applicable law, our rights, or the right of the applicable licensor to these trademarks and tradenames.

CAUTIONARY 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, expected 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 our stockholders' ownership interests;
- the clinical development, commercialization and market acceptance of our products;
- whether the clinical trial results for our products will be predictive of real-world results;
- 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 significant revenues from our products;
- estimates of our expenses, future revenues, capital requirements and our needs for and ability to access sufficient additional financing, including any unexpected costs or delays in the ongoing commercial launch of our products;
- 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;
- whether access to our products is achieved in a commercially viable manner and whether our products receive adequate reimbursement by governmental and other third-party payers;
- 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;
- security, political and economic instability in the Middle East that could harm our business, including due to the current security situation in Israel;
- current or future unfavorable economic and market conditions and adverse developments with respect to financial institutions and associated liquidity risk; and
- changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements and the impact of such policies on us, our customers and suppliers, and the global economic environment.

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.

PART I

Item 1. Business.

Overview

We are a medical device company specializing in the development and commercialization of products for the treatment of carotid artery disease and other vascular conditions. Our portfolio includes two commercial products based on our proprietary CGuard carotid stent technology, designed to provide market-leading embolic protection during and after stenting procedures. A stent is an expandable scaffold-like metallic device placed in an artery to widen the lumen and restore blood flow.

Our first product, the CGuard Carotid Embolic Prevention System ("CGuard EPS"), integrates a self-expanding nitinol stent with a MicroNet mesh sleeve as a single device for carotid artery revascularization. In January 2024, we received CE Mark recertification for CGuard EPS under the EU Medical Device Regulation ("MDR"). Our CGuard EPS previously held CE Mark approval under the former Medical Device Directive ("MDD"). CGuard EPS is marketed in over 30 countries outside the United States through a network of distributors.

Our second product, the CGuard Prime Carotid Stent System ("CGuard Prime"), uses the same stent and MicroNet mesh as the CGuard EPS with a differentiated deployment mechanism. CGuard Prime received premarket approval ("PMA") by the U.S. Food and Drug Administration ("FDA") on June 23, 2025, and is marketed exclusively in the United States through our direct salesforce. It also received MDR CE Mark approval on June 12, 2025.

In October 2024, the FDA approved the Company's IDE to initiate the CGUARDIANS II pivotal study of its CGuard Prime 80 cm carotid stent system during transcarotid revascularization ("TCAR") procedures. In the first quarter of 2026, we completed enrollment in the CGUARDIANS II pivotal study.

In October 2023, the Centers for Medicare & Medicaid Services ("CMS") issued its final National Coverage Determination ("NCD"), expanding coverage for both carotid artery stenting ("CAS") and TCAR procedures to include both asymptomatic and standard risk patients, significantly expanding and supporting the future growth of the U.S. addressable market for CAS.

In November 2025, the results of the CREST-2 study were released, which showed that CAS combined with medical therapy demonstrated a significantly lower stroke risk as compared to intensive medical management alone in patients with severe asymptomatic carotid stenosis. CREST-2 was an independent study sponsored by the National Institute of Health (NIH) with a set of two parallel, observer-blinded clinical trials across 155 centers globally. CREST-2 showed that, among patients with high-grade carotid stenosis without recent neurological symptoms, the addition of stenting led to significantly better outcomes than intensive medical management alone, as measured by a decreased risk of the composite of perioperative stroke or death or ipsilateral stroke within four years. In a separate arm of the same trial, carotid endarterectomy ("CEA") did not achieve a significant benefit for these patients as compared to intensive medical management alone.

We continue to invest in new product generations and potential new clinical indications for the CGuard platform with a strategy of focusing on advancing a "stent-first" approach to carotid revascularization. As part of this strategy, we are evaluating CGuard Prime in TCAR-based clinical programs, including the CGUARDIANS II pivotal trial, which studies the use of the CGuard Prime 80 cm carotid stent system in conjunction with an established neuroprotection device, and the CGUARDIANS III pivotal trial, which evaluates our proprietary SwitchGuard neuroprotection system ("SwitchGuard NPS") paired with CGuard Prime to enable flow-reversal neuroprotection during TCAR. In parallel, we are pursuing new clinical applications outside TCAR, including the treatment of acute ischemic stroke with tandem lesions, which is currently being studied in an early feasibility study conducted with the Jacobs Institute. In this acute-stroke setting, the flexible, low-metal-burden design and MicroNet mesh of CGuard Prime may offer advantages where traditional embolic-protection devices cannot be used.

We consider our current addressable market for our CGuard EPS, CGuard Prime, and SwitchGuard NPS to be both symptomatic and asymptomatic individuals with diagnosed high-grade carotid artery stenosis for whom intervention is preferable to medical (drug) therapy. This group includes not only patients eligible for either CAS or TCAR procedures, but also individuals who are candidates for CEA, as all three approaches can be options to treat these patients. Assuming full penetration of the intervention caseload, we estimate that the addressable market for CGuard EPS, CGuard Prime, and SwitchGuard NPS is approximately $1.3 billion (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 treatment for all individuals diagnosed with high-grade carotid artery stenosis, we estimate the total available market for CGuard EPS, CGuard Prime, and SwitchGuard NPS to be approximately $9.3 billion, which may grow over time if expanded treatment options such as our products lead to increased patient screening for carotid artery disease.

We were organized in the State of Delaware on February 29, 2008. In October 2024, we established our global headquarters in Miami, Florida to support the U.S. launch and commercialization of CGuard Prime.

Business Strategy

Our business strategy is focused on establishing the CGuard carotid stent system as global leader in carotid revascularization. Our business strategy includes:

- ***Drive adoption of a stent-first approach*****:** We are strategically aligned with the ongoing shift from CEA to CAS and TCAR (stenting). Clinical data, including results from the C-GUARDIANS pivotal trial and outcomes from CREST-2, support the safety and efficacy of carotid stents and reinforce clinical evidence and outcomes of carotid stents for stroke prevention. With FDA PMA approval of CGuard Prime received in June 2025 and U.S. commercial launch in July 2025, we are positioned to capitalize to lead this market shift with expanded reimbursement coverage and growing procedural volumes.

- ***Leverage clinical differentiation*****:** Our proprietary MicroNet mesh technology is designed to reduce plaque prolapse and embolic events, delivering strong periprocedural and long-term outcomes. Across multiple clinical trials and real-world studies, CGuard has demonstrated the lowest 30-day and one-year composite adverse event rates compared to historical carotid stent data. We intend to continue generating and publishing clinical evidence to support broader adoption, guideline inclusion, and physician confidence.

- ***Expand U.S. commercial infrastructure*****:** A core priority is building a high-performing U.S. commercial organization to accelerate penetration of the approximately 155,000 annual carotid procedures performed in the United States. We are expanding our U.S. direct sales force with experienced CAS and neurovascular specialists, leveraging claims data to identify high-opportunity accounts, and identifying centers with trained TCAR physicians for engagement following anticipated label expansion of CGuard Prime to include TCAR. Our objective is to drive consistent utilization growth and increase market share of CGuard Prime in both CAS and TCAR procedures.

- ***Broaden product portfolio***: We are advancing a broader carotid and neurovascular platform strategy, including development of SwitchGuard neuroprotection technology and additional indications for CGuard Prime, such as TCAR and acute stroke with tandem lesions. By offering a comprehensive procedural toolkit, we aim to deepen relationships with physicians and participate more fully across the carotid intervention continuum.

- ***Grow international presence***: We currently commercialize CGuard in more than 30 countries and maintain meaningful market share outside the United States. Following U.S. approval, we are exploring further expansion into Asia, including potential opportunities in Taiwan, Japan, and South Korea, while continuing to strengthen distribution partnerships and regulatory registrations globally.

- ***Protect and extend intellectual property***: Our MicroNet platform is supported by a robust and growing intellectual property portfolio. We intend to continue strengthening our patent position globally to protect our technology and enable future product pipeline expansion. Operationally, we are scaling manufacturing, quality systems, and corporate infrastructure to support sustained revenue growth and a path toward profitability.

Our Industry

Carotid Arteries

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 significant causes of stroke. According to the World Health Organization, 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, three 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 received intervention, according to a September 2021 report from Health Research International Personal Medical Systems, Inc. entitled *Update Report on Global Carotid Stenting Procedures and Markets by Major Geography and Addressable Markets*.

There are three current interventional treatments used to treat carotid artery disease. The first is CEA, in which a surgeon accesses the blocked carotid artery though an incision in the neck and then surgically removes the plaque. The second treatment is TCAR, a minimally invasive procedure in which a surgeon places a stent in the blocked carotid artery though a small incision in the neck while temporarily reversing blood flow to protect the brain from stroke during the procedure. The third treatment is CAS, a minimally invasive procedure in which a surgeon places a stent in the blocked carotid artery through access of the femoral, radial, or brachial arteries. We believe that the availability of minimally invasive treatment options like TCAR and CAS should increase the number of patients being treated since they avoid the need for complex surgery.

Our Products

MicroNet Mesh Platform Technology

MicroNet is our proprietary biocompatible polymer mesh material woven from a single strand of 23 μm polyethylene terephthalate ("PET"), a material widely used in medical implants. We apply the sleeve to our proprietary self-expanding stent to provide additional protection to patients from plaque prolapse and embolization following deployment of the stent in the patient's artery. The size, or aperture, of the MicroNet "pore" is only 150-180 microns, designed to maximize protection against the release of potentially dangerous plaque and thrombus by significantly limiting the size of any embolic debris that can dislodge from the diseased carotid artery and pass through the MicroNet mesh. The MicroNet mesh is the core technology around which we have developed our proprietary CGuard carotid stent technology.

CGuard EPS – Carotid Artery Applications

Our CGuard EPS combines our MicroNet mesh and a self- expanding 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 the outside of an open cell nitinol stent, forming a highly flexible implant that conforms to the carotid anatomy 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, non-mesh covered carotid stents.

We believe that our CGuard EPS design provides advantages over existing therapies in treating carotid artery stenosis, such as conventional carotid stenting and surgical CEA, given the superior embolic prevention characteristics provided by the MicroNet. We believe the MicroNet provides acute embolic protection at the time of the procedure, but more importantly, provides post-procedure protection against embolic dislodgement. According to an article published in the Journal of American College of Cardiology Cardiovascular Interventions entitled *Late cerebral embolization after emboli-protected carotid artery stenting assessed by sequential diffusion-weighted magnetic resonance imaging,* it is in this post-procedure time frame that embolization is the source of post-procedural strokes in the brain, which have shown that the majority of the incidents of embolic showers associated with carotid stenting occur post-procedure.

Our CGuard EPS originally 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 over 30 countries through a network of distributors. In January 2024, we received CE mark recertification under the EU's MDR regulatory framework.

CGuard Prime Stent System

Our CGuard Prime also combines our MicroNet mesh and a self-expanding nitinol stent, but with a differentiated deployment system as compared to the CGuard EPS. The CGuard Prime Carotid Stent is available in diameters ranging from 6mm 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. In the U.S., PMA approval was received for stent sizes in 8-, 9- and 10-mm diameters with lengths of 30 and 40 mm.

CGuard Prime advances the first generation CGuard transfemoral delivery system with a new handle design for ease of deployment and a new catheter design for more flexible navigation of tortuous anatomy. The CGuard Prime product was used in 32 patients out of 316 patients in the C-GUARDIANS study, since April 2023. In October 2024, the FDA approved the Company's IDE to initiate the CGUARDIANS II study of its CGuard Prime 80 cm carotid stent system for use in TCAR procedures. In the first quarter of 2026, we completed enrollment in the CGUARDIANS II pivotal study.

On June 23, 2025, the FDA approved our PMA for CGuard Prime. The approval was supported by data from our C-GUARDIANS pivotal trial, a prospective multicenter study that enrolled 316 patients in the U.S. and Europe . The trial demonstrated low rates of death, stroke, and myocardial infarction at 30 days (0.95%) and low rates of 30-day DSMI or ipsilateral stroke through one year (1.93%). For additional information, see "Item 1 – Business – Completed Clinical Trials for CGuard EPS – C-GUARDIANS."

On June 12, 2025, CGuard Prime stent system received MDR CE Mark approval.

SwitchGuard NPS

SwitchGuard NPS is a Class II neuroprotection system ("NPS") that we have developed and that is subject to regulatory approval, composed of medical grade tubing with male Luer lock connectors at each end and an in-line 200-micron blood filter. When connected to the included arterial and venous sheaths, the system 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.

SwitchGuard NPS is being developed to provide flow reversal for cerebral protection in carotid interventions utilizing the TCAR procedure 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.

We submitted an IDE to the FDA for the C-GUARDIANS III clinical trial in December 2024, which was approved in June 2025. This approval allows us to initiate a clinical trial to support the clearance of the SwitchGuard NPS coupled with CGuard Prime.

Acute Stroke with Tandem Lesions

It is estimated that 20-30% of acute ischemic strokes that are caused by large vessel occlusion involve tandem lesions- high grade stenosis/occlusion of the internal carotid artery plus thrombotic occlusion of an intracranial vessel. Currently there is no indicated use of CAS for these lesions during stroke treatment when the placement of an embolic protection device is not possible. We believe CGuard Prime is optimally suited for intervention in this acute setting by its design (flexible / low metal structure) as well as MicroNet mesh offering embolic protection both during and post procedure. Our goal is to develop CGuard Prime to mitigate strokes in this acute setting.

In November 2023, we announced a strategic agreement with Jacobs Institute to execute an early feasibility study of CGuard Prime for the treatment of acute stroke patients with tandem lesions. The study is expected to enroll 15 acute stroke patients across three U.S. sites to explore the safety and feasibility of using CGuard Prime in this setting.

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 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 within five 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 velocity) 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; and
- 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%; and
- 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-500 (**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-500) is an investigator-initiated, single center study designed to evaluate the outcomes of routine CGuard EPS in consecutive all-comer patients accepted by a multidisciplinary committee for carotid revascularisation. The PARADIGM-500 study is an extension of the PARADIGM-101 study, which was initiated in 2015.

An update of the PARADIGM-500 study was presented at the Veith 2024 conference in New York, held from November 19-23, 2024. Key findings were:

- 30-day death or stroke rate of 0.75%;
- 30-day death, stroke and myocardial infarction (DSMI) rate of 0.94%;
- 12-month freedom from ipsilateral stroke, in stent restenosis (ISR) and target lesion revascularization (TLR) combined rate of 99.6%;
- At 12-month, the ISR rate (by Core Lab) is lower than those reported in the literature of first-generation stents (Naylor R, et al. European Society for Vascular Surgery (ESVS) 2023 Clinical Practice Guidelines on the Management of Atherosclerotic Carotid and Vertebral Artery Disease. Eur J Vasc Endovasc Surg. 2023);and
- No cases of stent thrombosis (0%) with CGuard EPS through 12 months of follow up

The Paradigm-500 study confirms that CAS with the CGuard EPS stent delivers reliable and low rates of 30-day composite DSMI, 12-month ipsilateral stroke, ISR and no instances of stent thrombosis in a wide range of patients at standard and high risk for CEA.

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 were 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 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 Carotid 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 were 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;and
- 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-month, there were no new major neurological adverse events, thrombosis or external carotid occlusion recorded; and
- 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 EPS. 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 were 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 were 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^{TM}. 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 use of CGuard EPS 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^{TM}, versus the MicroNet-Covered Stent, CGuard.

Key findings from the study were 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; and

- 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).

C-GUARDIANS

C-GUARDIANS was a 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 study completed enrollment in June 2023. The primary endpoint was a composite of: (1) incidence of major adverse events including Death (all-cause mortality), any Stroke, and Myocardial Infarction (DSMI) through 30-days post index procedure, or (2) ipsilateral stroke from day 31 to day 365 post-procedure. All events were adjudicated by an independent clinical events committee. The composite index was compared to a performance goal based on the observed rate of the two components of the primary endpoint from previous pivotal stent trials which were considered industry standard. The performance goal was 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.

From July 2021 to June 2023, 316 patients were prospectively enrolled at 24 sites in the US and the EU and from April 2023 included deployment of the CGuard stent using CGuard Prime. All CAS procedures were performed utilizing the CGuard MicroNet mesh covered stent and cleared intra-procedural cerebral protection distal embolic filters or proximal embolic protection with flow cessation, or both. At 30 days, the hierarchical DSMI rate was 0.95% in the intent to treat (ITT) analysis and 0.63% in the per- protocol (PP) analysis. Three patients experienced major adverse cardiovascular events by 30-days: one patient who did not take dual antiplatelet therapy (protocol violation) had a major stroke and died and two other patients had a stroke. There was no myocardial infarction (MI). These results support a potential “neuroprotective” effect of the CGuard stent from the procedure to 30 days follow-up.

On May 28, 2024, we announced positive one-year follow up results from the C-GUARDIANS trial of the CGuard carotid stent system in which stenting with the CGuard carotid stent system in patients with carotid artery stenosis and at high risk for CEA had a 30-day DSMI and Ipsilateral stroke between 31 and 365 days rate of 1.95%, measured from procedure to 1-year follow-up in the ITT analysis, using Kaplan-Meier method. The primary endpoint rate was 1.71% in the per-protocol population.

On June 23, 2025, the FDA granted PMA approval of CGuard Prime in the U.S. with the following indication for use:

- CGuard Prime, when used in conjunction with embolic protection devices specified in the labeling, is indicated for improving carotid luminal diameter in patients at high risk for adverse events from carotid endarterectomy who require carotid revascularization and meet both criteria outlined below:

    - Patients with neurological symptoms and ≥50% stenosis of the common or internal carotid artery by angiogram, or
    - patients without neurological symptoms and ≥80% stenosis of the common or internal carotid artery by angiogram;

- Patients having a vessel with reference diameters between 6.4 mm and 9.0 mm at the target lesion.

On-going and Planned Clinical Trials

C-GUARDIANS Post-Market Approval Study

The C-GUARDIANS Post-Market Approval Study was a condition of PMA approval for CGuard Prime in the U.S. The C-GUARDIANS Post-Market Approval Study is a prospective, multicenter follow-up of the C-GUARDIANS pivotal study. It will evaluate the long-term safety and effectiveness of CGuard Prime. All 303 remaining subjects active at the end of the 12-month evaluation will continue to be followed annually through 36 months.

Early Feasibility Study of CGuard EPS for Acute Stroke Patients with Tandem Lesions

In November 2023, we announced the entry into a strategic agreement with the Jacobs Institute at the State University of New York at Buffalo to execute an early feasibility study of CGuard carotid stent system for the treatment of acute stroke patients with tandem lesions. The study, a prospective, single-arm, open label, non-blinded study is expected to enroll 15 acute stroke patients across three U.S. sites to assess the safety and feasibility of using CGuard carotid stent system to treat acute ischemic stroke patients with tandem lesions. of Dr. Adnan Siddiqui, Vice-Chairman and Professor of Neurosurgery at the State University of New York at Buffalo, CEO of the Jacobs Institute, is the Principal Investigator for the study. The trial began enrolling in the first quarter of 2025.

C-GUARDIANS II for TCAR procedures

On October 3, 2024, the FDA approved our IDE for CGUARDIANS II, a multicenter, single-arm, pivotal study to evaluate the safety and efficacy of the CGuard Prime 80 cm carotid stent system used in conjunction with the ENROUTE NPS during TCAR procedures. Patrick Geraghty, M.D., professor of surgery and radiology, section of vascular surgery at Washington University School of Medicine in St. Louis, MO, and Patrick Muck, M.D., program director and chief of vascular surgery at Good Samaritan Hospital in Cincinnati, OH, are lead principal investigators for the trial. In the first quarter of 2026, we completed enrollment of 50 patients in our CGUARDIANS II pivotal study.

C-GUARDIANS III for TCAR procedures using SwitchGuard NPS

The SwitchGuard NPS is designed to allow the treating physician to reverse cerebral blood flow during a TCAR procedure. SwitchGuard is intended to prevent embolic debris generated during the procedure from traveling to the brain, passing the blood through the filter before returning it to the patient to minimize blood loss.

On December 30, 2024, we submitted an IDE to the FDA for CGUARDIANS III, a multicenter, single-arm, pivotal study to evaluate the safety and efficacy of the SwitchGuard NPS used in conjunction with the CGuard Prime 80 cm carotid stent system for providing cerebral embolic protection during carotid artery stenting via the TCAR procedure. The IDE submission was approved on June 6, 2025 by the FDA. The C-GUARDIANS III study is expected to begin enrollment of patients during the second quarter of 2026.

Growth Strategy

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

- **Increase penetration of CGuard EPS and CGuard Prime in existing markets, particularly the United States**. Our proprietary MicroNet mesh technology is designed to reduce plaque prolapse and embolic events which we believe differentiates CGuard EPS and CGuard Prime to deliver strong periprocedural and long-term outcomes. Our CGuard carotid stent system has demonstrated the lowest 30-day and one-year composite adverse event rates compared to historical carotid stent data for competing products. We believe that these attributes provide a significant opportunity for us to gain market share in existing markets where we compete. In our most well-established markets, we believe we have achieved market share of at least 25%, while in markets we have more recently entered, such as the U.S., our market share is much lower. We believe that, through physician education about the superior attributes and safety outcomes of our products, we can expand awareness and utilization of our products in all markets, particularly the U.S. The potential for increased market penetration will provide us significant opportunity for growth.

- **Drive adoption of a stent-first approach**. Our long-term objective is to build a sustained clinical ecosystem by cultivating a global network of scientific and clinical advisors, supporting multi-year registries and multi-national clinical collaborations and participating in strategic alliances in stroke prevention and vascular innovation.

- **Broaden product portfolio.** We plan to expand the MicroNet platform with next-generation delivery system architectures designed to enable additional access routes, improved ease of use across physician specialties and support for future accessory devices and multi-procedural workflows.

- **Protect and extend intellectual property and leverage clinical differentiation.** In addition to the applications described above, we believe that we will eventually be able to utilize our proprietary MicroNet technology to address market needs for new product innovations to significantly improve patient 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 plan to pursue long-term strategic collaborations focused on technology development and integration, clinical research expansion and global market access enablement.

- **Expand U.S. commercial infrastructure.** We are seeking to expand U.S. direct sales force with experienced CAS and neurovascular specialists, leveraging claims data to identify high-opportunity accounts, and identifying centers with trained TCAR physicians as we aim to drive consistent utilization growth and increase market share of CGuard Prime in both CAS and TCAR procedures.

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.

With respect to competition for our carotid embolic prevention systems, CGuard EPS and CGuard Prime, the manufacturers of products used in connection with carotid stenting procedures include a number of large companies, such as Abbott Laboratories, Boston Scientific Corporation, Medtronic, Cordis Corporation and Terumo Medical Corporation.

Many of these competitors 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 and relationships with our target customers and worldwide distribution methods that are more extensive than ours.

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

- Strength of clinical evidence- patient outcomes and adverse event rates
- Scale and effectiveness of commercialization efforts/organizations
- Acceptance by treating physicians and referral sources
- Physician learning curve
- Ease-of-use and reliability
- Economic benefits and cost savings
- Availability of reimbursement
- Patient experience

Sales and Marketing

Sales and Marketing

In October 2024, we established our global headquarters in Miami, Florida to support the anticipated U.S. launch and commercialization of CGuard Prime. Since that time, we have continued building the infrastructure for commercial operations in the U.S. to support the commercialization of CGuard Prime.

We are designing our commercial strategy and expanding our direct sales force to drive adoption of CGuard Prime among U.S. interventionalists. In parallel, we aim to support the transition from CEA to CAS and TCAR, leveraging CGuard Prime 80 cm for TCAR procedures and accessory devices, including our SwitchGuard neuroprotection system. We plan to continue to focus our marketing efforts on key growth markets and to evaluate opportunities in new territories as they become available. In addition, we are using international medical conferences to gain market exposure and brand recognition. We continue to work with leading physicians to enhance our marketing efforts and are developing relationships with new key opinion leaders to champion our technology and participate in clinical studies.

In the United States, we market and sell CGuard Prime through a direct sales organization consisting of approximately 30 sales and clinical support personnel, as of February 2, 2026. Our sales professionals have substantial experience launching and establishing new disruptive therapies and converting open surgical procedures to minimally-invasive alternatives. We are continuing to expand our commercial and distribution capabilities to support the commercialization of CGuard Prime.

Previously, 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 have focused 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.

Product Positioning

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

We continue to invest in new product generations and potential new clinical indications for the CGuard platform with a strategy of focusing on advancing a “stent-first” approach to carotid revascularization. As part of this strategy, we are evaluating CGuard Prime in TCAR-based clinical programs, including the CGUARDIANS II pivotal trial, which studies the use of the CGuard Prime 80 cm carotid stent system in conjunction with an established neuroprotection device, and the CGUARDIANS III pivotal trial, which evaluates our proprietary SwitchGuard NPS paired with CGuard Prime to enable flow-reversal neuroprotection during TCAR. In parallel, we are pursuing new clinical applications outside TCAR, including the treatment of acute ischemic stroke with tandem lesions, which is currently being studied in an early feasibility study conducted with the Jacobs Institute. In this acute-stroke setting, the flexible, low-metal-burden design and MicroNet mesh of CGuard Prime may offer advantages where traditional embolic-protection devices cannot be used. We believe this strategy may allow us to increase penetration in our existing geographies and better position us for entry into new markets.

Insurance Reimbursement

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.

In October 2023, CMS issued its final National Coverage Determination (“NCD”), expanding coverage of both CAS and TCAR to include both asymptomatic and standard risk patients, significantly expanding the U.S. addressable market.

Intellectual Property

Patents

We have 71 issued patents, including 20 patents issued in the U.S., and 27 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 (a predecessor product) technology. Patents outside the U.S. have been filed in Canada, China, Europe, Israel, India, Japan, Australia, South Africa, and Hong Kong. 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		USA	8,961,586	24-Feb-2015
		China	ZL 20078046676.2	26-Sep-2012
Deformable tip for stent delivery and methods of use		USA	10,258,491	16-Apr-2019
		Israel	260,945	01-Jul-2020
Handle for Two-Stage Deployment of a Stent	China			
	Japan			
	India	USA	11,839,561	12-Dec-2023
	USA	Europe	EP4032509	18-Feb-2026
Shunts with Blood-Flow Indicators		USA	11,844,893	19-Dec-2023
	Europe	China	ZL 2022800089963	26-Nov-2024
	India	Japan	7449627	06-Mar-2024
	USA	Hong Kong	HK40100855	14-Mar-2025
	China	Japan DIV	7794484	22-Dec-2025
Device for Shunting Blood Between the Arterial and Venous Systems		USA	12,070,542	27-Aug-2024
		China	ZL 2022800098002	10-Sep-2024
		Japan	7576884	24-Oct-2024
		Unitary Patent	EP4313255	13/Aug/2025
		Ireland	EP4313255	13/Aug/2025
	India	UK	EP4313255	13/Aug/2025
	USA (CON)	Spain	EP4313255	13/Aug/2025
	China (DIV)	Switzerland	EP4313255	13/Aug/2025
	Japan (DIV)	Hong Kong	HK40096715	21/Feb/2025
Devices for shunting blood	USA			
	China			
	Europe			
	India			
	Japan			
In Vivo Filter Assembly		USA	9,132,261	15-Sep-2015
Knitted Stent Jackets		USA	10,137,015	27-Nov-2018
		China	ZL200780046697.4	10-Oct-2012
		India	323792	28-Oct-2019
		Canada	2666728	23-Jun-2015
		China	ZL201210320950.3	02-Dec-2015
		Canada	2887189	01-May-2018
		Germany	EP2076212	29-Mar-2017
		France	EP2076212	29-Mar-2017
		UK	EP2076212	29-Mar-2017

Optimized stent jacket		USA	10,070,976	11-Sep-2018
		Canada	2670724	11-Dec-2018
		China	ZL20078043259.2	02-Jan-2013
		India	297257	30-May-2018
		China	ZL201210454357.8	09-Dec-2015
		USA	9,132,003	15-Sep-2015
		USA	9,782,281	10-Oct-2017
		USA	9,526,644	27-Dec-2016
		USA	10,406,006	10-Sep-2019
		Israel	230,922	01-Oct-2020
		USA	10,406,008	10-Sep-2019
		USA	11,051,959	06-Jul-2021
		Canada	3,013,758	14-Sep-2021
		Belgium	EP2088962	11-Oct-2017
		Switzerland	EP2088962	11-Oct-2017
		Germany	EP2088962	11-Oct-2017
		France	EP2088962	11-Oct-2017
		UK	EP2088962	11-Oct-2017
		Italy	EP2088962	11-Oct-2017
		Ireland	EP2088962	11-Oct-2017
		Luxembourg	EP2088962	11-Oct-2017
		Netherlands	EP2088962	11-Oct-2017
		Europe	EP3292837	09-Nov-2022
		UK	EP3292837	09-Nov-2022
		Germany	EP3292837	09-Nov-2022
		France	EP3292837	09-Nov-2022
		Ireland	EP3292837	09-Nov-2022
Stent apparatus for treatment via body lumens and methods of use	Europe (Div)	Canada	2609687	22-Apr-2014
	Europe	South Africa	2007/10751	27-Oct-2010
	China	USA	10,070,977	11-Sep-2018
	USA	Canada	2843097	27-Oct-2015
		USA	10,058,440	28-Aug-2018
		USA	10,932,926	02-Mar-2021
		Germany	EP1885281	13-Feb-2019
		France	EP1885281	13-Feb-2019
		UK	EP1885281	13-Feb-2019
		Ireland	EP1885281	13-Feb-2019
		Italy	EP1885281	13-Feb-2019
		Switzerland	EP1885281	13-Feb-2019
Stent Thermoforming Apparatus and Methods		USA	9,527,234	27-Dec-2016
		USA	10,376,393	13-Aug-2019
		Japan	6553178	12-Jul-2019
Methods of using a self-adjusting stent assembly and kits including same		USA	11,684,498	27-Jun-2023
		China	ZL 2019800679437	03-May-2022
		China DIV	ZL 202210380047X	27-Feb 2026
Intravascular sheath	USA (UTI)			
	PCT			

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, EP and CN)
- SmartFit Logo (EP, UK, CN)
- CGuard Prime (EP, UK, US, CN, JP)
- SwitchGuard (EP, UK, US, JP)
- True North Medical (EP, UK)
- MicroMesh logo (EP, UK)
- Micronet logo (updated version) (US, EP, UK, 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

Our products and operations are subject to extensive regulation in the United States, the European Union, and other international markets in which we conduct business.

United States

Medical devices distributed in the United States are regulated by the FDA. On June 24, 2025, the FDA granted Premarket Approval (PMA) for CGuard Prime, authorizing commercial distribution in the United States. We began initial U.S. commercialization in July 2025, following receipt of PMA approval and the establishment of our direct sales organization.

Following approval, our U.S. operations remain subject to ongoing FDA regulatory requirements. These include compliance with the Quality System Regulation (21 CFR Part 820), labeling and promotional requirements, Medical Device Reporting obligations (21 CFR Part 803), reporting of corrections and removals (21 CFR Part 806), and any post-market surveillance activities required by the FDA. Our ability to expand U.S. sales depends on continued compliance with these regulatory obligations.

European Union and Other International Markets

Outside the United States, the sale of medical devices is regulated by foreign authorities whose requirements vary by country.

In order to sell our products in member countries of the European Economic Area, or EEA, our products must comply with the requirements of Regulation (EU) 2017/745 on medical devices (Medical Device Regulation – MDR). Compliance with these requirements is a prerequisite to be able to affix the CE mark to our products, without which they cannot be sold or marketed in the EEA. To demonstrate compliance, we must undergo a conformity assessment procedure, which varies according to the type of medical device and its classification. Except for low-risk medical devices (Class I), where the manufacturer can generally issue a EU Declaration of Conformity based on a self-assessment of the conformity of its products with the requirements of the MDR, a conformity assessment procedure requires the involvement of an organization designated by a member state of the EEA to carry out conformity assessments, called a Notified Body. Depending on the relevant conformity assessment procedure, the Notified Body would typically audit and examine the technical documentation and the quality management system for the life cycle of our devices regarding their safety and performance. The Notified Body may require the application to be completed by having further tests carried out or requesting further evidence to be provided to allow assessment of conformity with the relevant requirements of the MDR. The Notified Body issues certificates of conformity following successful completion of a conformity assessment procedure conducted in relation to the medical device and its manufacturer and their conformity with the requirements of the MDR. These certificates entitle the manufacturer to affix the CE mark to its medical devices after having prepared and signed a related EU Declaration of Conformity.

In January 2024, we received CE Mark recertification for CGuard EPS under the MDR. Our CGuard EPS previously held CE Mark approval under the former Medical Device Directive (MDD), which was replaced by the MDR on May 26, 2021. On June 12, 2025, we received CE Mark approval under the EU's MDR for the CGuard Prime Embolic Prevention System.

In the EU, the General Data Protection Regulation (EU) 2016/679 (GDPR), effective since May 2018, imposes comprehensive data protection requirements, including strict rules on international data transfers, enhanced individual rights, and significant penalties for non-compliance. The GDPR is supplemented by national laws and guidance from the European Data Protection Board.

We have obtained regulatory approvals for, and commercialized, CGuard EPS in multiple countries outside the United States, primarily through distributors. These international markets represented the majority of our revenues in 2025. Although certain countries accept CE Mark approval as the primary requirement for marketing authorization, others require additional regulatory steps, reimbursement approvals, or local registrations before commercial sale. Review timelines and reimbursement frameworks vary significantly by jurisdiction and may affect the pace and extent of market access.

FDA Government Regulation of Medical Devices for Human Subjects

Many of our activities are subject to regulatory requirements by the FDA under provisions of the Federal Food, Drug, and Cosmetic Act and regulations and guidance thereunder, including requirements governing the development, marketing, labeling, promotional efforts, manufacturing, and exporting 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 is marketed in the United States must receive either 510(k) clearance or PMA approval. Medical devices that are class II devices generally 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.

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 generally required to file a Premarket review, known as a 510(k) application, that may also require General Controls, and any other special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. Generally, the 510(k) submission is generally considered "substantially equivalent to a previously marketed device. 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.

Class III devices generally are more complex devices or new devices where there is no substantially equivalent device on the market and can have the greatest risk. Devices in this class must demonstrate safety and efficacy requirements and file a premarket filing reviewed by the FDA. In addition, Class III devices cannot generally be marketed until they receive FDA 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 generally require formal clinical studies to demonstrate safety and effectiveness. Under MDUFMA, 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 establishes requirements whether a device must undergo either the 510(k) clearance or premarket approval based on statutory criteria that utilize a risk-based classification system. Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices and, such reviews may also be done for 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, generally by a Class II 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 may 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 no predicate device exists, and FDA will determine which category is appropriate for that device and 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.

Premarket Approval Pathway

The CGuard carotid stent system is classified as a Class III medical device (considered a PMA) by the FDA. Class III medical devices are generally the highest risk devices and are subject to more rigorous regulatory requirements 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 approved the CGuard Prime PMA on June 23, 2025.

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 is safe and effective for its intended use. Before a premarket approval application is submitted, a manufacturer must generally 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 broader human clinical trials.

Part of the PMA process is to ensure that the IDE is the first application that 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.

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.

Following the IDE, a PMA application must be prepared and after a PMA is sufficiently complete, then 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, FDA review of the application generally takes 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 premarket notification to the FDA 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 is established as 180 days for review, however, it 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 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 may also apply to Class I devices.

A noncomprehensive list of the regulatory requirements that apply to our 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.

Advertising and promotion of medical devices, in addition to being regulated by the FDA, are also regulated by the FTC and by state regulatory and enforcement authorities. Recently, promotional activities for FDA-regulated products have been the subject of enforcement action brought under health care reimbursement laws and consumer protection statutes. Competitors and others can also initiate litigation relating to advertising claims under the federal Lanham Act and similar state laws. In general, if the FDA determines that our promotional materials or training constitutes promotion of an unapproved or uncleared use, then it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions. It is also possible that other federal, state, or foreign enforcement authorities might take action if they consider our promotional or training materials to constitute promotion of an unapproved or uncleared use, which could result in significant fines or penalties under other statutory authorities, such as laws prohibiting false claims for reimbursement.

At this time, we have one commercially approved medical device in the U.S., and we have filed for an Establishment Registration 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. In addition, our manufacturing facilities are subject to FDA inspections for compliance with the FDA's Quality System Regulation. Additionally, some of our subcontractors are also subject to FDA announced and unannounced inspections for compliance with the FDA's Quality System Regulation and assurances that the Company is marketing appropriately the indications for use of the product. These regulations require that we manufacture our products and maintain our documents in a prescribed manner with respect to design, manufacturing, testing and quality control activities and ensure that marketing materials and promotion are in compliance. As a medical device manufacturer, we are 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.

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

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

Many states require medical device manufacturers, distributors, and retailers to obtain a license, permit or certification to manufacture, distribute, or sell a medical device. Additionally, many states also require that medical device manufacturers, distributors, and retailers comply with manufacturing, labeling, packaging, sterilizing, distributing, and retailing requirements that are greater than those of the FDA. Failure by us or our manufacturing partners to comply with these licensing and regulatory requirements could have an adverse effect on our business.

Coverage and Reimbursement

There are many reimbursement programs through private payors as well as government programs. In some countries, government reimbursement is the predominant program available to patients and hospitals. Our commercial success depends in part on the extent to which governmental authorities, private health insurers and other third-party payors provide coverage for and establish adequate reimbursement levels for the procedures during which our products are used. Failure by physicians, hospitals, ambulatory surgery centers and other users of our products to obtain sufficient coverage and reimbursement from third-party payors for our products, or adverse changes in government and private third-party payors' coverage and reimbursement policies could materially adversely affect our business, financial condition, results of operations and prospects.

Some payors are moving toward a managed care system and control their health care costs by limiting authorizations for surgical procedures, including procedures using our devices. Although no uniform policy of coverage and reimbursement among payors in the United States exists and coverage and reimbursement for procedures can differ significantly from payor to payor, reimbursement decisions by particular third-party payors may depend upon a number of factors, including the payor's determination that use of a product is:

- a covered benefit under its health plan;
- appropriate and medically necessary for the specific indication;
- cost effective; and
- neither experimental nor investigational.

Third-party payors are increasingly auditing and challenging the prices charged for medical products and services with concern for upcoding, miscoding, using inappropriate modifiers, or billing for inappropriate care settings. Some third-party payors must approve coverage for new or innovative devices or procedures before they will reimburse health care providers who use the products or therapies. Even though a new product may have been cleared for commercial distribution by the FDA, we may find limited demand for the product unless and until reimbursement approval has been obtained from governmental and private third-party payors.

A key component in ensuring whether the appropriate payment amount is received for physician and other services, including those procedures using our products, is the existence of a common procedural terminology code, or CPT code, to describe the procedure in which the product is used. To receive payment, health care practitioners must submit claims to insurers using these codes for payment for medical services. CPT codes are assigned, maintained and annually updated by the American Medical Association and its CPT Editorial Board. If the CPT codes that apply to the procedures performed using our products are changed or deleted, reimbursement for performances of these procedures may be adversely affected.

In the United States, some insured individuals enroll in managed care programs, which monitor and often require pre-approval of the services that a member will receive. Some managed care programs pay their providers on a per capita (or per patient) basis, which puts the providers at financial risk for the services provided to their patients by paying these providers a predetermined payment per member per month and, consequently, may limit the willingness of these providers to use our products.

We believe the overall escalating cost of medical products and services being paid for by the government and private health insurance has led to, and will continue to lead to, increased pressures on the health care and medical device industry to reduce the costs of products and services. For example, HHS began implementation in 2025 of "Most Favored Nation" drug pricing by setting the Medicare price of single-source brand drugs without generic or biosimilar competition to the lowest price available in wealthy countries with a per capita GDP of at least 60% of that in the United States. All third-party reimbursement programs are developing increasingly sophisticated methods of controlling health care costs through prospective reimbursement and capitation programs, group purchasing, redesign of benefits, requiring second opinions before major surgery, careful review of bills, encouragement of healthier lifestyles and other preventative services and exploration of more cost-effective methods of delivering health care.

In addition to uncertainties surrounding coverage policies, there are periodic changes to reimbursement levels. Third-party payors regularly update reimbursement amounts and also from time to time revise the methodologies used to determine reimbursement amounts. This includes routine updates to payments to physicians, hospitals and ambulatory surgery centers for procedures during which our products are used. For example, CMS issued a national coverage determination on October 11, 2023, finding that Medicare coverage for percutaneous transluminal angioplasty of the carotid artery concurrent with stenting with an FDA-approved or -cleared device to be reasonable and necessary for Medicare reimbursement. These and other updates could directly impact the demand for our products.

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 and Medicaid Services (CMS), the Department of Justice (DOJ), in addition to other governmental reviews. 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 potential enforcement by CMS, 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;

- The federal Physician Self-Referral Law or "Stark" law prohibits a physician (defined to include a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor) from referring Medicare and Medicaid patients to certain types of entities with which the physician or any of the physician's immediate family members have a financial relationship, unless an exception to the law's prohibition is met;

- 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;

- 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 ("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, as well as state transparency 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.

Penalties for violation of any of the health care laws described above or any other governmental regulations that apply to us include, without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of an entity's operations.

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

Privacy and Security of Health Information

Various federal and state laws protect the privacy and security of health information. For example, HIPAA protects the privacy and security of individually identifiable health information by limiting its use and disclosure. Many states have implemented similar laws to limit the use and disclosure of patient specific health information.

The HIPAA transaction regulations establish form, format and data content requirements for most electronic healthcare transactions, such as healthcare claims that are submitted electronically. The HIPAA privacy regulations establish comprehensive requirements relating to the use and disclosure of protected health information or PHI. The HIPAA security regulations establish minimum standards for the protection of PHI that is stored or transmitted electronically. The HIPAA breach notification regulations establish the applicable requirements for notifying individuals, the HHS, and the media in the event of a data breach affecting protected health information. Violations of the privacy, security and breach notification regulations are punishable by civil and criminal penalties.

The American Recovery and Economic Reinvestment Act of 2009, or ARRA, increased the amount of civil monetary penalties that can be imposed for violations of HIPAA, and the amounts are updated annually for inflation. For 2026, penalties for HIPAA violations can range from $145 to $2,190,294 per violation with a maximum fine of $2,190,294 for identical violations during a calendar year. ARRA also authorized state attorneys general to bring civil enforcement actions under HIPAA, and attorney generals are actively engaged in enforcement. These penalties could be in addition to other penalties assessed by a state for a breach which would be considered reportable under the state's data breach notification laws.

HITECH was enacted in conjunction with ARRA. Among other things, HITECH makes business associates of covered entities directly liable for compliance with certain HIPAA requirements, strengthens the limitations on the use and disclosure of protected health information without individual authorizations, and adopts the additional enhancements, including enforcement of noncompliance with HIPAA due to willful neglect. The changes to HIPAA enacted as part of ARRA reflect a Congressional intent that HIPAA's privacy and security provisions be more strictly enforced. These changes have stimulated increased enforcement activity and enhanced the potential that healthcare providers and their business associates will be subject to financial penalties for violations of HIPAA. In addition, the Secretary of HHS is required to perform periodic audits to ensure covered entities (and their business associates, as that term is defined under HIPAA) comply with the applicable HIPAA requirements, increasing the likelihood that a HIPAA violation will result in an enforcement action.

In addition to the federal HIPAA regulations, the FTC and many states have laws that regulate the collection, storage, use, retention, security, disclosure, transfer and other processing of health information and other confidential, sensitive and personal data. Certain of these laws grant individual rights with respect to their information, and we may be required to expend significant resources to comply with these laws. For example, various states, such as California and Washington, have implemented privacy laws and regulations, such as the California Confidentiality of Medical Information Act, that impose restrictive requirements regulating the use and disclosure of personally identifiable information. These laws in many cases are more restrictive than, and may not be preempted by, the HIPAA rules and may be subject to varying interpretations by courts and government agencies.

Due to the rapidly changing nature of these data privacy laws, there is not always clear guidance from the respective governments and regulators regarding the interpretation of the law, which may create the risk of an inadvertent violation. Efforts to comply with these and other data privacy and security restrictions that may be enacted could require us to modify our data processing practices and policies and to incorporate privacy by design into our products and services, as well as significantly increase the cost of our operations. Failure to comply with such restrictions could subject us to criminal and civil sanctions and other penalties. In part due to the uncertainty of the legal climate, complying with regulations, and any applicable rules or guidance from self-regulatory organizations relating to privacy, data protection, information security, and consumer protection, may result in substantial costs and may necessitate changes to our business practices, which may compromise our growth strategy, adversely affect our ability to attract or retain customers, and otherwise adversely affect our business, financial condition, and operating results.

Health Care Reform

In the United States, there have been and continue to be a number of significant legislative initiatives to contain healthcare costs. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. These laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our drugs, if approved, and, accordingly, our financial operations.

Moreover, recently there has been heightened governmental scrutiny over the way manufacturers set prices for their commercial products. There have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to health care pricing, review the relationship between pricing and manufacturer patient programs, reduce the cost of health care products under Medicare, and reform government program reimbursement methodologies. On August 16, 2022, Congress enacted the Inflation Reduction Act allowing CMS to negotiate directly with drug manufacturers to lower the price of some of the costliest drugs under the Medicare program, as well as requiring drug manufacturers to provide Medicare with a rebate if the price of drugs increases faster than the rate of inflation. In 2025, HHS began implementation of "Most Favored Nation" drug pricing by setting the Medicare price of single-source brand drugs without generic or biosimilar competition to the lowest price available in wealthy countries with a per capita GDP of at least 60% of that in the United States. At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. Although a number of these, and other proposed measures may require authorization through additional legislation to become effective, Congress has indicated that it will continue to seek new legislative measures to control drug costs.

Additionally, CMS issued a final rule, effective on July 9, 2019, that requires direct-to-consumer advertisements of pharmaceutical and biological products, for which payment is available through or under Medicare or Medicaid, to include in the advertisement the Wholesale Acquisition Cost, or list price, of that pharmaceutical or biological product if it is equal to or greater than $35 for a monthly supply or usual course of treatment.

On September 9, 2025, the FDA began requiring pharmaceutical advertisements to include full safety warnings during direct-to-consumer advertisements, instead of footnoting such information. Additionally, the FDA expanded its oversight on social medial promotional activities, including influencer partnerships, algorithm-driven targeted advertising, and AI-generated health content, to ensure compliance with the FDA's advertisement requirements. The FDA has indicated it will begin enforcement actions for any advertisement violations.

Any adopted health reform measure could reduce the ultimate demand for our products, if approved, or put pressure on our product pricing. Individual states in the United States have also become increasingly active in passing legislation and implementing regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. In addition, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what pharmaceutical products and which suppliers will be included in their prescription drug and other healthcare programs. We expect that additional state and federal healthcare reform measures will be adopted in the future.

We expect that additional state and federal healthcare reform measures, as well as legal changes by foreign governments, will be adopted in the future, any of which could limit the amounts that governments will pay for healthcare products and services, which could result in reduced demand for our product candidates or additional pricing pressures.

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, and are in discussions with additional potential partners.

Our distribution agreements 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 other marketing activities, 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.

Since PMA approval in the U.S., our direct sales organization has built and supported a varied customer base of multiple interventional and surgical specialties, to include interventional cardiologists, neurologists, neuroradiologists and radiologists, as well as both vascular and neurosurgeons.

Manufacturing and Suppliers

The polymer fiber used to produce the MicroNet mesh for CGuard EPS and CGuard Prime is supplied by a specialty polymer manufacturer. The mesh is made from PET. During 2022, our supplier notified us of supply constraints related to its existing PET resin source. We subsequently purchased sufficient inventory to support expected production through early 2028 and identified a new PET resin source with equivalent mechanical and biocompatibility properties. Our supplier has produced initial samples using the new PET, and we are initiating the full validation process, which is expected to take up to 18 months.

The supplier of the CGuard EPS delivery system provides the core components that form the base of the delivery system used to deliver and deploy the CGuard EPS stent during carotid artery procedures. Under a 2019 amendment to our agreement, we purchase and maintain inventory of certain components, and the supplier performs the manufacturing process. Our delivery-system supplier for CGuard Prime provides the base delivery systems for the CGuard Prime stent system; this agreement includes non-binding minimum order commitments and may be terminated by us upon nine months' notice.

We currently perform the assembly of both CGuard EPS and CGuard Prime at our facility in Israel. Assembly includes knitting and securing the MicroNet mesh to a self-expanding nitinol stent and crimping the sleeved stent into the delivery system. The bare-metal nitinol stents used in both products are supplied by a third-party manufacturer under a per-unit pricing arrangement. After assembly, the stent systems are sterilized at a third-party facility in Israel and returned to our facility for final packaging and distribution.

To support expected future demand for CGuard Prime in the United States, we have engaged Aptyx Interventional Systems ("Aptyx"), an FDA-registered and ISO 13485-certified contract manufacturer, to transfer the production of finished CGuard Prime devices to their ISO Class 7 cleanroom facility in North Carolina. This transfer includes establishment of production lines, process and sterilization validations, operator training, and qualification builds. We expect this transition to significantly expand our annual production capacity from approximately 20,000 units in 2025 to an estimated 50,000 units by 2027.

We rely on key parts suppliers for major components of CGuard EPS and CGuard Prime, including the self-expanding nitinol stent, the MicroNet mesh sleeve, and the subassemblies that make up the deployment systems for each product. If a supplier becomes unable to provide a critical component, qualifying an alternative supplier may take up to one year depending on component complexity. To maintain CE Mark approval, we conduct periodic audits of key suppliers to ensure compliance with applicable quality-system and performance requirements.

Human Capital Management

As of December 31, 2025, we had 127 full-time employees. Of our 127 total employees, 5 serve as executive management while also functioning as heads of professional departments, and are therefore reflected within the following departmental breakdown: 8 employees in research and development, 17 in quality assurance and compliance, 10 in finance and accounting, 36 in operations/production, 42 in commercial (including sales and marketing), 2 in clinical and 12 in human resources, IT and administration.

Except for 4 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.

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.

Available Information

We maintain a corporate website at http://www.inspiremd.com. The information contained on, or that can be accessed through, our website is neither a part of nor incorporated into this Annual Report on Form 10-K.

Copies of our reports on Forms 10-K, Forms 10-Q and Forms 8-K, may be obtained, free of charge, electronically through our corporate website at http://www.inspiremd.com as soon as reasonably practicable after we file such material electronically with, or furnish to, the SEC. Additionally, the SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC at www.sec.gov.

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;
- 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 Prime Stent System and SwitchGuard NPS 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 products;
- 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 additional products receive FDA approval, 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 neighbors, 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;

- if we fail to maintain compliance with the Nasdaq minimum listing requirements, our common stock will be subject to delisting. Our ability to publicly or privately sell equity securities and the liquidity of our common stock could be adversely affected if our common stock delisted; and

- changes to trade policy, including tariff and customs regulations, or failure to comply with such regulations may have an adverse effect on our reputation, business, financial condition and results of operations.

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 $48.8 million for the fiscal year ended December 31, 2025, and had a net loss of approximately $32.0 million during the fiscal year ended December 31, 2024. As of December 31, 2025, we had an accumulated deficit of $302.3 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, 2025, 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:

- commercialization efforts in the United States following FDA approval of CGuard Prime;
- expansion of manufacturing and operational capabilities, including scaling up production to meet expected demand and establishing necessary infrastructure in the United States;
- development of our current and future products, including potential enhancements to CGuard Prime and advancing SwitchGuard NPS;
- pursuing growth opportunities, such as expanding commercial activities in key international markets and strengthening regional distribution networks;
- growing our U.S. commercial organization, including hiring and retaining qualified personnel to support sales, marketing, and operations;
- responding to competitive pressures and evolving market dynamics, including potential reimbursement challenges and pricing pressures;
- meeting regulatory and compliance obligations, including post-market surveillance, product registrations, and adherence to evolving regulatory frameworks; and
- maintaining compliance with applicable laws and corporate governance requirements.

In May 2023, we issued four series of warrants that expire upon the earlier of (i) five years following issuance or (ii) 20 trading days following the occurrence of certain milestones specific to each series. If all of the four series of warrants are exercised in cash in full, this would result in $71.4 million of gross proceeds. In July 2024, we received gross proceeds of approximately $17.9 million following the exercise of the Series H Warrants in full. In July 2025, we received gross proceeds of approximately $17.9 million following the exercise of the Series I Warrants in full. In July 2025, we completed a private placement that generated approximately $40.1 million in gross proceeds. For additional information, see "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations – Recent Developments – Private Placements." There can be no assurance that we will achieve any of the milestones set forth in the remaining unexercised Warrants or that these Warrants will be exercised in cash in full.

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

We have only recently transitioned to a commercial stage medical device company in the United States, which may make it difficult for analysts and investors to evaluate the success of our business to date and to assess our future viability.

We only recently launched CGuard Prime in the United States following FDA approval in June 2025. Consequently, any predictions that analysts and investors make about our future success or viability may not be as accurate as they could be if we had more experience commercializing CGuard Prime in the United States. To be profitable, we will need to successfully transition our focus to expand our commercialization capabilities through our direct sales organization and build our distribution capabilities to support the commercial launch of CGuard Prime in the United States. Ultimately, we may not be successful in such a transition.

CGuard Prime has been commercially launched in the United States, and we have limited experience manufacturing, selling, marketing and distributing products in the U.S. The timing of uptake and distribution efforts are unpredictable and there is a risk that we may not achieve and sustain commercial success for the CGuard Prime.

In July 2025, we announced the official commercial launch of CGuard Prime in the U.S. following FDA approval in June 2025, and we are currently executing on the commercialization plan. As part of our plan, we are building out sales, marketing and distribution capabilities and have engaged with a contract manufacturer to supplement our internal manufacturing capacity. Historically, prior to the commencement of our commercialization activities in the U.S., we did not have experience in manufacturing, selling, marketing or distributing products in the U.S. To be able to successfully commercialize CGuard Prime we may need to further develop our existing manufacturing, sales, marketing and distribution capabilities, which is expensive and time-consuming, or enter into arrangements with third parties to perform these services.

In October 2024, we established our global headquarters in Miami, Florida to support the U.S. commercial launch of CGuard Prime. During 2024, we started the build-out of the infrastructure for commercial operations in the U.S. designed to support the commercialization of CGuard Prime. In addition, to support our anticipated production growth in connection with the commercialization of CGuard Prime, we have engaged Aptyx a contract manufacturer that is a developer and manufacturer of complex components and devices for the life sciences, to transfer the manufacturing of CGuard Prime finished goods to full-scale production at their ISO Class 7 cleanroom facility in North Carolina.

There are risks involved in establishing our own sales, marketing and distribution capabilities and partnering with a third-party manufacturer. We must commit significant financial and managerial resources to develop a marketing and sales force with technical expertise and with supporting distribution capabilities. Factors that may inhibit our efforts to commercialize our products directly and without strategic partners include:

- our inability to recruit and retain adequate numbers of effective manufacturing, sales and marketing personnel;
- the inability of sales personnel to obtain access to or persuade physicians to use our stents;
- the inability to price our products at a sufficient price point to ensure an adequate and attractive level of profitability;
- the difficulty of obtaining reimbursement from governmental and commercial payers;
- the lack of complementary products offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines; and
- unforeseen costs and expenses associated with creating and sustaining an independent manufacturing, sales and marketing organization.

We are continuing to expand our commercialization capabilities and to build our distribution capabilities to support the commercialization of CGuard Prime. We expect that it will take time for this team to generate significant sales momentum, if it does so at all. We may not be successful in recruiting and retaining the manufacturing, sales and marketing personnel necessary to sell CGuard Prime, and we may not be successful in marketing CGuard Prime, which would have a material adverse effect on our business, financial condition and results of operations.

In addition, other factors that have and may continue to inhibit our efforts to successfully commercialize CGuard Prime in the United States include our ability to access key health care decision makers, price CGuard Prime at a sufficient price point to ensure an adequate and attractive level of profitability, and maintain sufficient financial resources to cover the costs and expenses associated with creating and sustaining a capable sales and marketing organization and related commercial infrastructure. If we are not successful in setting our marketing, pricing and reimbursement strategies, recruiting and maintaining effective sales and marketing personnel or building and maintaining the infrastructure to support commercial operations in the United States and elsewhere, we will have difficulty successfully commercializing CGuard Prime in the U.S. market, which would adversely affect our business and financial condition.

If we are unable to establish and maintain our own manufacturing, sales, marketing and distribution capabilities or enter into successful arrangements with third parties to perform these services, our future product revenues and profitability may be materially adversely affected. If we are not successful in commercializing CGuard Prime in the United States, we may be required to collaborate or partner with a third-party medical device or biotechnology company with existing products. To the extent we collaborate or partner, the financial value will be shared with another party and we will need to establish and maintain a successful collaboration arrangement, and we may not be able to enter into these arrangements on acceptable terms or in a timely manner in order to establish CGuard Prime in the U.S. market. To the extent that we enter into co-promotion or other arrangements, any revenues we receive will depend upon the efforts of third parties, which may not be successful and are only partially in our control. In that event, our product revenues may be lower than if we marketed and sold our products directly with the highest priority, and we may be required to reduce or eliminate much of our commercial infrastructure and personnel as a result of such collaboration or partnership.

CGuard Prime, or any other product candidate that may receive marketing approval in the future, may fail to achieve the degree of market acceptance by physicians, patients, third-party payors and others in the medical community necessary for commercial success and the market opportunity for CGuard Prime or any other product candidate may be smaller than our estimates.

CGuard Prime, or any other product candidate that may be approved in the future by the appropriate regulatory authorities for marketing and sale, may fail to gain sufficient market acceptance by physicians, patients, third-party payors and others in the medical community. Physicians are often reluctant to switch their patients from existing medical devices even when new and potentially more effective or convenient products enter the market.

Efforts to educate the medical community and third-party payors on the benefits of CGuard Prime over its competition have required significant resources and may not ultimately be successful. If CGuard Prime, or any other product candidate that may be approved in the future for marketing and sale in the future, does not achieve an adequate level of market acceptance, we may not generate significant revenues and we may not become profitable. The degree of market acceptance of CGuard Prime, or any other product candidate that may be approved in the future, will depend on a number of factors, including:

- the advantages of the product compared to competitive products;
- the number of competitors approved for similar uses;
- the relative promotional effort and marketing success of us as compared with our competitors;
- how the product is positioned in physician treatment guidelines and pathways;
- the prevalence and severity of any side effects;
- the functionality and ease of use of the product;

● the efficacy and safety of the product;

● our ability to offer the product for sale at competitive prices;

● the product's tolerability, consistency of performance, convenience and ease of administration compared to alternative product;

● the willingness of the target patient population to try, and of physicians to utilize, the product;

● limitations or warnings, including use restrictions, contained in the product's approved labeling;

● the strength of sales, marketing and distribution support;

● the timing of market introduction of our approved products as well as competitive products;

● adverse publicity about the product or favorable publicity about competitive products;

● potential product liability claims;

● changes in the standard of care for the targeted indications of the product; and

● availability and amount of coverage and reimbursement from government payors, managed care plans and other third-party payors.

In addition, the potential market opportunities for CGuard Prime and any other product are difficult to estimate precisely. Our estimates of the potential market opportunities are predicated on many assumptions, including industry knowledge and publications, third-party research reports and other surveys. While we believe that our internal assumptions are reasonable, these assumptions involve the exercise of significant judgment on the part of our management, are inherently uncertain and the reasonableness of these assumptions has not been assessed by an independent source. If any of the assumptions prove to be inaccurate, the actual markets for our therapeutic candidate could be smaller than our estimates of the potential market opportunities.

If the commercial launch of CGuard Prime in the United States for which we established a direct sales organization and distribution capabilities is not successful for any reason, we could incur substantial costs and our investment in our direct sales organization and distribution capabilities would be lost if we cannot retain or reassign our sales, marketing, market access and medical affairs personnel.

To achieve commercial success for CGuard Prime in the United States, we have expended and anticipate that we will continue to expend significant resources to support our direct sales organization and distribution capabilities. There are risks involved with establishing our own sales, marketing, distribution, training and support capabilities. For example, recruiting and training sales and marketing personnel is expensive and time consuming and could delay our ability to focus on other priorities. If the commercial launch of CGuard Prime in the United States is not successful for any reason, this would be costly, and our investment would be lost if we cannot retain or reassign our sales, marketing, market access and medical affairs personnel or terminate on favorable terms any agreements entered into with third parties to support our commercialization efforts.

Factors that may inhibit or limit our efforts to commercialize CGuard Prime in the United States on our own include:

- our inability to train and retain adequate numbers of effective sales, marketing, training and support personnel;

- the inability of sales personnel to obtain access to physicians, including key opinion leaders, or to educate an adequate number of physicians of the benefits of CGuard Prime over alternative treatment options; and

- unforeseen costs and expenses associated with establishing and maintaining an independent sales, marketing, training and support organization.

If our direct sales organization and distribution capabilities fail, or are otherwise unsuccessful, it would materially adversely impact the commercialization of CGuard Prime in the United States, impact our ability to generate revenue and harm our business.

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 abilities to successfully commercialize CGuard Prime and receive FDA approval of SwitchGuard and other products we may develop. If we fail to successfully commercializae CGuard Prime or obtain FDA approval for SwitchGuard 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, and we only recently announced the official commercial launch of CGuard Prime in July 2025. In addition, we have not received any approvals for SwitchGuard and there can be no assurance that we will be able to receive regulatory approvals to commence marketing and sales for our products in any jurisdiction where we are seeking approvals. Our ability to generate significant revenues and achieve profitability depends on our ability to successfully commercialize and manufacture commercial quantities of CGuard Prime and obtain required regulatory approvals for SwitchGuard and any other products we may develop at an acceptable cost. In addition, there may be insufficient demand for CGuard Prime, SwitchGuard and any other products we commercialize or develop. 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.

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.

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, Medtronic, Cordis Corporation and Terumo Medical Corporation produce a polytetrafluoroethylene mesh-covered stent and a double layer metal stent. As we develop and seek regulatory approval in the United States for our new TCAR neuroprotection system, SwitchGuard NPS, and continue to seek greater market share for CGuard Prime, we expect to compete with Silk Road Medical, which was acquired by Boston Scientific Corporation, in the TCAR market. 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 they are approved for sale. The worldwide market for stent products is characterized by intensive development efforts and rapidly advancing technology. 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 develop. If our technologies or products become obsolete or uncompetitive, our related revenue would decrease. This would have a material adverse effect on our business, financial condition and results of operations.

We may not be able to achieve or maintain satisfactory pricing and margins for our products.

Manufacturers of medical devices have a history of price competition, and we can give no assurance that we will be able to achieve satisfactory prices for our products or maintain prices at the levels we have historically achieved. Any decline in the amount that payers reimburse our customers for CAS could make it difficult for customers to continue using, or to adopt, our products and could create additional pricing pressure for us. In addition, the introduction of competitive stents that could be used in CAS procedures and other products could also put pressure on the pricing of our products. If we are forced to lower the price we charge for our products, our gross margins will decrease, which will adversely affect our ability to invest in and grow our business. If we are unable to maintain our prices, or if our costs increase and we are unable to offset such increase with an increase in our prices, our margins could erode. We will continue to be subject to significant pricing pressure, which could harm our business and results of operations. Also, our use of distributors in non-U.S. countries may adversely impact our gross margins.

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 our commercial sales expand geographically, the possibility of patent infringement by us or 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, C.R. Bard, Inc., W.L. Gore & Associates and Medtronic, 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.

Risks Related to our Clinical Trials and Regulatory Matters

Completion of clinical trials for CGuard Prime 80 cm in TCAR procedures (C-GUARDIANS II), SwitchGuard NPS (C-GUARDIANS III), and any other investigational product candidates requires compliance with FDA IDE regulations, and failure to meet these requirements could materially harm our business.

We recently completed patient enrollment in the C-GUARDIANS II IDE trial to evaluate the safety and efficacy of the CGuard Prime 80 cm carotid stent system used with the ENROUTE NPS during TCAR procedures, following FDA approval of the IDE on October 3, 2024. The study enrolled its first patient on December 6, 2024 and we completed enrollment of 50 patients in the first quarter of 2026. For additional information, see "Item 1 – Business – On-going and Planned Clinical Trials – C-GUARDIANS II for TCAR procedures." In addition, FDA approved the IDE for C-GUARDIANS III on June 6, 2025, a pivotal study evaluating the SwitchGuard NPS when used in conjunction with the CGuard Prime 80 cm system for TCAR. The C-GUARDIANS III study is expected to begin enrollment of patients during the second quarter of 2026. For additional information, see "Item 1 – Business – On-going and Planned Clinical Trials – C-GUARDIANS III for TCAR procedures using SwitchGuard NPS."

These and any future clinical studies must comply with FDA IDE regulations and Good Clinical Practice requirements, including IRB approvals, predefined protocols, informed consent, monitoring, data integrity, and reporting obligations. Delays in patient enrollment, site activation, supply availability, protocol deviations, investigator performance, or regulatory compliance issues could delay or disrupt these studies.

Because the TCAR indication for CGuard Prime and the SwitchGuard NPS remain investigational, the results from C-GUARDIANS II, C-GUARDIANS III, or any future clinical trials may not demonstrate safety and effectiveness to the FDA's satisfaction. Failure to generate acceptable clinical data could delay or prevent FDA approval of these expanded indications or new products, limit our commercial opportunities in the TCAR market, and materially harm our business, financial condition, and results of operations.

Clinical trials necessary to support regulatory submissions for our products, including the C-GUARDIANS II study evaluating the CGuard Prime 80 cm stent system for TCAR procedures and the C-GUARDIANS III study evaluating the SwitchGuard NPS, are often lengthy and difficult to conduct, and delays or failures in these trials could adversely affect our business.

We are currently conducting C-GUARDIANS II, an FDA-approved IDE study evaluating the safety and effectiveness of the CGuard Prime 80 cm carotid stent system when used with the ENROUTE NPS during TCAR procedures. Although CGuard Prime received PMA approval in June 2025 for transfemoral use, the TCAR indication remains investigational and will require a PMA supplement supported by C-GUARDIANS II data. We are also conducting C-GUARDIANS III, an FDA-approved IDE study evaluating the SwitchGuard NPS, which is expected to support a 510(k) submission for SwitchGuard as a standalone neuroprotection system for TCAR.

Clinical trials for these products may encounter delays related to patient enrollment, site activation, protocol adherence, availability of investigational product, competing studies, and investigator engagement. TCAR-eligible patients represent a more limited subset of the carotid stenosis population, and suitable patients may be difficult to identify and recruit, particularly across centers with variable TCAR procedure volumes. Patients may withdraw consent, fail to complete required follow-up, or experience unrelated adverse events that complicate interpretation of study data.

If we are unable to complete these studies successfully, or if the resulting data do not demonstrate safety and effectiveness to the FDA's satisfaction, we may be unable to obtain approval for the TCAR indication for CGuard Prime or clearance for the SwitchGuard NPS. Any such delays or failures could materially harm our business, financial condition, results of operations, and our commercial opportunities in the TCAR market.

The results of our C-GUARDIANS II and C-GUARDIANS III trials, as well as any other clinical trials, may be insufficient to obtain regulatory approval for our products.

We will only receive regulatory approval for additional indications of CGuard Prime, SwitchGuard or any other product we develop 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 is safe and effective. If we are unable to demonstrate that a product 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. We face risks that:

- the product may not prove to be safe or effective;
- the product'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 results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- 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 products 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 products 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.

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.

Even if we obtain regulatory approvals, our products will be subject to ongoing regulatory review and if we fail to comply with continuing U.S. and applicable foreign regulations, we could lose those approvals and our business would be seriously harmed.

Even if products we develop receive regulatory approval or clearance, we will be subject to ongoing reporting obligations, and the products and the manufacturing operations will be subject to continuing regulatory review, including FDA inspections. The outcome of this ongoing review may result in the withdrawal of a product from the market, the interruption of the manufacturing operations and/or the imposition of labeling and/or marketing limitations. Since many more patients are exposed to drugs and medical devices following their marketing approval, serious but infrequent adverse reactions that were not observed in clinical trials may be observed during the commercial marketing of the product. In addition, the manufacturer and the manufacturing facilities we will use to produce any product will be subject to periodic review and inspection by the FDA and other similar foreign regulators. Later discovery of previously unknown problems with any product, manufacturer or manufacturing process, or failure to comply with regulatory requirements, may result in actions such as:

- restrictions on such product, manufacturer or manufacturing process;
- warning letters from the FDA or other regulatory authorities;
- withdrawal of the product from the market;
- suspension or withdrawal of regulatory approvals;
- refusal to approve pending applications or supplements to approved applications that we submit;
- voluntary or mandatory recall;
- fines;
- refusal to permit the import or export of our products;
- product seizure or detentions;
- injunctions or the imposition of civil or criminal penalties; or
- adverse publicity.

If we, or supplier, third-party contractor, partner or clinical investigator is slow to adapt, or are unable to adapt, to changes in existing regulatory requirements or the adoption of new regulatory requirements or policies, we may lose marketing approval for any of our products, if any of our products are approved, resulting in decreased.

Even if products we develop receive marketing approval, we or others may later discover that the product is less effective than previously believed or causes undesirable side effects that were not previously identified, which could compromise our ability or that of any collaborators to market the product, and could cause regulatory authorities to take certain regulatory actions.

It is possible that our clinical trials may indicate an apparent positive effect of a product that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. For example, we, or others, may discover that our products are less safe and effective than previously believed. If, we, or others, discover that a product is less effective than previously believed or causes undesirable side effects that were not previously identified, any of the following adverse events could occur:

- regulatory authorities may withdraw their approval of the product or seize the product;
- we, or any of our collaborators, may be required to recall the product, change the way the product is administered or conduct additional clinical trials;
- additional restrictions may be imposed on the marketing of, or the manufacturing processes of, the particular product;
- we, or any of our collaborators, may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication including with the product;
- we, or any of our collaborators, may be required to create a Medication Guide outlining the risks of the previously unidentified side effects for distribution to patients;
- we could be sued and held liable for harm caused to patients;
- physicians and patients may stop using our product; and
- our reputation may suffer.

Any of these events could harm our business and operations and could negatively impact our stock price.

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 medical device vigilance system under Regulation (EU) 2017/745 on medical devices, or the MDR. Under this system, manufacturers are generally required to report serious incidents involving medical devices via an electronic system incorporated into the EU database on medical devices, called EUDAMED. Furthermore, 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. An 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. FSCAs must be reported to the relevant competent authorities, even if the FSCA was undertaken in a third country in relation to a device which is also legally made available on the Union market and the reason for the FSCA is not limited to the device made available in the third country.

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 SwitchGuard and any other product we may develop, 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 ten 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 products, 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 products; and
- injunctions, the imposition of civil penalties or criminal prosecution.

The FDA and the Federal Trade Commission (“FTC”) 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 and any warnings that may be required in the use of the device. 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 or FTC 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 CGuard EPS in certain international markets. In order to market any of 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 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 environment for health care policy generally may change when new Presidential administrations take office. President Trump has begun to reduce the numbers of employees that work at the Department of Health and Human Services, that includes the FDA and CMS. In addition, laws like the Affordable Care Act may be subject to modifications under the current leadership. With a reduction of employees at FDA, this would likely slow down the reviews and approvals of products. In addition, the reduction of employees from CMS may also slow down the payment for those individuals who have coverage under Medicare, Medicaid and the Affordable Care Act. It is difficult to assess what may occur. Uncertainties remain regarding what negative unintended consequences these provisions will have on patient access to new technologies, pricing and the market for our products. Any significant reductions in coverage or payment for services under Medicare, Medicaid and the Affordable Care Act may affect those beneficiaries who cannot get access to certain FDA approved products. In addition, lower reimbursement by government programs may shift costs to employees who have coverage from their employers or private payors. While there are some uncertainties regarding the U.S. coverage and payment for medical devices, the strength of the health care providers and payors are likely to work to mitigate some adverse issues that may impact the health care system.

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. The enactment of the Tax Act, on December 14, 2018, removed penalties for not complying with the Affordable Care Act's individual mandate to carry health insurance. 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 effect 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 2031 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 cause an 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. For example, CMS issued a national coverage determination on October 11, 2023, finding that Medicare coverage for percutaneous transluminal angioplasty of the carotid artery concurrent with stenting with an FDA-approved or -cleared device to be reasonable and necessary. Further, the federal, state and local governments, Medicare, Medicaid, managed care organizations, and foreign governments have considered in the past, 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. For example, the One Big Beautiful Bill Act of 2025 (OBBBA) went into effect on July 4, 2025, and greatly modified Medicaid reimbursements and enrollment to include work requirements and periodic eligibility determinations, all of which could reduce Medicaid enrollment. 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.

Third-party payors are developing increasingly sophisticated methods of controlling healthcare costs and increasingly challenging the prices charged for medical products and services. Additionally, the containment of healthcare costs has become a priority of federal and state governments and the prices of drugs have been a focus in this effort. The United States government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls and transparency requirements, restrictions on reimbursement and requirements for substitution of generic products. For example, HHS began implementation in 2025 of "Most Favored Nation" drug pricing by setting the Medicare price of single-source brand drugs without generic or biosimilar competition to the lowest price available in wealthy countries with a per capita GDP of at least 60% of that in the United States. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could limit our revenue and operating results.

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. 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) and (90/385/EEC). The regulation entered into full application on May 26, 2021. The MDR (as amended on January 10, 2025) imposes strict requirements on medical device manufacturers and strengthens the supervising competences of the competent authorities of EEA member states, the notified bodies and the authorized representatives. If we fail to comply with the MDR and applicable national legislation on medical devices in EEA member states, 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.

On January 12, 2025, Regulation (EU) 2021/2282 of the European Parliament and of the Council of December 15, 2021 on health technology assessment and amending Directive 2011/24/EU, or the EU HTA Regulation, became applicable. The EU HTA Regulation stipulates joint clinical assessments at EU level for certain medical devices. A Joint Clinical Assessment (JCA) under the EU HTA Regulation is a centralized, EU-level evaluation of the comparative clinical effectiveness and safety of health technologies, including medical devices. The JCA is designed to influence pricing and reimbursement decisions of EU member states at the national level, although its result does not pre-determine national decisions concerning reimbursement. Within the scope of the EU HTA Regulation are, among others, medical devices classified as class IIb or III under the MDR for which the relevant expert panels have provided a scientific opinion in the framework of the clinical evaluation consultation procedure. The medical devices under the EU HTA Regulation are subject to selection by the European Commission at least every two years, based on statutory criteria. Furthermore, the EU HTA Regulation provides a framework for voluntary cooperation of member states regarding the non-clinical assessment of health technologies and collaborative assessments on medical devices not already covered by the mandatory joint clinical assessment. The EU HTA Regulation may increase compliance costs and adversely affect pricing of our products.

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

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

Disruptions at the FDA and other agencies may also slow the time necessary for new medical devices or modifications to cleared or approved medical devices to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. Most recently, the federal government was shut down for approximately 43 days from October 1 to November 12, 2025, due to a lapse in appropriations, during which federal employees were furloughed and many agencies, including components of the HHS, operated with reduced staffing or suspended activities. In early 2025, following the inauguration of President Trump, the Trump Administration began terminating federal government employees, including approximately 3,500 employees at the FDA. Prior shutdowns, such as the 35-day shutdown beginning December 22, 2018, similarly resulted in furloughs and delays in regulatory review activities. Any future government shutdowns, funding lapses, continuing resolutions, or similar events could result in reduced agency staffing, delays in regulatory reviews, interruptions to critical government functions, or uncertainty in agency operations, each of which could materially and adversely affect our business, financial condition, and results of operations.

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 meaningful commercial 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 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 and related surgical technologies that we are developing. 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 or may make it more difficult to enforce proprietary rights than 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.

The failure to obtain or maintain patents, licensing agreements and other intellectual property rights that are sufficiently broad and protective could impact our ability to compete effectively.

To compete effectively, we need to develop and maintain a proprietary position with regard to our own technologies, intellectual property, licensing agreements, product candidates and business. Legal standards relating to the validity and scope of patent claims in the US and other countries tend to be uncertain and changeable. Therefore, the degree of future protection for our proprietary rights in our core technologies and any products that might be made using these technologies is also uncertain. The risks and uncertainties that we face with respect to our patents and other proprietary rights include the following:

- while some of our patents have been issued, the pending patent applications we have filed may not result in issued patents or may take longer than we expect to result in issued patents;
- a third party may initiate an inter parties review, or IPR, proceedings in the U.S.;
- we may be subject to interference proceedings in the U.S.;
- a third party may initiate opposition proceedings in foreign countries;
- any patents that are issued may not provide meaningful protection;
- we may not be able to develop additional proprietary technologies that are patentable;
- other companies may challenge patents licensed or issued to us;
- other companies may develop new and alternative technologies that do not fall within the scope of our patents;
- other companies may design around patents we have developed; and
- enforcement of patents is complex, uncertain and expensive.

If patent rights covering our products and methods are not sufficiently broad or not issued at all by the United States Patent and Trademark Office (the “USPTO”) or by foreign patent offices, we may not have adequate protection against competitors with similar products and technologies. Furthermore, if the USPTO or foreign patent offices issue patents to us or our licensors, others may challenge the patents or design around the patents, or the patent office or the courts may invalidate the patents. Thus, any patents we own or license from third parties may not provide any protection against our competitors.

We cannot be certain that patents will be issued as a result of any pending applications, and we cannot be certain that any of our issued patents will give us adequate protection from competing products. For example, issued patents may be circumvented or challenged, declared invalid or unenforceable, or narrowed in scope. In addition, since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain that we were the first to make our inventions or to file patent applications covering those inventions.

It is also possible that others may obtain issued patents that could prevent us from commercializing our products or require us to obtain licenses requiring the payment of significant fees or royalties in order to enable us to conduct our business.

In addition to patents and patent applications, we depend upon trade secrets and proprietary know-how to protect our proprietary technology. We require our employees, consultants, advisors and collaborators to enter into confidentiality agreements that prohibit the disclosure of confidential information to any other parties. We require our employees and consultants to disclose and assign to us their ideas, developments, discoveries and inventions. These agreements may not, however, provide adequate protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure.

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 products. 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 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, certain U.S. patent applications 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 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 are prosecuted and 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 products or services, the defendant could counterclaim that the patent covering our product 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 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 and inter partes review proceedings before the USPTO. The outcome following legal assertions of invalidity and unenforceability is unpredictable.

Derivation and interference proceedings initiated by third parties or brought by us may be necessary to determine the priority and ownership 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.

We may not be able to protect our intellectual property rights throughout the world.

A company may attempt to commercialize competing products utilizing our proprietary design, trademarks or tradenames in foreign countries where we do not have sufficient patent protection and where legal recourse may be limited. This may have a significant commercial impact on our foreign business operations.

Filing, prosecuting and defending patents or trademarks on our current and future products in all countries throughout the world would be prohibitively expensive. The requirements for patentability and trademarking may differ in certain countries, particularly developing countries. The laws of some foreign countries do not protect intellectual property rights to the same extent as laws in the United States. Consequently, we may not be able to prevent third parties from utilizing our inventions and trademarks in all countries outside the United States. Competitors may use our technologies or trademarks in jurisdictions where we have not obtained patent or trademark protection to develop or market their own products and further, may export otherwise infringing products to territories where we have patent and trademark protection, but enforcement on infringing activities is inadequate. These products or trademarks may compete with our products or trademarks, and our patents, trademarks or other intellectual property rights may not be effective or sufficient to prevent them from competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents, trademarks and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents and trademarks or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent and trademarks rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents and trademarks at risk of being invalidated or interpreted narrowly and our patent or trademark applications at risk, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, certain countries in Europe and certain developing countries, including India and China, have compulsory licensing laws under which a patent owner may be compelled to grant licenses to third parties. In those countries, we may have limited remedies if our patents are infringed or if we are compelled to grant a license to our patents to a third party, which could materially diminish the value of those patents. This could limit our potential revenue opportunities. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we own or license. Finally, our ability to protect and enforce our intellectual property rights may be adversely affected by unforeseen changes in foreign intellectual property laws.

Risks Related to Our Business and Operations

CGuard EPS, CGuard Prime, and SwitchGuard NPS are complex medical devices that require training for qualified personnel.

CGuard EPS, CGuard Prime, and SwitchGuard NPS are complex medical devices that require training for qualified personnel, including physicians. Although our distributors and direct salespeople will be required to ensure that CGuard EPS, CGuard Prime, and SwitchGuard NPS are prescribed only by trained clinicians, the potential for misuse of these products still exists due to their 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.

If we fail to maintain or establish reliable supply arrangements, or if we experience interruptions in the supply of key materials or components, our ability to manufacture and commercialize our products could be adversely affected.

We rely on external suppliers for certain raw materials, components, and sub-assemblies used in the manufacture of CGuard EPS, CGuard Prime, and our products under development. Some of these items are sourced from a single supplier. If any supplier is unable or unwilling to meet our quality standards, delivery schedules, or quantity requirements, or if they cease supplying us, we may not be able to obtain suitable alternative materials or components on acceptable terms, or at all.

Several critical components of our products are currently provided by single-source vendors. For example, in 2022 our mesh supplier notified us that it would no longer be able to supply the polymer fiber used to produce our MicroNet mesh because of supply constraints affecting its PET resin source. We subsequently purchased sufficient inventory to support our anticipated production needs through early 2028, and we have identified and begun validating an alternative PET resin with comparable mechanical and biocompatibility characteristics. However, there can be no assurance that this validation will be successful, that the alternative material will receive required regulatory approvals, or that additional or replacement PET sources will be available when needed. If we are unable to secure timely approval of an alternative PET resin supplier or are unable to qualify additional suppliers, we could face manufacturing delays, supply interruptions, increased component costs, or an inability to meet commercial demand.

Because CGuard Prime is approved in the United States under a PMA, any change to certain suppliers, components, or raw materials, including the PET resin used in MicroNet, requires FDA approval through a PMA supplement. Similar approvals or notifications may be required by foreign regulatory authorities. These processes can be time-consuming and may delay our ability to implement supplier changes or address supply shortages. As a result, commercial supply or clinical studies involving products under development could be adversely affected.

We also depend on a third-party sterilization vendor for our finished products. If this vendor experiences disruptions, capacity limitations, compliance issues, or quality failures, or if we are unable to obtain timely regulatory approval to qualify an alternative sterilization provider, we could face delays or interruptions in product release and distribution.

Any interruption in our supply chain, including raw materials, specialized components, or sterilization services, could impair our ability to meet demand, maintain inventory levels, or support ongoing commercial sales and clinical activities. This could materially harm our business, financial condition, and results of operations.

Our business is dependent upon the total market opportunity for CAS and our ability to penetrate it through continued adoption of CAS by hospitals and physicians.

Our future growth and profitability largely depend on the total market opportunity for CAS, the determination of which is inherently imprecise, and our ability to penetrate it, which is largely dependent upon our ability to increase physician awareness and adoption of CAS and on the willingness of physicians to recommend the procedure to more of their patients. While we are confident in our estimate of the annual total addressable market for our CAS products, especially since it is based on a number of internal and third-party estimates, it may prove to be incorrect. If the actual number of patients who would benefit from our products and the annual total addressable market for our products is smaller than we have estimated, it may impair our sales growth and have an adverse impact on our business. With respect to our ability to penetrate this market opportunity, physicians may not use our products unless they are able to determine, based on experience, clinical data, medical society recommendations and other analyses, that our products provide a safe and effective treatment alternative for carotid artery disease and other vascular conditions. Even if we are able to raise awareness and increase adoption of CAS among physicians, physicians tend to be slow in changing their medical treatment practices and may be hesitant to select our products or CAS for recommendation to patients for a variety of reasons, including:

- Long-standing relationships with competing companies and distributors that sell other products;
- Competitive response and negative selling efforts from providers of alternative carotid revascularization products;
- Perceived liability risk generally associated with the use of new products and procedures;
- Lack or perceived lack of sufficient clinical evidence, including long-term data or a randomized controlled trial, supporting clinical benefits;
- Lack of experience with CAS as a treatment alternative to CEA;
- Familiarity and experience with CEA, and reluctance to change to or use new products and procedures; and
- Time commitment and skill development that may be required to gain familiarity and proficiency with CAS and our products.

Physicians play a significant role in determining the course of a patient's treatment for carotid artery disease and, as a result, the type of treatment that will be recommended or provided to a patient. We focus part of our sales, marketing and education efforts primarily on interventional cardiologists, vascular surgeons, and neurosurgeons and aim to educate referring physicians such as internal medicine specialties, cardiologists, radiologists, neurologists, and general practitioners regarding the patient population that would benefit from CAS. However, we cannot assure you that we will achieve broad education or market acceptance among these practitioners. For example, if diagnosing physicians who serve as the primary point of contact for patients are not made aware of CAS, they may not refer patients to physicians for treatment using our products, and those patients may instead not seek treatment at all or may be treated with alternative procedures. In addition, some physicians may choose to utilize CAS on only a subset of their total patient population or may not adopt CAS at all. If a physician experiences an adverse event in one or more of their CAS patients or elects to convert CAS to CEA mid-procedure, they may not continue offering and performing CAS at the same rate or at all. Further, CAS may not fit into the workstreams of certain physicians. If we are not able to effectively demonstrate that CAS is beneficial in a broad range of patients, adoption of CAS will be limited and may not occur as rapidly as we anticipate, which would have a material adverse effect on our business, financial condition and results of operations. We cannot assure you that CAS or our products will achieve broad market acceptance among hospitals and physicians. Any failure of CAS or our products to satisfy demand or to achieve meaningful market acceptance and penetration will harm our future prospects and have a material adverse effect on our business, financial condition and results of operations.

In most cases, before physicians can use our products for the first time, our products must be approved for use by a hospital's new product or value analysis committee, or the staff of a hospital or health system. Following such approval, we may be required to enter into a purchase contract. Such approvals or requirements to enter into a purchase contract could deter or delay the use of our products by physicians. We cannot provide assurance that our efforts to obtain such approvals, enter into purchase contracts, or generate adoption will be successful or increase the use of our products, and if we are not successful, it could have a material adverse effect on our business, financial condition and results of operations.

In addition, if patient receptivity toward CAS becomes less favorable in the future, this shift could negatively impact market acceptance of CAS. Any negative change due to patient receptivity could also be compounded by patients reporting to physicians or other patients through word-of-mouth or social media.

Adoption of CAS depends upon appropriate physician training, and inadequate training may lead to adverse patient outcomes, adversely affect adoption of CAS and adversely affect our business.

The success of CAS depends in part on the skill of the physician who is performing the procedure and on our customers' adherence to appropriate patient selection and proper techniques provided in training sessions conducted by our training faculty. Physicians rely on their previous medical training and experience when performing CAS, and we cannot guarantee that all such physicians will have the necessary surgical and endovascular skills to perform the procedure. If physicians perform CAS in a manner that is inconsistent with its labeled indications, with components that are not our products or without adhering to or completing our training sessions, their patient outcomes may not be consistent with the outcomes achieved in our and other clinical trials, studies or registries of CAS. This result may negatively impact the perception of patient benefit and safety and limit adoption of CAS and our products that facilitate the procedure, which would have a material adverse effect on our business, financial condition and results of operations. Additionally, hospitals and physician organizations may adopt physician credentialing guidelines requiring CAS training that is more extensive than our training program. If physicians conclude that we do not provide adequate CAS training, they may be less likely to adopt CAS and our products, which could have a material adverse effect on our business, financial condition and results of operations.

The failure of third parties to meet their contractual, regulatory, and other obligations could adversely affect our business.

We have engaged Aptyx, a contract manufacturer, to expand our manufacturing capacity of CGuard Prime finished goods to full-scale production at their ISO Class 7 cleanroom facility in North Carolina. Using a third party poses a number of risks, such as: (i) they may not perform to our standards or legal requirements; (ii) they may not produce reliable results; (iii) they may not perform in a timely manner; (iv) they may not maintain confidentiality of our proprietary information; (v) disputes may arise with respect to ownership of rights to technology developed with our partners; and (vi) disagreements could cause delays in, or termination of, the research, development or commercialization of our products or result in litigation or arbitration. Moreover, some third parties are located in markets subject to political and social risk, corruption, violence, infrastructure problems and natural disasters, in addition to country-specific privacy and data security risk given current legal and regulatory environments. Failure of third parties to meet their contractual, regulatory, and other obligations may materially affect our business.

We face manufacturing risks that could adversely affect our ability to manufacture products, reduce our gross margins and negatively affect our business and operating results.

Our business strategy following the commercial launch of CGuard Prime depends on our ability to manufacture, and our contract manufacturers' ability to manufacture, our current and future products in sufficient quantities and on a timely basis to meet customer demand, while adhering to product quality standards, complying with regulatory quality system requirements and managing manufacturing costs. We currently manufacture our CGuard EPS and our CGuard Prime at our own facility in Israel where we handle the entire assembly process for CGuard EPS and CGuard Prime, including knitting and securing the sleeve to the stent and the crimping of the sleeved stent into a delivery catheter. In addition, to support our anticipated production growth following the commercialization of CGuard Prime, we have engaged Aptyx, a contract manufacturer, to expand our manufacturing capacity of CGuard Prime finished goods to full-scale production at their ISO Class 7 cleanroom facility in North Carolina. If our or our manufacturing partners' facilities suffers damage, or a force majeure event, this could materially affect our ability to operate.

We are also subject to numerous other risks relating to our manufacturing capabilities, including:

- quality and reliability of components, sub-assemblies and materials that we source from third-party suppliers, who are required to meet our quality specifications, the majority of which are our single-source suppliers for the products they supply;
- our or our manufacturing partners' inability to secure components, sub-assemblies and materials in a timely manner, in sufficient quantities or on commercially reasonable terms;
- our or our manufacturing partners' inability to maintain compliance with quality system requirements or pass regulatory quality inspections;
- our or our manufacturing partners' failure to develop products in a timely manner or to required specifications or to increase production capacity or volumes to meet demand;
- our or our manufacturing partners' inability to design or modify production processes to enable us to produce future products efficiently or implement changes in current products in response to design or regulatory requirements; and
- difficulty identifying and qualifying, and obtaining new regulatory approvals, for alternative suppliers for components in a timely manner.

As demand for our products increases, we will have to invest additional resources to purchase components, sub-assemblies and materials, hire and train employees, and enhance our manufacturing processes. If we or our manufacturing partners fail to increase our production capacity efficiently, we may not be able to fulfill customer orders on a timely basis, our sales may not increase in line with our expectations, and our operating margins could fluctuate or decline. In addition, although we expect some of our products in development to share product features, components, sub-assemblies and materials with our existing products, the manufacture of these products may require modification of our or our manufacturing partners' current production processes or unique production processes, the hiring of specialized employees, the identification of new suppliers for specific components, sub-assemblies and materials or the development of new manufacturing technologies. It may not be possible for us or our manufacturing partners to manufacture these products at a cost or in quantities sufficient to make these products commercially viable or to maintain current gross margins, all of which could have a material adverse effect on our business, financial condition and results of operations.

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 or our third-party manufacturer 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.

Our results of operations could be materially harmed if we are unable to accurately forecast customer demand for our products and manage our inventory.

We seek to maintain sufficient levels of inventory in order to protect ourselves from supply interruptions, but keep limited components, sub-assemblies, materials and finished products on hand. To ensure adequate inventory supply and manage our operations with our manufacturing partners and suppliers, we forecast anticipated materials requirements and demand for our products in order to predict inventory needs and then place orders with our suppliers based on these predictions. Our ability to accurately forecast demand for our products would be negatively affected by many factors, including our rapid growth, product recalls, pandemics, failure to accurately manage our expansion strategy, product introductions by competitors, an increase or decrease in customer demand for our products, our failure to accurately forecast customer acceptance of new products, changes to hospital capacity, staffing, procedure and protocol changes, unanticipated changes in general market conditions or regulatory matters, weakening of economic conditions or consumer confidence and the realization of other risks as described in this section.

Inventory levels in excess of customer demand may result in a portion of our inventory becoming obsolete or expiring, as well as inventory write-downs or write-offs. Conversely, if we underestimate customer demand for our products or our own requirements for components, sub-assemblies and materials, our manufacturing partners and suppliers may not be able to deliver components, sub-assemblies and materials to meet our requirements. If we do not have adequate supply of components, sub-assemblies and materials there may be interruptions, delays or cancellations of deliveries of our products to our customers, any of which would damage our reputation, customer relationships and business. In addition, several components, sub-assemblies and materials incorporated into our products require lengthy order lead times, and additional supplies or materials may not be available when required on terms that are acceptable to us or our manufacturing partners, or at all, and our manufacturing partners and suppliers may not be able to allocate sufficient capacity in order to meet our increased requirements, any of which could have an adverse effect on our ability to meet customer demand for our products and our results of operations.

Our quarterly and annual results may fluctuate significantly and may not fully reflect the underlying performance of our business.

Our quarterly and annual results of operations, including our revenue, net income or net loss and cash flow, may vary significantly in the future, and period-to-period comparisons of our operating results may not be meaningful. Accordingly, the results of any one quarter or period should not be relied upon as an indication of future performance. Our quarterly and annual financial results may fluctuate as a result of a variety of factors, many of which are outside our control and, as a result, may not fully reflect the underlying performance of our business. Fluctuations in quarterly and annual results may decrease the value of our common stock. Because our quarterly results may fluctuate, period-to-period comparisons may not be the best indication of the underlying results of our business and should only be relied upon as one factor in determining how our business is performing.

Defects or failures associated with our products could lead to additional recalls, safety alerts or litigation, as well as significant costs and negative publicity.

Our business is subject to significant risks associated with the manufacture, distribution and use of medical devices that are placed inside the human body, including the risk that patients may be severely injured by or even die from the misuse or malfunction of our products caused by design flaws or manufacturing defects. In addition, component failures, design defects, off-label uses or inadequate disclosure of product-related information could also result in an unsafe condition or the injury or death of a patient. These problems could lead to a recall or market withdrawal of, or issuance of a safety alert relating to, our products and could result in significant costs, negative publicity and adverse competitive pressure. The circumstances giving rise to recalls are unpredictable, and any recalls of existing or future products increase the probability of inspection by, or additional scrutiny from, the FDA and could have a material adverse effect on our business, financial condition and results of operations.

The medical device industry has historically been subject to extensive litigation over product liability claims. Operating in the area of the neck with the brain as the end organ is dangerous and presents risks of adverse events such as bleeding, arterial dissection, cranial nerve injury, myocardial infarction, stroke and death, which subject us to a greater risk of being involved in litigation than companies with products used in less critical areas of the body. We may be subject to product liability claims if our products cause, or merely appear to have caused, an injury or death, even if due to physician error. In addition, an injury or death that is caused by the activities of our suppliers, such as those that provide us with components and materials, or by an aspect of a treatment used in combination with our products, such as a complementary drug or anesthesia, may be the basis for a claim against us by patients, hospitals, physicians or others purchasing or using our products, even if our products were not the actual cause of such injury or death. We may choose to settle any claims to avoid fault and complication, not due to failure of our products. An adverse outcome involving one of our products could result in reduced market acceptance and demand for all of our products and could harm our reputation and our ability to market our products in the future. In some circumstances, adverse events arising from or associated with the design, manufacture or marketing of our products could result in the suspension or delay of regulatory reviews of our premarket notifications or applications for marketing. Any of the foregoing problems could disrupt our business and have a material adverse effect on our business, financial condition and results of operations.

Although we carry product liability insurance in the United States and in other countries in which we conduct business, including for clinical trials and product marketing, we can give no assurance that such coverage will be available or adequate to satisfy any claims. Product liability insurance is expensive, subject to significant deductibles and exclusions, and may not be available on acceptable terms, if at all. If we are unable to obtain or maintain insurance at an acceptable cost or on acceptable terms with adequate coverage or otherwise protect against potential product liability claims, we could be exposed to significant liabilities. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have a material adverse effect on our business, financial condition and results of operations. Defending a suit, regardless of its merit or eventual outcome, could be costly, could divert management's attention from our business and might result in adverse publicity, which could result in reduced acceptance of our products in the market, product recalls or market withdrawals.

We are required to file adverse event reports under MDR and regulations with the FDA, which reports are publicly available on the FDA's website. We are required to file MDRs if our products may have caused or contributed to a serious injury or death or malfunctioned in a way that could likely cause or contribute to a serious injury or death if it were to recur. Any such MDR that reports a significant adverse event could result in negative publicity, which could harm our reputation and future sales.

The use, misuse or off-label use of our products may result in injuries that lead to product liability suits, which could be costly to our business.

The CGuard Prime carotid stent system has been approved by the FDA for the treatment of patients who require carotid revascularization and meet certain treatment parameters. If physicians expand the patient population in which they elect to use our products that is outside of the intended use approved by the FDA, then the use, misuse, or off-label use of our products may result in outcomes and adverse events including stroke, myocardial infarction and death, potentially leading to product liability claims. However, we cannot prevent a physician from using our products for off-label applications or using components or products that are not our products when performing CAS. In addition, we cannot guarantee that physicians are trained by us or their peers prior to utilizing our products. Complications resulting from the use of our products off-label or use by physicians who have not been trained appropriately, or at all, may expose us to product liability claims and harm our reputation. Moreover, if the FDA determines that our promotional materials or physician training, including our paid consultants' educational materials, constitutes promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to enforcement action, including warning letters, untitled letters, fines, penalties, or seizures. If we are found to have promoted such off-label uses, we may become subject to significant liability. The federal government has levied large civil and criminal fines and/or other penalties against companies for alleged improper promotion and has investigated, prosecuted, and/or enjoined several companies from engaging in off-label promotion.

In addition, if our products are defectively designed, manufactured or labeled, contain defective components or are misused, we may become subject to costly litigation initiated by physicians, hospitals or patients. Product liability claims are especially prevalent in the medical device industry and could harm our reputation, divert management's attention from our core business, be expensive to defend and may result in sizable damage awards against us. Although we maintain product liability insurance, we may not have sufficient insurance coverage for future product liability claims. We may not be able to obtain insurance in amounts or scope sufficient to provide us with adequate coverage against all potential liabilities. Any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, harm our reputation, significantly increase our expenses, and reduce product sales. Product liability claims could cause us to incur significant legal fees and deductibles and claims in excess of our insurance coverage would be paid out of cash reserves, harming our financial condition and operating results.

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 arising in or outside the ordinary course of business that could negatively affect our business operations and financial condition. These suits could concern issues including contract disputes, employment actions, employee benefits, taxes, environmental, health and safety, fraud and abuse, personal injury, product liability matters and securities class actions, which are typically expensive to defend. Such claims and litigation proceedings may be brought by third parties, including our competitors, advisors, service providers, partners or collaborators, employees, and governmental or regulatory bodies. Any claims and lawsuits, and the disposition of such claims and lawsuits, could be time-consuming and expensive to resolve, divert management attention and resources, and lead to attempts on the part of other parties to pursue similar claims. We may not be able to determine the amount of any potential losses and other costs we may incur due to the inherent uncertainties of litigation and settlement negotiations. In the event we are required or decide to pay amounts in connection with any claims or lawsuits, such amounts could be significant and could have a material adverse impact on our liquidity, business, financial condition and results of operations. In addition, depending on the nature and timing of any such dispute, a resolution of a legal matter could materially affect our future operating results, our cash flows, or both. Additionally, we may be unable to maintain our existing directors' and officers' liability insurance in the future at satisfactory rates or adequate coverage amounts and may incur significant increases in insurance costs.

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 securityof 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.

If we are unable to manage the anticipated growth of our business, our future revenue and operating results may be harmed.

Our past growth has provided, and our future growth may create, challenges to our organization. The number of our employees has increased significantly during the past several years and in the future, we expect to hire and train new personnel as we continue to grow and expand our operations. Any growth that we experience in the future will require us to expand our sales, general and administrative personnel, manufacturing and distribution operations, and facilities and information technology, or IT, and infrastructure. In addition to the need to scale our organization, future growth will impose significant added responsibilities on management, including the need to identify, recruit, train and integrate additional employees. Rapid expansion in personnel could mean that less experienced people manufacture, market and sell our products, which could result in inefficiencies and unanticipated costs, reduced quality and disruptions to our operations. In addition, rapid and significant growth may strain our administrative and operational infrastructure. Our ability to manage our business and growth will require us to continue to improve our operational, financial and management controls, reporting systems and procedures. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy, and our business could be harmed.

As demand for our products or any of our future products increases, we will need to continue to scale our capacity, expand customer service, billing and systems processes and enhance our internal quality assurance program. We cannot assure you that any increases in scale, related improvements and quality assurance will be successfully implemented or that appropriate personnel will be available to facilitate the growth of our business. Failure to implement necessary procedures, transition to new processes or hire the necessary personnel could result in higher costs or inability to meet increased demand. If we encounter difficulty meeting market demand, quality standards or physician expectations, our reputation could be harmed and our business could suffer.

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.

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.

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 security situation in Israel and 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, 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.

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 reality 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.

Scrutiny of sustainability and environmental, social, and governance ("ESG") initiatives could increase our costs or otherwise adversely impact our business.

Public companies have recently faced scrutiny related to ESG practices and disclosures from certain investors, capital providers, shareholder advocacy groups, other market participants and other stakeholder groups. Such scrutiny may result in increased costs, enhanced compliance or disclosure obligations, or other adverse impacts on our business, financial condition, or results of operations. Scrutiny may come from stakeholders both supporting and opposing ESG initiatives, adding complexity to our compliance and communication efforts.

If our ESG practices and reporting do not meet investor or other stakeholder expectations, we may be subject to investor or regulator engagement regarding such matters. Failure to comply with applicable ESG rules or regulations could lead to penalties, enforcement actions, adverse publicity, or could negatively affect our reputation, access to capital, or employee retention.

Evolving ESG-related regulations, such as sustainability reporting requirements, supply-chain diligence obligations, and international frameworks (including the EU Corporate Sustainability Reporting Directive (CSRD)), may also affect our contract manufacturers, suppliers, and other third parties. Any inability of such third parties to comply with applicable ESG standards may disrupt our supply chain or otherwise negatively effect our business, financial condition, or results of operations.

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.

Changes to trade policy, including tariff and customs regulations, or failure to comply with such regulations may have an adverse effect on our reputation, business, financial condition and results of operations.

Changes in U.S. or international social, political, regulatory and economic conditions or in laws and policies governing trade, manufacturing, development and investment in the countries where we currently conduct our business could adversely affect our business, reputation, financial condition and results of operations. Changes or proposed changes in U.S. or other countries' trade policies may result in restrictions and economic disincentives on international trade.

We currently manufacture, package and distribute all of our products, including CGuard Prime, which we commercially launched in July 2025 following FDA approval of the PMA in June 2025, at our own facility in Israel. To support our anticipated production growth following the commercialization of CGuard Prime, we have engaged Aptyx to expand our manufacturing capacity of CGuard Prime finished goods to full-scale production at their ISO Class 7 cleanroom facility in North Carolina. While we are in the process of establishing manufacturing operations in the United States with Aptyx, this transition will take time, and until it is operational, we expect to rely entirely on product shipments from Israel to the U.S. market.

The U.S. government has recently imposed, or is currently considering imposing, tariffs on certain products, including medical devices, on certain trade partners, including Israel. On February 20, 2026, the Supreme Court ruled that the International Emergency Economic Powers Act ("IEEPA") does not authorize a U.S. President to impose tariffs during peacetime national emergencies and that the challenge to the legality of the tariffs imposed under IEEPA (the "incremental tariffs") was within the exclusive jurisdiction of the U.S. Court of International Trade. In response to this ruling, the U.S. President signed a proclamation imposing a new 10% global tariff under Section 122 of the Trade Act of 1974, effective February 24, 2026, and subsequently increased these tariffs to 15% on February 21, 2026. Section 122 tariffs are subject to a 150-day statutory limit unless extended by Congress. In addition, the Office of the U.S. Trade Representative has announced it will initiate new Section 301 investigations into trading partners' unfair practices, which could result in additional tariffs.

Tariffs, economic sanctions and other changes in U.S. trade policy have in the past and could in the future trigger retaliatory actions by affected countries, and certain foreign governments have instituted or are considering imposing retaliatory measures on certain U.S. goods. Further, any emerging protectionist or nationalist trends (whether regulatory- or consumer-driven) either in the United States or in other countries could affect the trade environment. Our business, like many other corporations, would be impacted by changes to the trade policies of the United States and foreign countries (including governmental action related to tariffs, international trade agreements, or economic sanctions). We cannot predict whether, and to what extent, trade policies will change in the future. If tariffs or other trade restrictions are imposed on products manufactured in Israel while we remain dependent on Israeli manufacturing, our cost of goods sold for the U.S. market may increase materially, which could negatively impact our gross margins and limit our pricing flexibility. Additionally, changes to trade agreements or customs regulations between the U.S. and Israel could increase lead times, introduce logistical complexities, or require modifications to our supply chain planning. These or similar trade-related developments may have a material adverse effect on our business, financial condition, and results of operations.

Changes in tax laws could have a material adverse effect on our business, cash flow, results of operations or financial conditions.

We are subject to tax laws, regulations, and policies of several taxing jurisdictions. Changes in tax laws, as well as other factors, could cause us to experience fluctuations in our tax obligations and effective tax rates and otherwise adversely affect our tax positions and/or our tax liabilities. Recently, legislation commonly known as the One Big Beautiful Bill Act (OBBBA) was signed into law in July 2025, which enacts significant changes to U.S tax and related laws, including but not limited to current deduction of domestic research expenses, increasing the limit of the deduction of interest expense to thirty percent of EBITDA and one hundred percent bonus depreciation on eligible property acquired after January 19, 2025. There were no changes to the Company's tax expense or effective income tax rate given the Company's valuation allowance position. Further, many countries, and organizations such as the Organization for Economic Cooperation and Development have proposed implementing changes to existing tax laws. Any of these developments or changes in federal, state, or international tax laws or tax rulings could adversely affect our effective tax rate and our operating results. There can be no assurance that our effective tax rates, tax payments, or tax credits and incentives will not be adversely affected by these or other developments or changes in law.

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 ("NIS").

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 ("NIS"). In 2025, approximately 39% of our revenues were denominated in U.S. dollars and approximately 61% in other currencies, primarily Euros. We expect a substantial portion of our revenues will continue to be generated in U.S. dollars and Euros, particularly as U.S. sales increase following FDA approval of CGuard Prime, while a significant portion of our expenses, principally salaries and related personnel expenses, is paid in NIS. As a result, our operating results are exposed primarily to movements in the USD/NIS and EUR/NIS exchange rates. Appreciation of the NIS against the U.S. dollar or the Euro increases the U.S. dollar cost of our shekel-denominated expenses and may adversely impact our net loss or net income (if any). Based on our 2025 expense levels, a 10% appreciation of the NIS against the U.S. dollar would have decreased our net income by approximately $1.1 million.

Foreign exchange rates may fluctuate due to many factors, including interest-rate differentials between markets, capital flows, monetary policy decisions, geopolitical events, global macroeconomic developments, and investor sentiment toward Israel and regional markets. These factors may cause the NIS to appreciate or depreciate against the U.S. dollar or the Euro independent of local inflation levels. If the NIS strengthens without a corresponding increase in our foreign-currency revenues, our U.S. dollar-measured costs will rise.

The value of the NIS relative to the Euro, the U.S. dollar, and other currencies has fluctuated significantly. For example, the shekel appreciated on average by 12.5% relative to the U.S. dollar in 2025, after depreciating by 0.4% in 2024 and by 3.1% in 2023, thereby increasing, in 2025, the U.S. dollar cost of our shekel-denominated expenses. The Euro also appreciated relative to the dollar in 2025 on average, by 11.3%, thereby increasing the U.S. dollar cost of our Euro-denominated expenses. 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 operations and ability to reach profitability.

Although we are incorporated in the State of Delaware and our headquarters are in Miami, Florida, our current manufacturing facility, certain of our key personnel and one of our offices 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 neighboring countries and terrorist organizations active in the region, including Iran, Hamas (an Islamist terrorist militia and political group that controls the Gaza strip), Hezbollah (an Islamist terrorist militia and political group based in Lebanon) and other terrorist organizations active in the region. These conflicts have involved missile strikes, hostile infiltrations and terrorism against civilian targets in various parts of Israel, which have negatively affected business conditions in Israel.

In recent years, Israel has been engaged in sporadic armed conflicts with Hamas, an Islamist terrorist group that controls the Gaza Strip, with Hezbollah, an Islamist terrorist group that controls large portions of southern Lebanon, and with Iranian-backed military forces in Syria. In addition, Iran has threatened to attack Israel and may be developing nuclear weapons. Iran is also believed to have a strong influence among extremist groups in the region, such as Hamas in Gaza, Hezbollah in Lebanon, the Houthi movement in Yemen and various rebel militia groups in Syria and Iraq. On October 7, 2023, Hamas launched a series of attacks on civilian and military targets in Southern Israel and Central Israel, to which the Israel Defense Forces responded. On October 9, 2025, Israel, Hamas, the United States and other countries in the region agreed to a framework for a ceasefire in Gaza between Israel and Hamas.

In addition, both Hezbollah and the Houthi movement attacked military and civilian targets in Israel, to which Israel responded, including through increased air and ground operations in Lebanon. In addition, the Houthi movement attacked international shipping lanes in the Red Sea, to which both Israel and the United States responded. While a ceasefire was brokered between Israel and Hezbollah in November 2024, in March 2026, hostilities resumed along Israel's northern border with Lebanon, when Hezbollah resumed its attacks as part of a broader regional escalation. In response, Israel resumed military operations against Hezbollah in Lebanon.

Further, in April 2024 and October 2024, Iran launched a series of drone and missile strikes against Israel, to which Israel responded. In addition, in response to ongoing Iranian aggression and support of proxy attacks against Israel, on June 13, 2025, Israel conducted a series of preemptive defensive air strikes in Iran targeting Iran's nuclear program and military commanders. While a ceasefire was reached in June 2025 following 12 days of hostilities, on February 28, 2026, the United States and Israel launched coordinated military strikes against Iran, including attacks on strategic military infrastructure and leadership targets, with the stated aim of degrading Iran's capacity to conduct or support hostile operations against them. In response, Iran has fired missiles and drones toward population centers and military installations in Israel, Europe and neighboring countries in the Gulf region, and also launched counter-strikes against U.S. forces and allied bases throughout the Gulf region. A broader regional conflict involving additional state and non-state actors remains a significant risk How long and how severe the conflicts in Gaza, Northern Israel, Lebanon, Iran or the broader region last and become is unknown at this time and any renewed or continued clash among Israel, Hamas, Hezbollah, Iran or other countries or militant groups in the region may escalate in the future into a greater regional conflict. Continued military escalation, retaliatory actions, or broader regional involvement may adversely affect economic conditions, disrupt markets, and create uncertainty that could negatively impact our business, financial condition and results of operations.

In connection with the Israeli security cabinet's declaration of war against Hamas and possible hostilities with other organizations, several hundred thousand Israeli military reservists were drafted to perform immediate military service, including five full time employees in Israel of ours. Although many of such military reservists have since been released, including all our employees, they may be called up for additional reserve duty, depending on developments in the war in Gaza and along Israel's other borders. Military service call ups that result in absences of personnel from us for an extended period of time may materially and adversely affect our business, prospects, financial condition and results of operations. As of the date hereof, we currently have 66 full-time employees located in Israel.

To date, our operations have not been adversely affected by this situation. Five of our full-time employees in Israel were called to reserve duty in the Israel Defense Forces, all of whom have since been released. We currently manufacture our CGuard EPS and CGuard Prime at our facility in Tel Aviv, Israel. If there were a disruption to our existing manufacturing facility or our ability to procure raw materials and ship our products, we would have no other means of manufacturing and distributing CGuard EPS or CGuard Prime until we were able to restore the manufacturing and distribution capability at our facility or develop alternative manufacturing facilities and distribution capabilities. However, the intensity and duration of the security situation in Israel have been difficult to predict, as are the economic implications on our business and operations and on Israel's economy in general. If the war extends for a long period of time or expands to other fronts, our operations may be harmed.

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.

Under applicable U.S. and Israeli law, we may not be able to enforce covenants not to compete and therefore may be unable to prevent our competitors from benefiting from the expertise of some of our former employees. In addition, employees may be entitled to seek compensation for their inventions irrespective of their agreements with us, which in turn could affect our future profitability.

We generally enter into non-competition agreements with our employees and certain key consultants, or our employment and consulting agreements contain non-competition provisions. These agreements, to the extent they are in place and in effect, prohibit our employees and certain key consultants, if they cease working for us, from competing directly with us or working for our competitors or clients for a limited period of time. We may be unable to enforce these agreements under the laws of the jurisdictions in which our employees work and it may be difficult for us to restrict our competitors from benefitting from the expertise our former employees or consultants developed while working for us. For example, Israeli courts have required employers seeking to enforce non-compete undertakings of a former employee to demonstrate that the competitive activities of the former employee will harm one of a limited number of material interests of the employer which have been recognized by the courts, such as the secrecy of a company's confidential commercial information or the protection of its intellectual property. If we cannot demonstrate that such interests will be harmed, we may be unable to prevent our competitors from benefiting from the expertise of our former employees or consultants and our ability to remain competitive may be diminished.

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.

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.

If we fail to maintain compliance with the Nasdaq minimum listing requirements, our common stock will be subject to delisting. Our ability to publicly or privately sell equity securities and the liquidity of our common stock could be adversely affected if our common stock delisted.

Our common stock is listed on the Nasdaq Capital Market. To maintain our listing, we are required to satisfy certain continued listing requirements, including, among other things, minimum bid price, minimum market value of publicly held shares, minimum stockholders' equity (or other financial metrics), corporate governance requirements, and timely filing of periodic reports with the SEC.

There can be no assurance that we will be able to comply with Nasdaq's continued listing standards in the future. If we fail to satisfy any of Nasdaq's continued listing requirements, we may receive a deficiency notice from Nasdaq and, depending on the nature of the deficiency, may be afforded a limited period of time to regain compliance. However, certain deficiencies may not be subject to a cure period or may result in immediate delisting. If we do not regain compliance within any applicable cure period, or if Nasdaq determines that we are not eligible for a compliance period, Nasdaq may determine to delist our common stock.

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 takeovers 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 1C. Cybersecurity

Risk Management and Strategy

We maintain a cybersecurity risk-management program that is scaled to our business, products, and data environment. Our products are physical medical devices without integrated software, and we do not collect or store patient health information in the ordinary course. However, we do rely on information systems that support our operations, and we maintain sensitive business information.

Our cybersecurity processes include written policies and procedures that address threat identification, user practices, incident response, backup and recovery, and data handling. We periodically engage third parties to assess our environment. We periodically engage independent third-party cybersecurity experts to perform risk assessments and penetration testing. In the past, external providers conducted cybersecurity assessments and provided advisory services, including CISO-as-a-service support. In early 2026, we engaged another independent cybersecurity firm to perform an updated cybersecurity risk assessment, and management intends to prioritize remediation activities once the results are completed.

We also manage certain third-party risks through vendor selection and contract provisions and by limiting access to our systems and data to an extent reasonably practicable for business operations. We do not disclose further technical details of our controls to avoid increasing security risk.

Governance

Our board of directors oversees enterprise-level risks generally as part of its overall risk-management responsibilities. Cybersecurity risk is managed at the executive level and incorporated into this broader framework. Management provides updates to our board of directors on cybersecurity matters as appropriate in the context of overall operational risk.

Management's Role and Expertise

Our Executive Vice President of Finance and Regional Manager has executive responsibility for cybersecurity risk management and coordinates the program with our internal information technology ("IT") team and external advisors. Day-to-day cybersecurity activities are performed by our internal IT staff, including an IT professional with hands-on experience in systems administration and cybersecurity disciplines. Our Management experience has been developed through overseeing our cybersecurity processes and working with external providers. These responsibilities include, but are not limited to, maintaining and updating policies, coordinating periodic assessments and testing, managing user access practices and backup routines, and leading incident response activities if needed.

Third-Party Engagement

We use external cybersecurity firms for risk assessments, penetration testing, and advisory services. These engagements supplement our internal capabilities and help identify and prioritize risk mitigation. Contracts with key providers contain customary security and confidentiality provisions.

Incident Experience and Materiality

As of the date of this Annual Report on Form 10-K, we have not identified any cybersecurity incidents that have materially affected our business strategy, results of operations, or financial condition. We cannot guarantee that future incidents will not occur, and we may not promptly detect all incidents despite our efforts. For more information about these risks, please see "Item 1.A – Risk Factors – Risks Related to Our Business Operations – Our business and operations would suffer in the event of computer system failures, cyber-attacks or deficiencies in our cyber-security." in this Annual Report on Form 10-K.

Insurance

We maintain cyber risk insurance. However, such insurance may not cover all losses or may be subject to exclusions or disputes.

Item 2. Properties.

United States

In October 2024, we established our global headquarters in Miami, Florida. We lease approximately 10,782 square feet of general office space, including onsite shipping and receiving areas, located in Suites 215 and 280 at 6303 Waterford District Drive, Miami, Florida 33126.

We took possession of Suite 215 on November 1, 2024, and Suite 280 on May 18, 2025, following the landlord's completion of construction. The lease for the combined premises extends through September 30, 2030, and includes a five-year extension option in accordance with the terms of the lease.

We have provided a $500,000 security deposit under the lease, which is refundable in stages over the lease term, subject to our compliance with the lease. Pursuant to the lease, we paid a base rent of $22,911.75 per month during the first year of the Term, increasing on an incremental basis each subsequent year of the Term, which as of March 18, 2026 is $22,911.75. In addition to base rent, we are responsible for customary lease-related expenses, including taxes, operating costs, and utilities.

Israel

We also maintain a leased 1,830-square-meter office and manufacturing facility in Tel Aviv, Israel, where we produce and assemble our CGuard EPS and CGuard Prime products. The facility has capacity to manufacture approximately 5,500 products per quarter based on a single-shift schedule. We believe our current facility is sufficient to meet anticipated demand through additional staffing or the addition of a second production shift. The lease for this facility currently runs through December 31, 2028.

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 17, 2026, was $1.79 per share.

Record Holders

As of March 18, 2026, we had 329 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. Any future determination relating to our dividend policy will be at the discretion of our board of directors and will depend on a number of factors, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects, our strategic goals and plans to expand our business, applicable law and other factors that our board of directors may deem relevant.

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. The discussion that follows includes a comparison of our results of operations and liquidity and capital resources for fiscal years 2025 and 2024. For a comparison of our results of operations and financial condition for fiscal years 2024 and 2023, see "Item 7—Management's Discussion and Analysis of Financial Condition and Results of Operations" of our 2024 Annual Report on Form 10-K, filed with the SEC on March 12, 2025.

Overview

We are a medical device company specializing in the development and commercialization of products for the treatment of carotid artery disease and other vascular conditions. Our portfolio includes two commercial products based on our proprietary CGuard carotid stent technology, designed to provide market-leading embolic protection during and after stenting procedures. A stent is an expandable scaffold-like metallic device placed in an artery to widen the lumen and restore blood flow.

Our first product, the CGuard Carotid Embolic Prevention System ("CGuard EPS"), integrates a self-expanding nitinol stent with a MicroNet mesh sleeve as a single device for carotid artery revascularization. In January 2024, we received CE Mark recertification for CGuard EPS under the EU Medical Device Regulation ("MDR"). Our CGuard EPS previously held CE Mark approval under the former Medical Device Directive ("MDD"). CGuard EPS is marketed in over 30 countries outside the United States through a network of distributors.

Our second product, the CGuard Prime Carotid Stent System ("CGuard Prime"), uses the same stent and MicroNet mesh with a differentiated deployment mechanism. CGuard Prime received premarket approval ("PMA") by the U.S. Food and Drug Administration ("FDA") on June 23, 2025, and is marketed exclusively in the United States through our direct salesforce. It also received MDR CE Mark approval on June 12, 2025.

For more information regarding our business and operations, see "Item 1 – Business" above.

Recent Developments

Private Placements

May 2023 Private Placement Offering

On May 12, 2023, we entered into a securities purchase agreement pursuant to which we issued and sold in a private placement (the "May 2023 Private Placement Offering") (i) an aggregate of 10,266,270 shares of common stock (the "May 2023 Shares"), (ii) pre-funded warrants to purchase up to 15,561,894 shares of common stock (the "May 2023 Pre-Funded Warrants"), and (iii) warrants to purchase up to an aggregate of 51,656,328 shares of common stock (the "May 2023 Warrants"), consisting of Series H warrants, Series I warrants, Series J warrants and Series K warrants.

The May 2023 Shares and associated warrants were sold at an offering price of $1.6327 per share and associated warrants, and the May 2023 Pre-Funded Warrants were sold at an offering price of $1.6326 per May Pre-Funded Warrant and associated warrants. Aggregate gross proceeds totaled approximately $42.2 million, and after deducting placement agent fees and other issuance costs of approximately $4.6 million, net proceeds to the Company were approximately $37.6 million.

Terms of the May 2023 Pre-Funded Warrants

The May 2023 Pre-Funded Warrants were immediately exercisable at an exercise price of $0.0001 per share and did not expire until exercised in full. As of the date of this Annual Report on Form 10-K, the May 2023 Pre-Funded Warrants have been exercised in full. Under their terms, holders were not able to exercise a Pre- May 2023 Funded Warrant if the exercise would result in the holder beneficially owning more than 4.99% or 9.99% of our outstanding shares of common stock (as elected by the holder), subject to customary permitted increases with advance notice.

Terms of the May 2023 Warrants (Series H, I, J and K)

The May 2023 Warrants were immediately exercisable at an exercise price of $1.3827 per share and are exercisable until the earlier of (i) five years after issuance and (ii) the applicable milestone-triggered expiration date, as follows:

- Series H Warrants: expire 20 trading days following our public release of one-year primary and secondary endpoint results from the C-GUARDIANS pivotal trial.
- Series I Warrants: expire 20 trading days following the announcement of PMA by the FDA for CGuard Prime 135 cm carotid stent system.
- Series J Warrants: expire 20 trading days following our announcement of FDA approval for the SwitchGuard system and CGuard Prime 80 cm carotid stent system.
- Series K Warrants: expire 20 trading days following the end of the fourth fiscal quarter after the fiscal quarter in which the first U.S. commercial sale of the CGuard carotid stent system occurs.

The May 2023 Warrants may be exercised on a cashless basis if there is no effective registration statement for the underlying shares of common stock issuable upon the exercise thereof. A registration statement on Form S-3 (File No. 333-272149) registering the shares underlying the May 2023 Warrants was declared effective on June 2, 2023.

Milestone-Based Exercises Under the May 2023 Warrants

Following the achievement of the applicable milestones during 2024 and 2025, the May 2023 Warrants were exercised as follows:

Series H Warrant Exercise

After we announced positive one-year results from the C-GUARDIANS pivotal trial, all Series H Warrants were exercised in full into 292,996 shares of common stock and 12,621,090 pre-funded warrants. Gross proceeds totaled approximately $17.9 million, and after deducting placement agent fees and issuance costs of approximately $1.0 million, net proceeds were approximately $16.9 million.

Series I Warrant Exercise

Following our June 24, 2025 announcement that the FDA granted PMA approval for CGuard Prime in the United States, all Series I Warrants were exercised in full into 2,352,393 shares of common stock and 10,561,685 pre-funded warrants. Gross proceeds totaled approximately $17.9 million, and net proceeds were approximately $16.9 million after issuance costs of approximately $1.0 million.

August 2025 Private Placement Offering

On July 30, 2025, we entered into a securities purchase agreement with investors pursuant to which we issued and sold in a private placement (the "August 2025 Private Placement Offering") an aggregate of 6,791,380 shares (the "August 2025 Shares") of common stock and pre-funded warrants (the "August 2025 Pre-Funded Warrants") to purchase up to 9,764,804 shares of common stock, at an offering price of $2.42 per August 2025 Share and $2.4199 per August 2025 Pre-Funded Warrant. The August 2025 Pre-Funded Warrants are immediately exercisable at an exercise price of $0.0001 per share and will not expire until exercised in full.

Aggregate gross proceeds totaled approximately $40.1 million, after deducting placement agent fees and other issuance costs of approximately $3.1 million, net proceeds to the Company were approximately $37 million.

PMA approval of the CGuard Prime Carotid Stent System and Commercial Launch in the United States

On June 23, 2025, the FDA granted PMA approval of CGuard Prime in the United States.

Following such approval, in July 2025, we announced the official commercial launch of CGuard Prime in the United States. In October 2024, we established our global headquarters in Miami, Florida to support the U.S. launch and commercialization of CGuard Prime.

CE Mark Approval for CGuard Prime Under European MDR

On June 12, 2025, we received CE Mark approval under the EU's MDR for CGuard Prime.

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

As applicable to these consolidated financial statements, the most significant estimates and assumptions relate to the determination of the lease terms in operating leases.

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.

Results of Operations

Year ended December 31, 2025 compared to the year ended December 31, 2024

Revenues. For the year ended December 31, 2025, revenue was $8,979,000, an increase of $1,970,000, or 28.1%, compared to $7,009,000 during the year ended December 31, 2024. The increase was driven by the commercial launch of the CGuard Prime product through direct sales in the U.S. following FDA approval in June 2025, and continued growth in sales of the CGuard EPS product through distributors in international markets.

With respect to regions, the increase in revenue was primarily attributable to $1,385,000 increase in North America due to the commercial launch of CGuard Prime in the U.S. in the second half of 2025, and a $585,000 increase in international markets from continued penetration of our CGuard EPS product.

Gross Profit. For the year ended December 31, 2025, gross profit (revenue less cost of revenues) was $2,649,000 compared to gross profit of $1,506,000 for 2024. The increase resulted mainly from the increase in revenue year-on-year.

Gross margin represents our gross profit as a percentage of our revenue. Gross margin was 29.5% for the year ended December 31, 2025, an increase of 8.0 percentage points compared to 21.5% for the year ended December 31, 2024. This increase in gross margin resulted primarily from a more favorable revenue mix driven by direct U.S. sales, which carry higher margins due to a higher average selling price per unit compared with international distributor sales.

Research and Development Expenses. For the year ended December 31, 2025, research and development expenses were $15,003,000, an increase of $1,369,000, or 10.0%, compared to $13,634,000 during the year ended December 31, 2024. This increase resulted primarily due to higher staff levels in connection with our expansion in the U.S., and higher development and clinical expenses for the SwitchGuard NPS and CGuard Prime 80 cm carotid stent system, respectively. These increases were partially offset by a decrease in expenses for the C-GUARDIANS clinical study and related product preparation activity prior to the FDA approval of CGuard Prime in June 2025.

Selling and Marketing Expenses. For the year ended December 31, 2025, selling and marketing expenses were $16,553,000, an increase of $10,484,000, or 172.7%, compared to $6,069,000 during the year ended December 31, 2024. This increase resulted primarily from higher commercial staffing levels in connection with the commercial launch of CGuard Prime in the U.S.

General and Administrative Expenses. For the year ended December 31, 2025, general and administrative expenses were $20,707,000, an increase of $5,401,000, or 35.3%, compared to $15,306,000 during the year ended December 31, 2024. The increase was primarily driven by new hires, professional services expenses, and occupancy-related costs related to the Company's expansion of U.S. operations to support the commercial launch of CGuard Prime.

Financial Income, net. For the year ended December 31, 2025, financial income was $891,000, a decrease of $666,000, compared to $1,557,000 during the year ended December 31, 2024. The decrease in financial income primarily resulted from a $403,000 increase in financial expenses related to changes in exchange rates and a $264,000 decrease in income from investment in marketable securities and money market funds due to lower interest rates.

Tax Expenses. For the year ended December 31, 2025, tax expenses increased by $4,000 compared to the year ended December 31, 2024. Our expenses for income taxes reflect primarily the tax liability due to potential tax exposure.

Net Loss. Our net loss for the year ended December 31, 2025 was $48,786,000, an increase of $16,781,000, or 52.4%, compared to $32,005,000 during the year ended December 31, 2024. The increase in net loss resulted primarily from an increase of $17,254,000 in operating expenses.

Liquidity and Capital Resources

We had an accumulated deficit as of December 31, 2025, of $302.3 million, as well as a net loss of $48.8 million and negative operating cash flows for fiscal year 2025. We expect to continue incurring losses and negative cash flows from operations until we expand our commercial revenue to a scale that funds our commercial resources, development activities and support functions. As a result of these expected losses and negative cash flows from operations, along with our current cash position, we believe we do not have sufficient resources to fund operations for at least the next 12 months. Therefore, there is substantial doubt about our ability to continue as a going concern.

Our plans include continued commercialization of our products and raising capital through sale of additional equity securities, debt or capital inflows from strategic partnerships and exercise of warrants. There are no assurances, however, that we will be successful in obtaining the level of financing needed for our operations. If we are unsuccessful in commercializing our products or raising capital, we may need to reduce activities, curtail or cease operations.

In May 2023, we closed the May 2023 Private Placement Offering that resulted in aggregate gross proceeds of approximately $42.2 million, before deducting fees payable to the placement agent and other offering expenses payable by us. If the May 2023 Warrants are exercised in cash in full this would result in an additional $71.4 million of gross proceeds (of which approximately $33.8 million has been received as of the date of this Annual Report on Form 10-K). There can be no assurance that we will achieve any of the remaining milestones set forth in the May 2023 Warrants or that the outstanding May 2023 Warrants will be exercised in cash in full.

Following the announcement of the one year follow up study results from the Company's C-GUARDIANS trial, Series H Warrants to purchase 12,914,086 shares of common stock were exercised in full into 292,996 shares of common stock and pre-funded warrants to purchase 12,621,090 shares of common stock. The net proceeds from the exercise of the Series H Warrants were $16.9 million after deducting placement agent fees. The Series H warrants, each exercisable at $1.3827 per common share and $1.3826 per pre-funded warrant, were issued as part of the May 2023 Private Placement Offering.

Following the announcement of the PMA approval of the CGuard Prime carotid stent system in the United States, Series I warrants to purchase 12,914,078 shares of common stock were exercised in full into 2,352,393 shares of common stock and pre-funded warrants to purchase 10,561,685 shares of common stock during June and July 2025. The net proceeds from the exercise of the Series I Warrants were $16.9 million after deducting placement agent fees. The Series I warrants, each exercisable at $1.3827 per common share and $1.3826 per pre-funded warrant, were issued as part of the May 2023 Private Placement Offering.

In May 2024, we entered into an Equity Distribution Agreement (the "Distribution Agreement") with Piper Sandler & Co., as sales agent ("Piper Sandler"). Pursuant to the Distribution Agreement, we may offer and sell from time to time, at our option, through or to Piper Sandler shares of our common stock having an aggregate offering price of up to $75 million (the "ATM Facility"). We will pay Piper Sandler a commission at a fixed rate of 3.0% of the aggregate gross proceeds from each sale of the shares under the Distribution Agreement. As of the date hereof, we sold 1,366,190 shares pursuant to the Distribution Agreement for aggregate gross proceeds of approximately $3,473,314.

In July 2025, we closed August 2025 that resulted in aggregate gross proceeds of approximately $40.1 million, before deducting fees payable to the placement agent and other offering expenses payable by us.

Year ended December 31, 2025 compared to the year ended December 31, 2024

General. As of December 31, 2025, we had cash and cash equivalents of $8,939,000 and marketable securities of $45,272,000, as compared to $18,916,000 of cash and cash equivalents and $15,721,000 marketable securities as of December 31, 2024. 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 manufacturing costs, research and development activities, sales and marketing efforts, finance and administrative expenses, capital expenditures and general working capital.

For the year ended December 31, 2025, net cash used in our operating activities increased by $13,235,000 to $35,103,000, from $21,868,000 during the same period in 2024. The primary reason for the increase in cash used in our operating activities was an increase of $13,163,000 in compensation costs paid during the year ended December 31, 2025 (from $12,013,000 in the year ended December 31, 2024 to $25,176,000 in the year ended December 31, 2025) and an increase of $1,509,000 in payments for third party related expenses and for professional services, offset, in part, by an increase of $1,374,000 in payments received from customers to $8,590,000 during the year ended December 31, 2025, from $7,216,000 during the same period in 2024.

Cash used in our investing activities was $30,560,000 during the year ended December 31, 2025, compared to cash provided by our investing activities of $12,641,000 during the year ended December 31, 2024. The primary reason for the increase in cash used in our investing activities is investments of $43,748,000, net of withdrawal in marketable securities.

Cash provided by financing activities for the year ended December 31, 2025, was $55,569,000. The source of the cash provided by financing activities during the year ended December 31, 2025, were the proceeds from the August 2025 Private Placement Offering as well as proceeds from issuance of shares received from our ATM Facility that resulted in approximately of $38,714,000 aggregate net proceeds and proceeds from the exercise of Series I Warrants of $16,855,000. Cash provided by financing activities for the year December 31, 2024, was $18,452,000. The principal source of the cash provided by financing activities during the year ended December 31, 2024, was the proceeds from exercise of warrants of $16,854,000 net of issuance costs and funds received from our ATM Facility that resulted in approximately $1,598,000 of aggregate net proceeds.

Contractual Obligations

Operating lease payments represent our commitment for future rent made under non-cancelable lease for our offices in the U.S. and Israel. The total future payments for our operating lease obligation on December 31, 2025, were approximately $3,966,000. For additional details regarding our lease, see Note 7 to our consolidated financial statements included in this Annual Report on Form 10-K.

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.

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):

- Report of Kesselman & Kesselman, Independent Registered Public Accounting Firm (PCAOB name: Kesselman & Kesselman C.P.A.s and PCAOB ID: 1309)
- Consolidated Balance Sheets as of December 31, 2025 and 2024
- Consolidated Statements of Operations for the Years Ended December 31, 2025 and 2024
- Consolidated Statements of Changes in Equity for the Years Ended December 31, 2025 and 2024
- Consolidated Statements of Cash Flows for the Years Ended December 31, 2025 and 2024
- Notes to Consolidated Financial Statements

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, 2025, 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, 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, 2025.

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, 2025. 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, 2025.

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, 2025, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

Insider Trading Plans and Arrangements

During the quarter ended December 31, 2025, none of our directors or officers notified us that they adopted, modified or terminated any Rule 10b5-1 trading arrangement or any non-Rule 10b5-1 trading arrangement as defined in Item 408(a) of Regulation S-K.

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

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

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.

Insider Trading Policy

We have adopted a statement of trading policies that governs the trading in our securities by our directors, officers and certain other covered persons, and which is reasonably designed to promote compliance with applicable insider trading laws, rules and regulations, and any listing standards applicable to the Company. A copy of the Insider Trading Policy is included as Exhibit 19.1 to this annual report. In addition, with regard to any trading in our own securities, it is our policy to comply with the federal securities laws and the applicable exchange listing requirements.

Clawback Policy

We have adopted an Executive Officer Clawback Policy (the "Clawback Policy"), in accordance with the Nasdaq listing standards and Exchange Act Rule 10D-1, which applies to our current and former executive officers. Under the Clawback Policy, we are required to recoup the amount of any Erroneously Awarded Compensation (as defined in the Clawback Policy) on a pre-tax basis within a specified lookback period in the event of any Accounting Restatement (as defined in the Clawback Policy), subject to limited impracticability exception.

Other Information

The remaining information required by this Item 10 will be included in our definitive Proxy Statement for the 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this Item 11 will be included in our definitive Proxy Statement for the 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

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

The information required by this Item 12 will be included in our definitive Proxy Statement for the 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

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

The information required by this Item 13 will be included in our definitive Proxy Statement for the 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

Item 14. Principal Accountant Fees and Services.

The information required by this Item 14 will be included in our definitive Proxy Statement for the 2026 Annual Meeting of Stockholders and is incorporated herein by reference.

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:

- Report of Kesselman & Kesselman, Independent Registered Public Accounting Firm (PCAOB name: Kesselman & Kesselman C.P.A.s and PCAOB ID: 1309)
- Consolidated Balance Sheets as of December 31, 2025 and 2024
- Consolidated Statements of Operations for the Years Ended December 31, 2025 and 2024
- Consolidated Statements of Changes in Equity for the Years Ended December 31, 2025 and 2024
- Consolidated Statements of Cash Flows for the Years Ended December 31, 2025 and 2024
- Notes to Consolidated Financial Statements

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 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)
3.8	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)
3.9	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)
3.10	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 13, 2023)
3.11	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)
4.1*	Description of Securities
10.1+	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)
10.2+	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)

10.3+	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)
10.4+	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)
10.5+	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)
10.6+	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)
10.7+	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)
10.8+	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)
10.9+	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)
10.10+	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)
10.11+	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)
10.12+	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)
10.13+	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)
10.14+	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)
10.15+	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)
10.16+	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)

10.17+	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)
10.18+	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).
10.19+	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).
10.20+	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)
10.21+	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)
10.22	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)).
10.23	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))
10.24+	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)
10.25+	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)
10.26+	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).
10.27+	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).
10.28+	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)
10.29+	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)

10.30+	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)
10.31+	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)
10.32+	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)
10.33+	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)
10.34+	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)
10.35+	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)
10.36+	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)
10.37+	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)
10.38+	Third Amendment to Employment Agreement, dated January 5, 2023, by and between InspireMD, Inc. and Marvin Slosman (incorporated by reference to Exhibit 10.64 to the Annual Report on Form 10-K filed on March 30, 2023)
10.39+^	Employment Agreement, dated November 2, 2020, by and between the Company and Andrea Tommasoli (incorporated by reference to Exhibit 10.66 to the Annual Report on Form 10-K filed on March 30, 2023)
10.40	Form of Securities Purchase Agreement dated as of May 12, 2023 between the Company and purchasers identified therein (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K dated May 15, 2023)
10.41	Form of Pre-Funded Warrant dated May 15, 2023 (incorporated by reference to Exhibit 10.2 of the Current Report on Form 8-K dated May 15, 2023)
10.42	Form of Series J Warrant dated May 15, 2023 (incorporated by reference to Exhibit 10.5 of the Current Report on Form 8-K dated May 15, 2023)

10.43	Form of Series K Warrant dated May 15, 2023 (incorporated by reference to Exhibit 10.6 of the Current Report on Form 8-K dated May 15, 2023)
10.44	Form of Registration Rights Agreement dated as of May 12, 2023 between the Company and purchaser identified therein (incorporated by reference to Exhibit 10.7 of the Current Report on Form 8-K dated May 15, 2023)
10.45+	Fourth Amendment to Employment Agreement, dated April 1, 2024, by and between InspireMD, Inc. and Marvin Slosman (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K dated April 2, 2024)
10.46	Equity Distribution Agreement by and between InspireMD, Inc. and Piper Sandler & Co., dated May 31, 2024 (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K dated May 31, 2024)
10.47	InspireMD, Inc. 2024 Inducement Plan (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K dated October 1, 2024)
10.48	Form of Inducement Restricted Stock Award Agreement (incorporated by reference to Exhibit 10.2 of the Current Report on Form 8-K dated October 1, 2024)
10.49	Form of Inducement Nonqualified Stock Option Agreement (incorporated by reference to Exhibit 10.3 of the Current Report on Form 8-K dated October 1, 2024)
10.50	Form of Inducement Restricted Stock Unit Award Agreement (incorporated by reference to Exhibit 10.4 of the Current Report on Form 8-K dated October 1, 2024)
10.51	Lease Agreement, dated October 9, 2024, by and between InspireMD, Inc. and ROIB Waterford, LLC (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K dated October 15, 2024)
10.52+	Employment Agreement, dated February 12, 2023, by and between InspireMD, Inc. and Shane Gleason (incorporated by reference to Exhibit 10.68 to the Annual Report on Form 10-K filed on March 12, 2025)
10.53+	Employment Agreement, dated June 2, 2025, by and between the Company and Michael Lawless (incorporated by reference to Exhibit 99.2 of the Current Report on Form 8-K dated June 3, 2025)
10.54	Form of Securities Purchase Agreement dated as of July 30, 2025 between the Company and purchasers identified therein (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K dated July 31, 2025)
10.55	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 10.2 of the Current Report on Form 8-K dated July 31, 2025)
10.56	Form of Registration Rights Agreement (incorporated by reference to Exhibit 10.3 of the Current Report on Form 8-K dated July 31, 2025)
10.57+	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)
10.58+	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)
10.59+	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)

10.60+	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)
10.61+	Fourth Amendment to Employment Agreement, dated August 14, 2020, by and between InspireMD, Inc. and Craig Shore (incorporated by reference to Exhibit 10.62 to the Annual Report on Form 10-K filed on March 5, 2024)
10.62+	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).
10.63+	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)
10.64+	Seventh Amendment to Employment Agreement, dated January 18, 2023, by and between InspireMD, Inc. and Craig Shore (incorporated by reference to Exhibit 10.65 to the Annual Report on Form 10-K filed on March 30, 2023)
10.65+	Eighth Amendment to Employment Agreement, dated April 1, 2024, by and between InspireMD, Inc. and Craig Shore (incorporated by reference to Exhibit 10.2 of the Current Report on Form 8-K dated April 2, 2024)
10.66+	Ninth Amendment to Employment Agreement, dated December 10, 2024, by and between InspireMD, Inc. and Craig Shore (incorporated by reference to Exhibit 10.1 of the Current Report on Form 8-K dated December 12, 2024)
19.1*	Insider Trading Policy
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
97.1	InspireMD, Inc. Executive Officer Clawback Policy (incorporated by reference to Exhibit 97.1 to the Annual Report on Form 10-K filed on March 5, 2024)
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 18, 2026

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 18, 2026
/s/ Michael Lawless Michael Lawless	Chief Financial Officer, Chief Administrative Officer, Secretary and Treasurer (principal financial and accounting officer)	March 18, 2026
/s/ Paul Stuka Paul Stuka	Chairman of the Board of Directors	March 18, 2026
/s/ Michael Berman Michael Berman	Director	March 18, 2026
/s/ Raymond Cohen Raymond Cohen	Director	March 18, 2026
/s/ Dan Dearen Dan Dearen	Director	March 18, 2026
/s/ Gary Roubin Gary Roubin	Director	March 18, 2026
/s/ Scott R. Ward Scott R. Ward	Director	March 18, 2026

INSPIREMD, INC.
CONSOLIDATED FINANCIAL STATEMENTS
AS OF AND FOR THE YEAR ENDED DECEMBER 31, 2025

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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, 2025 and 2024, 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, 2025 and 2024, 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 audits 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 firm of PricewaterhouseCoopers International Limited

Tel-Aviv, Israel

March 18, 2026

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

INSPIREMD, INC.
CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands, except share and per share data)

	December 31,	
	2025	**2024**
ASSETS		
CURRENT ASSETS:		
Cash and cash equivalents	$ 8,939	$ 18,916
Marketable securities	45,272	15,721
Accounts receivable:		
Trade, net	2,168	1,572
Other	400	682
Prepaid expenses	1,296	1,060
Inventory	3,396	2,570
TOTAL CURRENT ASSETS	61,471	40,521
NON-CURRENT ASSETS:		
Long term deposit	442	426
Property, plant and equipment, net	3,584	2,371
Operating lease right of use assets	2,758	2,360
Fund in respect of employee rights upon retirement	1,149	1,129
TOTAL NON-CURRENT ASSETS	7,933	6,286
TOTAL ASSETS	$ 69,404	$ 46,807

INSPIREMD, INC.
CONSOLIDATED BALANCE SHEETS
(U.S. dollars in thousands, except share and per share data)

	December 31,	
	2025	**2024**
LIABILITIES AND EQUITY		
CURRENT LIABILITIES:		
Accounts payable and accruals:		
Trade	1,255	1,254
Other	9,457	6,424
TOTAL CURRENT LIABILITIES	10,712	7,678
LONG-TERM LIABILITIES:		
Operating lease liabilities net of current maturities	2,224	1,796
Liability for employee rights upon retirement and others	1,267	1,247
TOTAL LONG-TERM LIABILITIES	3,491	3,043
TOTAL LIABILITIES	14,203	10,721
COMMITMENTS AND CONTINGENT LIABILITIES		
EQUITY:		
Common stock, par value $0.0001 per share; 150,000,000 shares authorized at December 31, 2025 and 2024; 43,532,281 and 26,611,033 shares issued and outstanding at December 31, 2025 and 2024, respectively	4	3
Preferred C shares, par value $0.0001 per share; 1,172,000 shares authorized at December 31, 2025 and 2024; 1,718 shares issued and outstanding at December 31, 2025 and 2024, respectively	*	*
Additional paid-in capital	357,489	289,589
Accumulated deficit	(302,292)	(253,506)
Total equity	55,201	36,086
Total liabilities and equity	$ 69,404	$ 46,807

* Represents an amount less than $1thousand

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

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

	Year Ended December 31,	
	2025	**2024**
REVENUES	$ 8,979	$ 7,009
COST OF REVENUES	6,330	5,503
GROSS PROFIT	2,649	1,506
OPERATING EXPENSES:		
Research and development	15,003	13,634
Selling and marketing	16,553	6,069
General and administrative	20,707	15,306
Total operating expenses	52,263	35,009
LOSS FROM OPERATIONS	(49,614)	(33,503)
FINANCIAL INCOME, net:	891	1,557
LOSS BEFORE TAX EXPENSES	(48,723)	(31,946)
TAX EXPENSES	63	59
NET LOSS	$ (48,786)	$ (32,005)
NET LOSS PER SHARE - basic and diluted	(0.76)	(0.76)
WEIGHTED AVERAGE NUMBER OF COMMON STOCK USED IN COMPUTING NET LOSS PER SHARE - basic and diluted	64,325,810	41,928,360

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		Preferred C shares		Additional paid-in capital	Accumulated deficit	Total equity
	Shares	Amount	Shares	Amount			
BALANCE as of January 1, 2025	**26,611,033**	**3**	**1,718**	*****	**289,589**	**(253,506)**	**36,086**
Net loss						**(48,786)**	**(48,786)**
Exercise of pre-funded warrants**	**3,381,651**	*****			*****		*****
Issuance of common stock, included at the market offering and pre-funded warrants net of $3,148 issuance costs	**7,510,293**	**1**			**38,713**		**38,714**
Exercise of Warrants Series I to 10,561,685 pre-funded warrants and 2,352,393 common stock, net of $1,000 issuance costs	**2,352,393**	*****			**16,855**		**16,855**
Share-based compensation related to restricted stock, restricted stock units and stock options award, net of forfeitures of 256,170 shares	**3,676,911**	*****			**12,332**		**12,332**
BALANCE as of December 31, 2025	**43,532,281**	**4**	**1,718**	*****	**357,489**	**(302,292)**	**55,201**

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

****** Until June 30, 2025, pre-funded warrants were exercised on a cashless basis; from July 1 through December 31, 2025, pre-funded warrants were exercised for cash.

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		Preferred C shares		Additional paid-in capital	Accumulated deficit	Total equity
	Shares	Amount	Shares	Amount			
BALANCE as of January 1, 2024	**21,841,215**	**2**	**1,718**	*****	**261,000**	**(221,501)**	**39,501**
Net loss						**(32,005)**	**(32,005)**
Exercise of pre-funded warrants	**1,728,382**	*****					*****
Exercise of Warrants Series H to 12,621,090 pre-funded warrants and 292,996 common stock, net of $1,000 issuance costs	**292,996**	**1**			**16,853**		**16,854**
Issuance of common stock, included at the market offering net of $81 issuance costs	**647,277**	*****			**1,598**		**1,598**
Share-based compensation related to restricted stock, restricted stock units and stock options award, net of forfeitures of 128,660 shares	**2,101,163**	*****			**10,138**		**10,138**
BALANCE as of December 31, 2024	**26,611,033**	**3**	**1,718**	*****	**289,589**	**(253,506)**	**36,086**

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

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

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

	Year ended December 31,	
	2025	**2024**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (48,786)	$ (32,005)
Adjustments required to reconcile net loss to net cash used in operating activities:		
Depreciation	476	280
Gain from sale of property, plant and equipment	(14)	-
Change in fair value of marketable securities, net of interest received	(359)	(894)
Change in liability for employees rights upon retirement	20	163
Other financial income	(133)	(51)
Change in operating right of use asset and operating leasing liability	554	(144)
Share-based compensation expenses	12,332	10,138
Gain on amounts funded in respect of employee rights upon retirement, net	(299)	(91)
Changes in operating asset and liability items:		
Increase in prepaid expenses	(236)	(482)
Decrease (increase) in trade receivables	(596)	232
Decrease (increase) in other receivables	282	(34)
Increase in inventory	(826)	(464)
Increase in trade payables	1	315
Increase in other payables	2,481	1,169
Net cash used in operating activities	(35,103)	(21,868)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of property, plant and equipment	(1,662)	(1,402)
Proceeds from sale of property, plant and equipment	15	-
Investment in long-term deposit	-	(426)
Investments in marketable securities	(56,840)	(14,444)
Proceeds from matured marketable securities	27,648	29,000
Amounts funded in respect of employee rights upon retirement	(91)	(87)
Amounts withdrawn in respect of employee rights upon retirement	370	-
Net cash provided by (used in) investing activities	(30,560)	12,641
CASH FLOWS FROM FINANCING ACTIVITIES:		
Proceeds from exercise of warrants, net of $1,000 issuance costs	16,855	16,854
Proceeds from issuance of shares and pre-funded warrants, net of $ 3,148 and $81 issuance costs, respectively	38,714	1,598
Net cash provided by financing activities	55,569	18,452
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	117	51
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(9,977)	9,276
BALANCE OF CASH AND CASH EQUIVALENTS AT BEGINNING OF YEAR	18,916	9,640
BALANCE OF CASH AND CASH EQUIVALENTS AT END OF YEAR	8,939	$ 18,916
SUPPLEMENTAL NON-CASH INVESTING AND FINANCING ACTIVITIES:		
Acquisition of right-of-use assets by means of lease liabilities	994	1,344
Non-cash purchase of property and equipment	28	189

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 in Israel and Germany, is a medical device company specializing in the development and commercialization of products for the treatment of carotid artery disease and other vascular conditions. The Company's portfolio includes two commercial products based on its proprietary CGuard™ carotid stent technology, designed to provide market-leading embolic protection during and after stenting procedures. A stent is an expandable scaffold-like metallic device placed in an artery to widen the lumen and restore blood flow.

The Company's first product, the CGuard™ Carotid Embolic Prevention System ("CGuard EPS"), integrates a self-expanding nitinol stent with a MicroNet™ mesh sleeve as a single device for carotid artery revascularization. In January 2024, the Company received CE Mark recertification for CGuard EPS under the EU Medical Device Regulation ("MDR"). The Company's CGuard EPS previously held CE Mark approval under the former Medical Device Directive ("MDD"). CGuard EPS is marketed in over 30 countries outside the United States, mainly in Europe, through a network of distributors.

The Company's second product, the CGuard™ Prime Carotid Stent System ("CGuard Prime"), uses the same stent and MicroNet mesh with a differentiated deployment mechanism. CGuard Prime received premarket approval ("PMA") by the U.S. Food and Drug Administration ("FDA") on June 23, 2025, and is marketed exclusively in the United States through the Company's direct salesforce. It also received MDR CE Mark approval on June 12, 2025.

b. Liquidity

The Company has an accumulated deficit as of December 31, 2025, as well as a history of net losses and negative operating cash flows. The Company expects to continue incurring losses and negative cash flows from operations until the Company expands its commercial revenue to a scale that funds its commercial resources, development activities and support functions. As a result of these expected losses and negative cash flows from operations, along with the Company's current cash position, the Company does not have sufficient resources to fund operations for at least the next 12 months. Therefore, there is substantial doubt about the Company's ability to continue as a going concern. These consolidated 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 products and raising capital through the sale of additional equity securities, debt or capital inflows from strategic partnerships and exercises of warrants. 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.

c. Risks Related to the Company's Operations in Israel

In recent years, Israel has been engaged in sporadic armed conflicts with neighboring countries and terrorist organizations active in the region, including Iran, Hamas, an Islamist terrorist group that controls the Gaza Strip, with Hezbollah, an Islamist terrorist group that controls large portions of southern Lebanon, and with Iranian-backed military forces in Syria. As of October 9, 2025, Israel, Hamas, the United States and other countries in the region agreed to a framework for a ceasefire in Gaza between Israel and Hamas. However, there are no assurances that such agreement will hold. In June 2025, following escalating threats and intelligence reports of imminent attacks, Israel conducted preemptive strikes on military and nuclear infrastructure in Iran. Iran responded with drones and missiles attacks, some of which caused civilian casualties and infrastructure damage. After 12 days of hostilities, a ceasefire between Israel and Iran was reached in June 2025. While a ceasefire was reached between Israel and Iran in June 2025 after 12 days of hostilities, on February 28, 2026, the United States and Israel launched coordinated military strikes against Iran, including attacks on strategic military infrastructure and leadership targets, with the stated aim of degrading Iran's capacity to conduct or support hostile operations against them. In response, Iran has fired missiles and drones toward population centers and military installations in Israel, Europe and neighboring countries in the Gulf region, and also launched counter-strikes against U.S. forces and allied bases throughout the Gulf region. In addition, in March 2026, hostilities resumed along Israel's northern border with Lebanon, when Hezbollah resumed its attacks as part of a broader regional escalation. In response, Israel resumed military operations against Hezbollah in Lebanon. A broader regional conflict involving additional state and non-state actors remains a significant risk. The intensity and duration of the security situation in Israel have been difficult to predict, as are the economic implications on our business and operations and on Israel's economy in general. As of the date of these consolidated financial statements, conflict continues in parts of the region. The Company's operations, including its current production facility, are located in Israel. At this time, these activities remain largely unaffected.

During the years ended December 31, 2025 and 2024, the impact of this war on the Company's results of operations and financial condition was immaterial, but such impact may increase, which could be material, as a result of the continuation, escalation or expansion of such war.

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 the determination of the lease terms in operating leases.

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 purchased with original maturities of three months or less from the purchase date to be cash equivalents. As of December 31, 2025 and 2024, cash and cash equivalents consisted of cash, short-term deposits (up to three months from the date of deposit) and money market funds.

e. Marketable securities

Marketable securities consist of debt securities. The Company elected the fair value option to measure and recognize its investments in debt securities in accordance with ASC 825, Financial Instruments as the Company manages its portfolio and evaluates the performance on a fair value basis. Changes in fair value, realized gains and losses on sales of marketable securities, are reflected in the consolidated statements of operation as finance expense (income), net. Marketable securities are classified under current assets in the consolidated balance sheets as they represent the investment of funds available for the Company's current operations.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

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, marketable securities and long-term deposits, which are deposited in major financially sound institutions in the U.S, Israel and Germany, and trade accounts receivable and other receivables. The Company's marketable securities include investments in highly-rated U.S governmental bonds. The financial institutions that hold the Company's debt marketable securities are major financial institutions located in the United States. The Company's trade accounts receivable are 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 the allowance for estimated losses resulting from the inability of the Company's customers to make required payments. The allowance represents the current estimate of lifetime expected credit losses over the remaining duration of existing accounts receivable considering current market conditions and supportable forecasts when appropriate. The estimate is a result of the Company's ongoing evaluation of collectability, customer creditworthiness, historical levels of credit losses, and future expectations. The allowance for expected credit losses was immaterial during the periods presented.

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. There were no impairments or inventory allowances during the years ended December 31, 2025 and 2024.

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. Cost includes expenditures that are directly attributable to placing an asset in the location and condition necessary for its intended use. 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). Assets under construction or not yet placed into service are not depreciated until they are ready for their intended use. Leasehold improvements are amortized on a straight-line basis over the shorter of the lease term, or the estimated useful 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. There were no impairments in value of long-lived assets during the years ended December 31,2025 and 2024.

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 and direct sales to medical centers, is recognized at the point in time when control of the product transfers to the customer. Control generally transfers upon shipment or delivery of the product to the customer, depending on the contractual shipping terms, at which point the Company has a present right to payment and the customer has obtained legal title and the significant risks and rewards of ownership are obtained by the customer.

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 12.

Revenue is recognized net of sales taxes and value added taxes collected on behalf of governmental authorities.

l. Research and development costs

Research and development costs are charged to the consolidated statements 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, directors and service providers. Employee and service providers equity awards are 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. The attribution for nonemployee awards is in the same manner as if the Company had paid cash for the goods or services. In addition, some of our share-based awards to service providers are performance based, i.e., the vesting of these awards depends upon achieving certain goals. The Company recognizes compensation expenses for awards with performance conditions when the company concludes that it is probable that the performance condition will be achieved.

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 to be 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 income - 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 consolidated 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 expenses as incurred. Advertising expenses were approximately $1,595 and $691 thousand for the years ended December 31, 2025, and 2024, respectively.

q. Net loss per share

Basic and diluted net loss per share is computed by dividing the net loss for the period by the weighted average number of shares of common stock, pre-funded warrants and fully vested restricted stock units outstanding during the period. The calculation of diluted net loss per share excludes the effect of potential dilution of share options, warrants, and unvested restricted stocks, unvested restricted stock units and Series C preferred stock as the effect is anti-dilutive. For the purpose of calculating basic net loss per share, the additional shares of common stock that are issuable upon exercise of the Pre-funded Warrants have been included since the shares are issuable for negligible consideration, as determined by the Company according to ASC 260-10-45-13, and have no vesting or other contingencies associated with them. The total number of shares of common stock related to outstanding options, warrants, unvested restricted stock, unvested restricted stock units and Series C Preferred Stock, which were excluded from the calculations of diluted loss per share were 37,498,531 and 48,681,495 for the years ended December 31, 2025 and 2024, respectively. This amount includes 5,177,186 and 4,073,966 unvested restricted stock included in the number of issued and outstanding shares as of December 31, 2025, and 2024, respectively. For the years ended December 31, 2025 and 2024 the weighted average number of common stock used in computing net loss per share - basic and diluted was as follows:

	2025	2024
Weighted average number of common stock	30,116,091	20,501,816
Weighted average Vested restricted stock units	979,078	306,731
Weighted average Pre-funded Warrants	33,230,641	21,119,813
Total Weighted average number of common stock used in computing net loss per share - basic and diluted	64,325,810	41,928,360

r. Segment reporting

The Company has one operating and reportable segment, see note 13.

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 liability in an orderly transaction between market participants at the measurement date.

NOTE 2 - SIGNIFICANT ACCOUNTING POLICIES (continued):

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.

t **New accounting pronouncements**

Recently adopted accounting pronouncements

1) In December 2023, the FASB issued ASU 2023-09 “Income Taxes (Topic 740): Improvements to Income Tax Disclosures.” This guidance is intended to enhance the transparency and decision-usefulness of income tax disclosures. The amendments in ASU 2023-09 address investor requests for enhanced income tax information primarily through changes to disclosure regarding rate reconciliation and income taxes paid both in the U.S. and in foreign jurisdictions. ASU 2023-09 is effective for the Company’s annual reporting period beginning January 1, 2025. The Company has adopted this update on a retrospective basis. The adoption of this guidance resulted in expanded disclosures in its consolidated financial statements. (see note 10).

2) In July 2025, the FASB issued ASU 2025-05, Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses for Accounts Receivable and Contract Assets, which provides a practical expedient when estimating credit losses on accounts receivable and contract assets arising from transactions accounted for under ASC 606, Revenue from Contracts with Customers. Under this practical expedient, an entity is allowed to assume that the current conditions it has applied in determining credit loss allowances for current accounts receivable and current contract assets remain unchanged for the remaining life of those assets. The ASU is effective for annual periods beginning after December 15, 2025, and interim periods within those annual reporting periods. The Company early adopted ASU 2025-05 on a prospective basis, effective January 1, 2025, and did not apply the standard in interim (quarterly) reporting periods prior to that date. The adoption of this guidance did not have a material impact on the Company’s consolidated financial statements and related disclosures.

Recently issued accounting pronouncement, not yet adopted:

1) In November 2024, the FASB issued ASU No. 2024-03 Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40). The ASU improves the disclosures about a public business entity’s expense and provides more detailed information about the types of expenses in commonly presented expense captions. The amendments require that at each interim and annual reporting period an entity will, inter alia, disclose amounts of purchases of inventory, employee compensation, depreciation and amortization included in each relevant expense caption (such as cost of sales, G&A, S&M and research and development) as well as disclosures about selling expenses. The ASU is effective for fiscal years beginning after December 15, 2026, and interim periods within fiscal years beginning after December 15, 2027. Early adoption is permitted. The Company is currently evaluating this ASU to determine its impact on the Company’s financial statements and disclosures.

2) In December 2025, the FASB issued ASU 2025-12 “Codification Improvements” to address suggestions received from stakeholders on the Accounting Standards Codification and to make other incremental improvements to U.S. GAAP. The update represents changes to the Codification that (1) clarify, (2) correct errors, or (3) make minor improvements. The amendments make the Codification easier to understand and apply. The guidance is effective for fiscal years beginning after December 15, 2026, including interim periods within those fiscal years. The Company is currently evaluating this guidance to determine the impact it may have on its consolidated financial statements.

NOTE 3 **– FAIR VALUE MEASUREMENTS**

As of December 31, 2025 and 2024, the carrying amounts of accounts payable, accounts receivable and other receivables approximate their fair values due to the short-term maturities of these instruments.

The carrying amount of the long-term deposit approximates its fair value since it is measured at its present value applying prevailing interest rates, see note 7.

The Company's financial assets subject to fair value measurements on a recurring basis and the level of inputs used in such measurements were as follows:

	As of December 31, 2025 ($ in thousands)			
	Total	**Level 1**	**Level 2**	**Level 3**
Assets:				
Cash equivalents-				
Money market funds	$ 5,116	$ 5,116	$ -	$ -
Marketable securities-				
U.S government bonds	$ 45,272	$ -	$ 45,272	$ -

	As of December 31, 2024 ($ in thousands)			
	Total	**Level 1**	**Level 2**	**Level 3**
Assets:				
Cash equivalents-				
Money market funds	$ 6,281	$ 6,281	$ -	$ -
Marketable securities-				
U.S. government bonds	$ 15,721	$ -	$ 15,721	$ -

The Company's cash equivalents and marketable securities are classified within Level 1 and Level 2 because it uses quoted market prices or alternative pricing sources and models utilizing market observable inputs to determine their fair value.

The cost of marketable securities as of December 31, 2025, and 2024 is $45,091 and $15,277 thousand, respectively.

NOTE 4 - MARKETABLE SECURITIES

As of December 31, 2025, and 2024, all of the Company's investment in marketable securities had contractual maturity of less than one year.

The following table sets forth the Company's marketable securities for the indicated period:

	December 31,	
	2025	2024
	($ in thousands)	
U.S. government bonds	$ 45,272	$ 15,721

The table below sets forth a summary of the changes in the fair value of the Company's marketable securities for the years ended December 31, 2025, and 2024:

	2025	2024
	($ in thousands)	
Balance at beginning of the year	$ 15,721	$ 29,383
Additions	56,840	14,444
Maturity	(27,648)	(29,000)
Interest received	(253)	(299)
Changes in fair value during the year	612	1,193
Balance at end of the period	45,272	15,721

NOTE 5 - PROPERTY, PLANT AND EQUIPMENT

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

	December 31,	
	2025	2024
	($ in thousands)	
Cost:		
Computer equipment	$ 949	$ 726
Office furniture and equipment	595	464
Machinery and equipment	3,678	2,640
Leasehold improvements	1,087	861
	6,309	4,691
Less - accumulated depreciation	(2,725)	(2,320)
Net carrying amount	$ 3,584	$ 2,371

b. Depreciation and amortization expenses totaled approximately $476,000 and $280,000 for the years ended December 31, 2025, and 2024, respectively, excluding fixed assets that the company purchased that are not yet ready for use and, therefore not depreciated.

NOTE 6 - LIABILITY FOR EMPLOYEE RIGHTS UPON RETIREMENT AND OTHERS

Defined Contribution Plans

Under Israeli labor law, the Company's subsidiary Israeli employees are generally entitled to severance pay upon dismissal or certain other termination events.

Pursuant to Section 14 of the Israeli Severance Compensation Act, 1963, most of the employees of the Company's subsidiary in Israel 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 $376,000 and $293,000 for the years ended December 31, 2025, and 2024, respectively.

The Company sponsors a defined contribution retirement plan for its U.S. employees under Section 401(k) of the Internal Revenue Code. The plan is structured as a Qualified Automatic Contribution Arrangement (QACA) Safe Harbor plan, which includes automatic enrollment and requires the Company to make mandatory employer contributions in accordance with IRS Safe Harbor regulations. Employer contributions under the plan were immaterial for the year ended December 31, 2025. The Company has no further obligation to fund benefits beyond these required contributions.

Postemployment Benefit Plans

The severance pay liability of the Company for the rest of its subsidiary Israeli employees not covered under Section 14 amounting to $1,082 thousand and $1,224 thousand as of December 31, 2025, and 2024, respectively, reflects the undiscounted amount of the liability and 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 $126,000 and $124,000 for the years ended December 31, 2025, and 2024, respectively.

NOTE 7 – LEASE AGREEMENTS

1) U.S. Lease

On October 9, 2024, the Company entered into a lease agreement in Miami, Florida (the "U.S. Lease") for the establishment of its global headquarters. The U.S. Lease provides for the phased delivery of the leased premises located in Suites 215 and 280 at 6303 Waterford District Drive, Miami, Florida 33126. Rent commencement and lease recognition occur upon the Company obtaining control of each portion of the premises, in accordance with the lease terms. The lease term extends through September 30, 2030 and includes an option to extend the lease for an additional five years. The Company has determined that the renewal option is not reasonably certain to be exercised due to operational and strategic considerations.

The Company took possession of Suite 215 on November 1, 2024, which represented the commencement date for that portion of the leased premises. On May 18, 2025, the Company took possession of Suite 280 following the landlord's completion of construction, which represented the commencement date for Suite 280. As a result of obtaining possession of Suite 280, during the year ended December 31, 2025, the Company recognized an increase of $302 thousand in operating lease right-of-use assets and a corresponding increase of $302 thousand in operating lease liabilities.

Under the U.S. Lease, the Company paid a security deposit of $500 thousand. Provided the Company does not default under the lease, the security deposit is refundable at specified intervals throughout the lease term. The present value of the deposit as of November 1, 2024, was $422 thousand and is classified as a long-term deposit. The remaining balance was assigned to operating lease right-of-use assets.

2) Israeli Lease

The Company's Israeli subsidiary leases a facility in Israel under an operating lease (the "Israeli Lease"). The Israeli Lease was amended multiple times in prior years to extend the lease term and modify the leased premises. In prior periods, management concluded that optional extension periods through December 31, 2027 were reasonably certain to be exercised and were included in the lease term for accounting purposes.

On May 28, 2025, the Company amended the Israeli Lease, extending the lease term through December 31, 2028 and leasing additional space within the facility. As a result of this amendment, the Company recognized an increase of $692 thousand in operating lease right-of-use assets and a corresponding increase of $692 thousand in operating lease liabilities.

As of December 31, 2025, the Israeli Lease remains in effect through December 31, 2028.

3) Lease Cost

Operating lease cost for the years ended December 31, 2025 and 2024 was $470 thousand and $423 thousand, respectively, related to the Israeli Lease, and $251 thousand and $34 thousand, respectively, related to the U.S. Lease.

In addition to fixed lease payments under the U.S. Lease, the Company incurred variable lease costs, primarily related to utilities, maintenance, and other common area costs, totaling approximately $103 thousand for the year ended December 31, 2025.

4) Supplemental Lease Information

Supplemental balance sheet information related to leases was as follows:

	December 31,	
	2025	**2024**
	($ in thousands)	
Operating lease right-of-use assets	2,758	2,360
Current Operating lease liabilities	(1,066)	(542)
Non-current operating lease liabilities	(2,224)	(1,796)

Other information:

Operating cash flows from operating leases (cash paid in thousands)	(820)	(745)
Weighted Average Remaining Lease Term	3.57	3.93
Weighted Average Discount Rate	11.72%	11.82%

5) Maturities of Operating Lease Liabilities

Maturities of lease liabilities as of December 31, 2025, are as follows:

	Amount ($ in thousands)
2026	1,133
2027	1,141
2028	1,150

2029	306
2030	236
Total lease payments	3,966
Less imputed interest	(676)
Total	3,290

NOTE 8 – EQUITY

a. Stockholders' Equity

1. Share capital and listing

The Company's authorized share capital consists of common stock and preferred stock. The Company's shares of common stock are listed on the Nasdaq Capital Market.

2. May 2023 private placement financing

In May 2023, the Company entered into a securities purchase agreement pursuant to which it issued and sold in a private placement offering (the "May 2023 Private Placement Offering") shares of its common stock, pre-funded warrants to purchase shares of common stock (the "May 2023 Pre-Funded Warrants"), Series H warrants to purchase shares of common stock (the "Series H Warrants"), Series I warrants to purchase shares of common stock (the "Series I Warrants"), Series J warrants to purchase shares of common stock (the "Series J Warrants") and Series K warrants to purchase shares of common stock (the "Series K Warrants" and together with the Series H Warrants, Series I Warrants and Series J Warrants, the "May 2023 Warrants"). The May 2023 Private Placement Offering closed on May 16, 2023 and resulted in aggregate gross proceeds of approximately $42.2 million. Fees payable to the placement agent and other offering expenses amounted to approximately $4.6 million, resulting in net proceeds to the Company of approximately $37.6 million.

The May 2023 Pre-Funded Warrants are immediately exercisable at an exercise price of $0.0001 per share and will not expire until they are exercised in full. The May 2023 Warrants are immediately exercisable upon issuance at an exercise price of $1.3827 per share. The May 2023 Warrants have a term of the earlier of (i) five years from the date of issuance and (ii) (A) in the case of the Series H Warrants, 20 trading days following the Company's public release of primary and secondary end points related to one year follow up study results from the Company's C-Guardians pivotal trial, (B) in the case of the Series I Warrants, 20 trading days following the Company's announcement of receipt of PMA from the FDA, for CGuard Prime (135 cm), (C) in the case of the Series J Warrants, 20 trading days following the Company's announcement of receipt of FDA approval for SwitchGuard and CGuard Prime 80 cm and (D) in the case on the Series K Warrants, 20 trading days following the end of the fourth fiscal quarter after the fiscal quarter in which the first commercial sales of CGuard Prime in the U.S. begin. The May 2023 Warrants may be exercised on a cashless basis if there is no effective registration statement registering the shares underlying the warrants.

3. Exercise of Series H Warrant

Following the Company's announcement on May 28, 2024 of the one-year follow-up study results from the Company's C-GUARDIANS pivotal trial, which constituted the applicable contractual milestone under the Series H Warrants, the Series H Warrants were exercised in full into 292,996 shares of common stock and pre-funded warrants exercisable into 12,621,090 shares of common stock. The exercise resulted in gross proceeds of approximately $17.9 million. After deduction of placement agent fees and other issuance costs of approximately $1.0 million, net proceeds to the Company amounted to approximately $16.9 million.

4. Exercise of Series I Warrant

Following the Company's announcement on June 24, 2025 that the FDA approved the PMA of CGuard Prime in the U.S., which constituted the applicable contractual milestone under the Series I Warrants, the Series I Warrants were exercised in full into 2,352,393 shares of common stock at an exercise price of $1.3827 per share and 10,561,685 pre-funded warrants at an exercise price of $1.3826 per pre-funded warrant. The exercise resulted in gross proceeds of approximately $17.9 million. After deduction of issuance costs of approximately $1.0 million, net proceeds to the Company amounted to approximately $16.9 million.

5. **August 2025 private placement financing**

On July 30, 2025, the Company entered into a securities purchase agreement with investors pursuant to which it issued and sold in a private placement offering (the "August 2025 Private Placement Offering") an aggregate of 6,791,380 shares of common stock and pre-funded warrants to purchase up to 9,764,804 shares of common stock, at an offering price of $2.42 per share and $2.4199 per pre-funded warrant (the "August 2025 Pre-Funded Warrants"). The August 2025 Private Placement Offering closed on August 1, 2025. The August 2025 Pre-Funded Warrants are immediately exercisable at an exercise price of $0.0001 per share and will not expire until exercised in full. The August 2025 Private Placement Offering resulted in gross proceeds to the Company of approximately $40.1 million. Issuance costs amounted to approximately $3.1 million.

6. **Pre-funded warrants**

During the years ended December 31, 2025 and 2024, the Company issued 3,381,651 and 1,728,382 shares of its common stock, respectively, in connection with the exercise of pre-funded warrants originally issued in the May 2023 Private Placement Offering and August 2025 Private Placement Offering. As of December 31, 2025, and 2024, pre-funded warrants to purchase an aggregate of 43,092,107 and 26,147,323 shares of common stock, respectively, were outstanding.

7. **Preferred stock**

As of December 31, 2025 and 2024, there were 1,718 shares of Series C Preferred Stock outstanding, convertible into an aggregate of 7,952 shares of the Company's common stock, with an aggregate stated value of $10,997.

8. **At-the-market equity offering**

On May 31, 2024, the Company entered into an at-the-market equity distribution agreement with Piper Sandler & Co., pursuant to which the Company was initially able to offer and sell shares of its common stock having an aggregate offering price of up to $17.0 million. On April 10, 2025, the Company amended the agreement to increase the aggregate offering capacity to $75.0 million, exclusive of any prior sales made under the facility. During the years ended December 31, 2025 and 2024, the Company issued 718,913 and 647,277 shares of common stock, respectively, under the at-the-market facility. Net proceeds to the Company from these issuances amounted to approximately $1.7 million and $1.6 million for the years ended December 31, 2025 and 2024, respectively, after deduction of issuance costs of $64 and $81 thousand for the years ended December 31, 2025, and 2024, respectively.

9. **Outstanding warrants**

As of December 31, 2025, the Company had outstanding warrants to purchase an aggregate of 26,920,508 shares of common stock, as follows:

	Number of underlying Common stock		Exercise price	Expiration date
Series G Warrants	1,092,344	$	10.230	February 8, 2026
Series J Warrants	12,914,086	$	1.3827	*
Series K Warrants	12,914,078	$	1.3827	*
Total Warrants	26,920,508			

* The Series J Warrants and Series K Warrants have a term of the earlier of (i) May 15, 2028 and (ii) (A) in the case of the Series J Warrants, 20 trading days following the Company's announcement of receipt of FDA approval for the SwitchGuard and CGuard Prime 80 cm and (B) in the case on the Series K Warrants, 20 trading days following the end of the fourth fiscal quarter after the fiscal quarter in which the first commercial sales of CGuard Prime in the U.S. begins.

During the years ended December 31, 2025 and 2024, a total of 433,878 and 213,458 warrants expired unexercised, respectively.

On February 8, 2026, a total of 1,092,344 Series G warrants expired unexercised.

b. Share-Based Compensation

1) **Equity Incentive Plans**

2021 Equity Incentive Plan

On September 30, 2021, at the Company's 2021 annual meeting of stockholders, the Company's stockholders approved the 2021 Equity Incentive Plan.

The Company's 2021 Equity Incentive Plan provides for the granting of incentive stock options, non-qualified 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.

As of December 31, 2025, the Company had 5,098,395 shares of common stock available for future issuance under the 2021 Equity Incentive Plan.

2024 Inducement Plan

On September 30, 2024, the compensation committee of the Company's board of directors approved the InspireMD, Inc. 2024 Inducement Plan (the "2024 Inducement Plan") to be used exclusively for grants of equity-based awards to individuals who were not previously employees or directors of the Company, as an inducement material to the individual's entry into employment with the Company.

As of December 31, 2025, the Company had 703,315 shares of common stock available for future issuance under the 2024 Inducement Plan.

2) **Stock Options – Employees**

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

	Year ended December 31	
	2025	
	Number of options	**Weighted average exercise price**
Outstanding - beginning of the year	2,154,143	2.76
Granted	1,119,127	2.63
Forfeited	(79,541)	3.25
Outstanding- end of year	3,193,729	2.70
Exercisable at the end of the year	1,612,755	2.79

3) **Stock Options – Non-Employees**

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

	Year ended December 31	
	2025	
	Number of options	Weighted average exercise price
Outstanding - beginning of the year	916,669	2.10
Granted	-	-
Outstanding - end of year	916,669	2.10
Exercisable at the end of the year	639,003	2.19

4) **Restricted Stock – Employees and non-employees**

The following table summarizes information about restricted stock granted to employees and non-employees:

	Year ended December 31 2025
	Number of restricted stock
Outstanding - beginning of the year	4,073,966
Granted	3,933,081
Forfeited	(256,170)
Vested	(2,573,691)
Outstanding - end of the year	5,177,186

5) **Restricted Stock Units (RSUs) – Employees**

The following table summarizes information about RSUs granted to employees:

	Year ended December 31 2025
	Number of RSUs
Outstanding - beginning of the year	1,845,727
Granted	558,417
Outstanding - end of the year	2,404,144

6) **Options Outstanding and Exercisable**

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

		Outstanding as of December 31, 2025		
Exercise price		**Options outstanding**	**Weighted average remaining contractual life (years)**	**Options exercisable**
$	1.15-3.14	3,772,718	6.98	1,926,991
$	3.30-4.12	181,352	5.28	168,439
$	4.95-10.05	152,275	4.27	152,275
$	16.50	4,053	4.01	4,053
		4,110,398	6.80	2,251,758

The weighted average of the remaining contractual life of total vested and exercisable options as of December 31, 2025 was 5.53 years.

The aggregate intrinsic value of the total exercisable options as of December 31, 2025 was approximately $46 thousand.

7) **Fair Value of Awards**

The weighted average fair value of options granted to employees was $1.96 and $2.54 for the years ended December 31, 2025 and 2024, respectively. The weighted average fair value of options granted was estimated using the Black-Scholes option-pricing model.

The weighted average fair value of options granted to consultants was $1.87 for the year ended December 31, 2024. The weighted average fair value of options granted was estimated using the Black-Scholes option-pricing model.

The weighted average fair value of restricted stock granted was $2.56 and $2.94 for the years ended December 31, 2025 and 2024, respectively.

The weighted average fair value of RSU granted was $2.76 and $3.14 for the years ended December 31, 2025 and 2024, respectively.

No stock options were exercised during the year.

The total fair value of shares vested during the year was $6,325,416.

The vesting period for outstanding stock options, restricted stock, and RSUs is typically three years, with one-third of the awards vesting annually. The options and restricted stock to directors are subject to a one-year vesting period. Additionally, some of our share-based awards to service providers are performance-based, vesting upon the achievement of specified performance criteria related to clinical or marketing activities.

8) **Valuation Assumptions (Black-Scholes)**

The following table sets forth the assumptions that were used in determining the fair value of options granted to employees and consultants for the year December 31, 2025 and 2024:

	Year ended December 31	
	2025	**2024**
Expected life	2; 5.5-6.5	5.125-10 years
Risk-free interest rates	3.45% - 3.64%; 3.64%-4.68%	3.93%-4.44%
Volatility	38.69%- 49.34%; 75.74%-92.69%	91.82%-119.38%
Dividend yield	-	-

- During 2025, the Company modified certain outstanding stock options held by retired directors, including accelerated vesting and an extension of the post-retirement exercise period. The Company recognized the incremental compensation cost resulting from the modifications in accordance with ASC 718.

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.

9) **Unrecognized Compensation Cost**

As of December 31, 2025, 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 $7,926 thousand. This cost is expected to be recognized over a weighted-average period of approximately 0.94 years. This expected cost does not include the impact of any future stock-based compensation awards.

10) **Share-Based Compensation Expense**

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

	Year ended December 31	
	2025	**2024**
	($ in thousands)	
Cost of revenues	$ 218	$ 256
Research and development	2,559	2,412
Sales and marketing	1,888	1,025
General and administrative	7,667	6,445
	$ 12,332	$ 10,138

NOTE 9 – RELATED PARTIES TRANSACTIONS

On September 15, 2023, the Company's board of directors approved the Company's entry into a consultancy agreement (the "Consultancy Agreement") with a member of the immediate family of the Company's Chief Executive Officer to provide services related to certain administrative projects in connection with the Company's expansion into the United States until a full-time employee is retained in such capacity.

Under the original terms of the Consultancy Agreement, the Company paid a fixed hourly fee of $50 for up to 20 hours per week, plus reimbursement of customary expenses.

On July 1, 2024, the audit committee of the Company's board of directors approved an amendment to the Consultancy Agreement pursuant to which the consultant was paid a fixed hourly fee of $100 for up to 95 hours per month, in an aggregate amount not to exceed $120,000, including expenses, for the twelve-month period ending June 30, 2025.

Consulting expenses recognized for the years ended December 31, 2025 and 2024 were $56 thousand and $76 thousand, respectively.

The engagement was terminated in July 2025.

NOTE 10 - TAXES ON INCOME:

a. Tax laws applicable to the Company and its subsidiaries

Taxation in the United States

The Company is subject to U.S. federal income tax at a statutory rate of 21% and state income taxes at varying rates.

Taxation in Israel

InspireMD Ltd., the Company's Israeli subsidiary, is subject to Israeli corporate income tax at a statutory rate of 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% in 2025 and 2024.

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

The Israeli subsidiary may qualify for tax benefits under the Law for the Encouragement of Capital Investments, 1959. As of December 31, 2025 and 2024 the Company has not recognized any material tax benefit related to such incentives due to cumulative losses and the existence of a full valuation allowance.

c. Carry forward tax losses

As of December 31, 2025, the Company had U.S. federal net operating loss ("NOLs") carryforwards of approximately $66 million. Of this amount, approximately $35 million arose prior to January 1, 2018 and expire through 2038. Net operating losses generated after December 31, 2017 may be carried forward indefinitely but are limited to offsetting 80% of taxable income in the year utilized.

As of December 31, 2025, and 2024, InspireMD Ltd., the Company's Israeli subsidiary, had a net carry forward tax loss of approximately $180 and $126 million. Under Israeli tax laws, the carry forward tax losses can be utilized indefinitely.

The Company's Israeli subsidiary is taxed in New Israeli Shekel ("NIS"), which is different from its functional currency (U.S. Dollar). The change in the Company's Israeli subsidiary NOLs for tax purposes 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	
	2025	2024
	($ in thousands)	
Loss before taxes on income:		
InspireMD, Inc.	$ (10,834)	$ (10,385)
Subsidiaries	(37,889)	(21,561)
	$ (48,723)	$ (31,946)

e. Changes in valuation allowance

The changes in the valuation allowance for the years ended December 31, 2025, and 2024 were as follows:

	Year ended December 31	
	2025	2024
	($ in thousands)	
Balance at the beginning of the year	$ 48,430	$ 42,651
Changes during the year	15,138	5,779
Balance at the end of the year	$ 63,568	$ 48,430

f. Accounting for Uncertain Tax positions

The following is a reconciliation of the total amounts of the Company's uncertain tax positions during the years ended December 31, 2025, and 2024:

	Year ended December 31,	
	2025	2024
	($ in thousands)	
Balance at beginning of the year	$ 225	$ 168
Additions related to uncertain tax positions taken this year	61	57
Balance at end of the year	$ 286	$ 225

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

Jurisdiction	Years
U.S.	2021-2025
Israel	2021-2025
Germany	2022-2025

g. Deferred income tax:

	December 31,	
	2025	2024
	($ in thousands)	
Carry forward tax losses	55,346	41,699
Provision for vacation and recreation pay	98	82
R&D expenses	2,843	2,204
Operating lease right of use assets	(613)	(525)
Operating lease liabilities	735	554
Share-based compensation	5,174	4,489
Marketable securities	(41)	(100)
Accrued severance pay, net	26	27
	63,568	48,430
Less-valuation allowance	(63,568)	(48,430)
	-	-

h. Reconciliation of Statutory Federal Income Tax Rate to the Effective Income Tax Rate:

The provision for income taxes differs from the expected amount calculated by applying the Company's federal statutory rate to loss before tax expenses for 2025 and 2024 as follows:

	2025		2024	
	($ in thousands)			
	$	%		
US federal statutory	(10,232)	21	(6,709)	21
Foreign tax effects				
Israel				
Statutory tax rate differences between United States and Israel	(758)	1.6	(428)	1.3
Difference resulting from using NIS as the measurement basis for tax purposes	(4,627)	9.5	223	(0.7)
Changes in valuation allowance	13,096	(26.9)	3,590	(11.2)
Non- taxable or non-deductible items	1,171	(2.4)	1,020	(3.2)
Other adjustments	(254)	(0.5)	-	-
Changes in valuation allowance	2,043	(4.2)	2,189	(6.9)

Non- taxable or non-deductible items	27	(-0.1)	1	(0.0)
Changes in unrecognized tax benefits	61	(-0.1)	57	(0.2)
Other adjustments	(464)	1.0	116	(0.4)
Effective tax expense	63	-	59	-

NOTE 11 - SUPPLEMENTARY FINANCIAL STATEMENT INFORMATION:

Balance sheets:

a **Inventory:**

	December 31,	
	2025	**2024**
	($ in thousands)	
Finished goods	$ 352	$ 18
Work in process	930	638
Raw materials and supplies	2,114	1,914
	$ 3,396	$ 2,570

b **Accounts payable and accruals-other:**

	December 31,	
	2025	**2024**
	($ in thousands)	
Employees and employee institutions	$ 4,925	$ 3,414
Accrued vacation and recreation pay	430	369
Accrued expenses	1,545	1,325
Clinical trial accrual	1,155	519
Current Operating lease liabilities	1,066	542
Other	336	255
	$ 9,457	$ 6,424

NOTE 12 – 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,	
	2025	**2024**
	($ in thousands)	
USA	$ 1,417	$ 32
Germany	1,233	926
Italy	1,232	1,223
Russia	-	713
Poland	1,036	694
Other*	4,061	3,421
	$ 8,979	$ 7,009

* Other individual countries do not exceed 10% in the year ended December 31, 2025 and 2024.

By principal customers (part of revenues):

	Year ended December 31,	
	2025	**2024**
Customer A	14%	13%
Customer B	12%	10%
Customer C	-	10%

The following table presents the Company's long-lived assets by geographic region, which consist of property, plant and equipment, net and operating lease right of use assets:

	December 31,	
	2025	**2024**
	($ in thousands)	
Israel	3,899	2,750
United States	2,443	1,981
Total long-lived assets	$ 6,342	4,731

NOTE 13 – SEGMENT INFORMATION

The Company has one operating and reporting segment, that develops, manufactures and markets products for the treatment of carotid artery disease and other vascular disease, including the Company's proprietary CGuard™ stent platform. The Company's Chief Operating Decision Maker ("CODM"), who is the CEO evaluates the Company's performance based on its internal reporting which is consistent with the presentation in the Company's consolidated financial statements. Accordingly, our CODM uses consolidated net loss to measure segment profit or loss, allocate resources, and assess performance.

The CODM examines, within each operational function, the employee salaries including the bonus and share based compensation. In addition, the CODM examines the clinical trials expenses within the research and development operations.

	Year ended December 31,	
	2025	**2024**
Revenues	8,979	7,009
Cost of Revenues:		
Material and Labor	5,200	4,698
Other cost of revenues	1,130	805
Total Cost of revenues	6,330	5,503
Research and development (R&D)		
Payroll and Benefits	4,052	2,858
Share based compensation	2,559	2,412
Clinical trials	4,488	3,815
Other R&D	3,904	4,549
Total Research and development	15,003	13,634
Selling and marketing (S&M)		
Payroll and Benefits	11,346	3,769
Share based compensation	1,888	1,025
Other S&M	3,319	1,275
Total Selling and marketing	16,553	6,069
General and administrative (G&A)		
Payroll and Benefits	6,650	4,221
Share based compensation	7,667	6,445
Other G&A	6,390	4,640
Total General and administrative	20,707	15,306
Financial Income, net;	891	1,557
Tax Expenses	63	59
Segment net Loss	(48,786)	(32,005)

NOTE 14 - SUBSEQUENT EVENTS:

Subsequent to December 31, 2025, the Company granted 3,455,519 restricted shares of the Company's common stock to employees and directors. The shares to employees are subject to a three-year vesting period, with one-third of such awards vesting each year. The shares to directors are subject to a one-year vesting period.

Subsequent to December 31, 2025, the Company granted 1,114,792 restricted share units of the Company's common stock to the chief executive officer. The shares are subject to a three-year vesting period, with one-third of such awards vesting each year.

Exhibit 4.1

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

General

The following description of our capital stock is a summary. This summary is subject to the Delaware General Corporation Law, as amended (the "DGCL") and the complete text of our amended and restated certificate of incorporation, as amended (the "Certificate of Incorporation") and our amended and restated bylaws, as amended (the "Bylaws").

We encourage you to read our Certificate of Incorporation and amendments thereto, our Bylaws and the applicable provisions of 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. However, holders of our common stock are not entitled to vote on any amendment to our Certificate of Incorporation that relates solely to the terms of one or more outstanding classes or series of preferred stock if the holders of such affected classes or series are entitled, either separately or together with the holders of one or more other such class or series, to vote thereon pursuant to our Certificate of Incorporation or the DGCL.

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.

Generally, our Bylaws provide that, subject to applicable law or our Certificate of Incorporation and/or our Bylaws, all corporate actions to be taken by vote of the stockholders are authorized by a majority of the votes cast by the stockholders entitled to vote thereon who are present in person, or by remote communication, if applicable, or represented by proxy, and where a separate vote by class or series is required, a majority of the votes cast by the stockholders of such class or series who are present in person, or by remote communication, if applicable, or represented by proxy will be the act of such class or series. Directors are elected by a plurality of the votes cast at a meeting of our stockholders for the election of directors at which a quorum is present.

Subject to the rights of holders of any then outstanding class or series of preferred stock, the holders of our common stock are entitled to receive ratably such dividends and other distributions in cash, stock or property, if any, as may be declared by our board of directors from time to time out of legally available funds , and share equally on a per share basis in all such dividends and other distributions.

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. All outstanding shares of our common stock are be fully paid and non-assessable.

Transfer Agent and Registrar

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.

Stock Exchange Listing

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 DGCL 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 18, 2026, there were 1,718 shares of Series C Preferred Stock outstanding, convertible into an aggregate of 2,284 shares of our common stock.

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.

Federal Forum for Securities Act Claims

Section 22 of the Securities Act of 1933, as amended (the "Securities Act"), creates concurrent jurisdiction for federal and state courts over all suits brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. However, our Bylaws contains a federal forum provision which provides that unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States of America will be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Any person or entity purchasing or otherwise acquiring any interest in our shares of capital stock are deemed to have notice of and consented to this provision. The Supreme Court of Delaware has held that this type of exclusive federal forum provision is enforceable. There may be uncertainty, however, as to whether courts of other jurisdictions would enforce such a provision, if applicable.

This choice of federal forum for Securities Act claims may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable, which may discourage such lawsuits against us and our directors, officers and other team members.

Exhibit 19.1

Insider Trading Policy

1 Purpose

This Insider Trading Policy (the "***Policy***") provides guidelines with respect to transactions in the securities of InspireMD, Inc. (the "***Company***") and the handling of confidential information about the Company and the companies with which the Company does business. The Company's Board of Directors has adopted this Policy to promote compliance with federal, state and foreign securities laws that prohibit certain persons who are aware of material nonpublic information about a company from: (i) trading in securities of that company; or (ii) providing material nonpublic information to other persons who may trade on the basis of that information.

2 Scope

This Policy applies to all officers of the Company and its subsidiaries, all members of the Company's Board of Directors, and all employees of the Company and its subsidiaries. The Company may also determine that other persons should be subject to this Policy, such as contractors or consultants who have access to material nonpublic information. This Policy also applies to Family Members, other members of a person's household and entities controlled by a person covered by this Policy, as described below (collectively referred to in this Policy as "Insiders").

3 Applicable Documents

Appendix 1 - GUIDELINES FOR RULE 10B5-1 PLANS

4 Policy

4.1 Transactions Subject to the Policy

This Policy applies to transactions in the Company's securities (collectively referred to in this Policy as "***Company Securities***"), including the Company's common stock, options to purchase common stock, preferred stock, warrants, restricted shares or units or any other type of securities that the Company may issue, including (but not limited to), convertible debentures, as well as derivative securities that are not issued by the Company, such as exchange-traded options or swaps relating to the Company's Securities.

4.2 Individual Responsibility

Persons subject to this Policy have ethical and legal obligations to maintain the confidentiality of information about the Company and to not engage in transactions in Company Securities while in possession of material nonpublic information. Each individual is responsible for making sure that he or she complies with this Policy, and that any family member household member or entity whose transactions are subject to this Policy, as discussed below, also comply with this Policy. In all cases, the responsibility for determining whether an individual is in possession of material nonpublic information rests with that individual, and any action on the part of the Company, the Compliance Officer or any other employee or director pursuant to this Policy (or otherwise) does not in any way constitute legal advice or insulate an individual from liability under applicable securities laws. You could be subject to severe legal penalties and disciplinary action by the Company for any conduct prohibited by this Policy or applicable securities laws, as described below in more detail under the heading "*Consequences of Violations*."

4.3 Administration of the Policy

The Company's Chief Financial Officer shall serve as the Compliance Officer for the purposes of this Policy, and in his absence, the Company's Chief Executive Officer, or another employee designated by the Compliance Officer shall be responsible for administration of this Policy. All determinations and interpretations by the Compliance Officer shall be final and not subject to further review.

4.4 Statement of Policy

It is the policy of the Company that no Insider of the Company (or any other person designated by this Policy or by the Compliance Officer as subject to this Policy) who is aware of material nonpublic information relating to the Company may, directly, or indirectly through Family Members (as defined below) or other persons or entities:

1. Engage in transactions in Company Securities, except as otherwise specified in this Policy under the headings "*Transactions Under Company Plans*," "*Transactions Not Involving a Purchase or Sale*" and "*Rule 10b5-1 Plans*;"

2. Recommend the purchase or sale of any Company Securities;

3. Disclose material nonpublic information to persons within the Company whose jobs do not require them to have that information, or outside of the Company to other persons, including, but not limited to, family, friends, business associates, investors and expert consulting firms, unless any such disclosure is made in accordance with the Company's policies regarding the protection or authorized external disclosure of information regarding the Company;

4. Disclose, or participate in the disclosure of, any information related to the Company's business, prospects, financial condition or employees by means of an Internet "chat room" or other similar space on the Internet in which either the Company's business or the value of its securities is discussed or posted.

5. Assist anyone engaged in the above activities.

In addition, it is the policy of the Company that no Insider of the Company (or any other person designated as subject to this Policy) who, in the course of working for the Company, learns of material nonpublic information about a company with which the Company does business, including a customer or supplier of the Company, may trade in that company's securities until the information becomes public or is no longer material.

There are no exceptions to this Policy, except as specifically noted herein. Transactions that may be necessary or justifiable for independent reasons (such as the need to raise money for an emergency expenditure), or small transactions, are not excepted from this Policy. The securities laws do not recognize any mitigating circumstances, and, in any event, even the appearance of an improper transaction must be avoided to preserve the Company's reputation for adhering to the highest standards of conduct.

4.5 Definition of Material Nonpublic Information

Material Information. It is not possible to define all categories of material nonpublic information. However, information should be regarded "material" if a reasonable investor would consider that information important in making a decision to buy, hold or sell securities. Any information that could be expected to affect the Company's stock price, whether it is positive or negative, should be considered material. There is no bright-line standard for assessing materiality; rather, materiality is based on an assessment of all of the facts and circumstances, and is often evaluated by enforcement authorities with the benefit of hindsight. While it is not possible to define all categories of material information, some examples of information that ordinarily would be regarded as material are:

- Projections of future earnings or losses, or other earnings guidance;
- Changes to previously announced earnings guidance, or the decision to suspend earnings guidance;
- A pending or proposed merger, acquisition or tender offer;
- A pending or proposed acquisition or disposition of a significant asset;
- A pending or proposed joint venture;
- A Company restructuring;
- Significant related party transactions;
- A change in dividend policy, the declaration of a stock split, or an offering of additional securities;
- Bank borrowings or other financing transactions out of the ordinary course;
- The establishment of a repurchase program for Company Securities;
- A change in the Company's pricing or cost structure;
- Major marketing changes;
- A change in management;
- A change in auditors or notification that the auditor's reports may no longer be relied upon;
- Development of a significant new product, process, or service;
- Pending or threatened significant litigation, or the resolution of such litigation;
- Impending bankruptcy or the existence of severe liquidity problems;
- The gain or loss of a significant customer or supplier;
- The imposition of a ban on trading in Company Securities or the securities of another company;
- News of major clinical or development milestones;
- The results of clinical trials; and
- Significant communications to or from regulatory agencies or other significant regulatory developments.

When Information is Considered Public. To be "public" the information must have been disseminated in a manner designed to reach investors generally, and the investors must be given the opportunity to absorb the information. Information that has not been disclosed to the public is generally considered to be nonpublic information. In order to establish that the information has been disclosed to the public, it may be necessary to demonstrate that the information has been widely disseminated. Information generally would be considered widely disseminated if it has been disclosed through the newswire services or public disclosure filed with the SEC that are available on the SEC's website. By contrast, information would likely not be considered widely disseminated if it is available only to the Company's employees, or if it is only available to a select group of analysts, brokers and institutional investors.

Once information is widely disseminated, it is still necessary to afford the investing public with sufficient time to absorb the information. As a general rule, information should not he considered fully absorbed by the marketplace until such information has been publicly known for at least one full Trading Day. lf, for example, the Company were to make an announcement pre-market Monday, you should not trade in Company Securities until market open on Tuesday. Depending on the particular circumstances, the Company may determine that a longer or shorter period should apply to the release of specific material nonpublic information. As used herein, the term "Trading Day" shall mean a day on which the Nasdaq Capital Market (or such other market or exchange on which the Company's common stock is then listed or traded to the extent such other market or exchange is the principal trading market or exchange for the Company's common stock) is open for trading.

4.6 Transactions by Family Members and Others

This Policy applies to your family members who reside with you (including a spouse, a child, a child away at college, stepchildren, grandchildren, parents, stepparents, grandparents, siblings and in-laws), anyone else who lives in your household, and any family members who do not live in your household but whose transactions in Company Securities are directed by you or are subject to your influence or control, such as parents or children who consult with you before they trade in Company Securities (collectively referred to as "***Family Members***"). You are responsible for the transactions of these other persons and therefore should make them aware of the need to confer with you before they trade in Company Securities, and you should treat all such transactions for the purposes of this Policy and applicable securities laws as if the transactions were for your own account. This Policy does not, however, apply to personal securities transactions of Family Members where the purchase or sale decision is made by a third party not controlled by, influenced by or related to you or your Family Members.

4.7 Transactions by Entities that You Influence or Control

This Policy applies to any entities that you influence or control, including any corporations, partnerships or trusts (collectively referred to as "***Controlled Entities***"), and transactions by these Controlled Entities should be treated for the purposes of this Policy and applicable securities laws as if they were for your own account.

4.8 Transactions Under Company Plans

This Policy does not apply in the case of the following transactions, except as specifically noted:

Stock Option Exercises. This Policy does not apply to the exercise of an employee stock option acquired pursuant to the Company's plans if the shares acquired upon exercise are held rather than sold, or to the exercise of a tax withholding right pursuant to which a person has elected to have the Company withhold shares subject to an option to satisfy tax withholding requirements. This Policy does apply, however, to any sale of stock as part of a broker-assisted cashless exercise of an option, or any other market sale for the purpose of generating the cash needed to pay the exercise price of an option.

Restricted Stock Awards. This Policy does not apply to the vesting of restricted stock, or the exercise of a tax withholding right pursuant to which you elect to have the Company withhold shares of stock to satisfy tax withholding requirements upon the vesting of any restricted stock. The Policy does apply, however, to any market sale of restricted stock.

401(k) Plan. This Policy does not apply to purchases of Company Securities in a Company 401(k) plan resulting from your periodic contribution of money to the plan pursuant to your payroll deduction election. This Policy does apply, however, to certain elections you may make under the 401(k) plan, including: (a) an election to increase or decrease the percentage of your periodic contributions that will be allocated to the Company stock fund; (b) an election to make an intra-plan transfer of an existing account balance into or out of the Company stock fund; (c) an election to borrow money against your 401(k) plan account if the loan will result in a liquidation of some or all of your Company stock fund balance; and (d) an election to pre-pay a plan loan if the pre-payment will result in allocation of loan proceeds to the Company stock fund.

Employee Stock Purchase Plan. This Policy does not apply to purchases of Company Securities in an employee stock purchase plan resulting from your periodic contribution of money to the plan pursuant to the election you made at the time of your enrollment in the plan. This Policy also does not apply to purchases of Company Securities resulting from lump sum contributions to the plan, provided that you elected to participate by lump sum payment at the beginning of the applicable enrollment period. This Policy does apply, however, to your election to participate in the plan for any enrollment period, and to your sales of Company Securities purchased pursuant to the plan.

Dividend Reinvestment Plan. This Policy does not apply to purchases of Company Securities under a Company dividend reinvestment plan resulting from your reinvestment of dividends paid on Company Securities. This Policy does apply, however, to voluntary purchases of Company Securities resulting from additional contributions you choose to make to the dividend reinvestment plan, and to your election to participate in the plan or increase your level of participation in the plan. This Policy also applies to your sale of any Company Securities purchased pursuant to the plan.

Sale of Shares to Cover Tax Withholdings. The trading restrictions under this Policy do not apply to the sale of shares of common stock issued upon vesting of stock options, restricted stock units or restricted stock for the limited purpose of covering tax withholding obligations (and any associated broker or other fees) (a "***Sell-to-Cover Transaction***"). Sell-to-Cover Transactions shall be the default action for all employees at the time of vesting events unless the employee elects in advance that she/he will pay the withholding obligations directly through payment to the Company. In this event, the employee must notify the Company of her/his intent to directly pay the withholding obligations during a period when no Blackout Period (as defined below) is in effect, and the employee is not in possession of material nonpublic information. Sell-to-Cover Transactions must be strictly limited to the number of securities needed to cover such person's tax obligations and the employee may not be permitted to exercise control over the timing of such sales. This exemption does not apply to plans for sales incident to the exercise of option awards.

Other Similar Transactions. Any other purchase of Company Securities from the Company or sales of Company Securities to the Company are not subject to this Policy.

4.9 Transactions Not Involving a Purchase or Sale

Bona fide gifts are not transactions subject to this Policy, unless the person making the gift has reason to believe that the recipient intends to sell the Company Securities while the Insider is aware of material nonpublic information, or the person making the gift is subject to the trading restrictions specified below under the heading "*Additional Procedures*" and the sales by the recipient of the Company Securities occur during a blackout period. Further, transactions in mutual funds that are invested in Company Securities are not transactions subject to this Policy.

4.10 Special and Prohibited Transactions

The Company has determined that there is a heightened legal risk and/or the appearance of improper or inappropriate conduct if the persons subject to this Policy engage in certain types of transactions. It therefore is the Company's policy that any persons covered by this Policy may not engage in any of the following transactions, or should otherwise consider the Company's preferences as described below:

Short-Term Trading. Short-term trading of Company Securities may be distracting to the person and may unduly focus the person on the Company's short-term stock market performance instead of the Company's long-term business objectives. For these reasons, any Insider of the Company who purchases Company Securities in the open market may not sell any Company Securities of the same class during the six months following the purchase (or vice versa) unless you first pre-clear the proposed transaction with the Chief Compliance Officer.

Short Sales. No Insider shall engage in a short sale of the Company's Securities. A short sale is in general a sale of securities not owned by the seller. Transactions in certain put and call options for the Company's Securities may in some instances constitute a short sale. Short sales of Company Securities may evidence an expectation on the part of the seller that the

securities will decline in value and therefore have the potential to signal to the market that the seller lacks confidence in the Company's prospects. In addition, short sales may reduce a seller's incentive to seek to improve the Company's performance. For these reasons, short sales of Company Securities are prohibited. In addition, Section 16(c) of the Securities Exchange Act of 1934, as amended (the "***Exchange Act***") prohibits officers and directors from engaging in short sales at any time that the Company is subject to such section.

Publicly-Traded Options. Given the relatively short term of publicly-traded options, transactions in options may create the appearance that a director, officer or employee is trading based on material nonpublic information and focus a director's, officer's or other employee's attention on short-term performance at the expense of the Company's long- term objectives. Accordingly, transactions in put options, call options or other derivative securities, on an exchange or in any other organized market, by an Insider are prohibited by this Policy. (Option positions arising from certain types of hedging transactions are governed by the paragraph below captioned "*Hedging Transactions*.")

Hedging Transactions. Hedging or monetization transactions can be accomplished through a number of possible mechanisms, including through the use of financial instruments such as prepaid variable forwards, equity swaps, collars and exchange funds. Such hedging transactions may permit an Insider to continue to own Company Securities obtained through employee benefit plans or otherwise, but without the full risks and rewards of ownership. When that occurs, the Insider may no longer have the same objectives as the Company's other shareholders. As a result, these types of transactions are prohibited by Company policy.

Margin Accounts and Pledged Securities. Securities held in a margin account as collateral for a margin loan may be sold by the broker without the customer's consent if the customer fails to meet a margin call. Similarly, securities pledged (or hypothecated) as collateral for a loan may be sold in foreclosure if the borrower defaults on the loan. Because a margin sale or foreclosure sale may occur at a time when the pledgor is aware of material nonpublic information or otherwise is not permitted to trade in Company Securities, Insiders are prohibited from holding Company Securities in a margin account or otherwise pledging Company Securities as collateral for a loan.

Standing and Limit Orders. Standing and limit orders (except standing and limit orders under approved Rule 10b5-1 Plans, as described below) create heightened risks for insider trading violations similar to the use of margin accounts. There is no control over the timing of purchases or sales that result from standing instructions to a broker, and as a result the broker could execute a transaction when an Insider is in possession of material nonpublic information. The Company therefore discourages placing standing or limit orders on Company Securities. If a person subject to this Policy determines that they must use a standing order or limit order, the order should be limited to short duration and should otherwise comply with the restrictions and procedures outlined below under the heading "*Additional Procedures*."

4.11 Additional Procedures

The Company has established additional procedures in order to assist the Company in the administration of this Policy, to facilitate compliance with laws prohibiting insider trading while in possession of material nonpublic information, and to avoid the appearance of any impropriety. These additional procedures are applicable only to those individuals described below.

Pre-Clearance Procedures. All officers, directors and such other persons designated by the Compliance Officer because of their access to the Company's internal financial statements or other material nonpublic information regarding the Company's performance during annual and quarterly fiscal periods as well as the Family Members and Controlled Entities of such persons ("Designated Insiders") may not engage in any transaction in Company Securities without first obtaining pre-clearance of the transaction from the Compliance Officer or designee. A request for pre-clearance should be submitted to the Compliance Officer at least one business day in advance of the proposed transaction. The Compliance Officer is under no obligation to approve a transaction submitted for pre-clearance and may determine not to permit the transaction. If a person seeks pre-clearance and permission to engage in the transaction is denied, then he or she should refrain from initiating any transaction in Company Securities and should not inform any other person of the restriction.

When a request for pre-clearance is made, the requestor should carefully consider whether he or she may be aware of any material non-public information about the Company and should describe fully those circumstances to the Compliance Officer. The requestor should also indicate whether he or she has effected any non-exempt "opposite-way" transactions within the past six months, and should be prepared to report the proposed transaction on an appropriate Form 4 or Form 5, if the Company is then subject to Section 16. The requestor should also be prepared to comply with SEC Rule 144 and file Form 144, if necessary, at the time of any sale.

Pre-cleared trades must be effected within five business days of receipt of pre-clearance unless an exception is granted. Transactions not effected within such time limit are subject to pre-clearance again.

Quarterly Trading Restrictions. Designated Insiders may not conduct any transactions involving the Company's Securities (other than as specified by this Policy) during a "Blackout Period" beginning on the 16th of each month prior to the end of each fiscal quarter and ending one trading session after the public release of the Company's earnings results for that quarter. The sensitivity arises because directors, officers and certain employees involved in the preparation of the financial results will often possess material nonpublic information.

Event-Specific Trading Restriction Periods. From time to time, an event may occur that is material to the Company and is known by only a few directors, officers and/or employees. So long as the event remains material and nonpublic, the Designated Insiders may not trade Company Securities. In addition, the Company's financial results may be sufficiently material in a particular fiscal quarter that, in the judgment of the Compliance Officer, designated persons should refrain from trading in Company Securities even sooner than the typical Blackout Period described above. In that situation, the Compliance Officer may notify these persons that they should not trade in the Company's Securities, without disclosing the reason for the restriction. The existence of an event-specific trading restriction period or extension of a Blackout Period will not be announced to the Company as a whole, and should not be communicated to any other person. Even if the Compliance Officer has not designated you as a person who should not trade due to an event-specific restriction, you should not trade while aware of material nonpublic information.

Exceptions. The quarterly trading restrictions and event-driven trading restrictions do not apply to those transactions to which this Policy does not apply, as described above under the headings "*Transactions Under Company Plans*" and "*Transactions Not Involving a Purchase or Sale*." Further, the requirement for pre-clearance, the quarterly trading restrictions and event-driven trading restrictions do not apply to transactions conducted pursuant to approved Rule 10b5-1 plans, described under the heading "*Rule 10b5-1 Plans*."

4.12 Rule 10b5-1 Plans

Rule 10b5-1 under the Exchange Act provides a defense from insider trading liability under Rule 10b-5. In order to be eligible to rely on this defense, a person subject to this Policy must enter into a Rule 10b5-1 plan for transactions in Company Securities that meets certain conditions specified in the Rule (a "***Rule 10b5-1 Plan***"). If the plan meets the requirements of Rule 10b5-1, Company Securities may be purchased or sold without regard to certain insider trading restrictions. To comply with the Policy, a Rule 10b5-1 Plan must be approved by the Compliance Officer and meet the requirements of Rule 10b5-1 and the Company's "Guidelines for Rule 10b5-1 Plans," which are attached hereto. In general, a Rule 10b5-1 Plan must be entered into at a time when the person entering into the plan is not aware of material nonpublic information. Once the plan is adopted, the person must not exercise any influence over the amount of securities to be traded, the price at which they are to be traded or the date of the trade. The plan must either specify the amount, pricing and timing of transactions in advance or delegate discretion on these matters to an independent third party.

Any Rule 10b5-1 Plan must be submitted for approval five days prior to the entry into the Rule 10b5-1 Plan. No further pre-approval of transactions conducted pursuant to the Rule 10b5-1 Plan will be required.

4.13 Post-Termination Transactions

This Policy continues to apply to transactions in Company Securities even after termination of service to the Company. If an individual is in possession of material nonpublic information when his or her service terminates, that individual may not trade in Company Securities until that information has become public or is no longer material. The pre-clearance procedures specified under the heading "*Additional Procedures*" above, however, will cease to apply to transactions in Company Securities upon the expiration of any Blackout Period or other Company-imposed trading restrictions applicable at the time of the termination of service.

4.14 Consequences of Violations

The purchase or sale of securities while aware of material nonpublic information, or the disclosure of material nonpublic information to others who then trade in the Company's Securities, is prohibited by the federal and state laws. Insider trading violations are pursued vigorously by the SEC, U.S. Attorneys and state enforcement authorities as well as the laws of foreign jurisdictions. Punishment for insider trading violations is severe and could include significant fines and imprisonment. While the regulatory authorities concentrate their efforts on the individuals who trade, or who tip inside information to others who trade, the federal securities laws also impose potential liability on companies and other "controlling persons" if they fail to take reasonable steps to prevent insider trading by company personnel.

In addition, an individual's failure to comply with this Policy may subject the individual to Company-imposed sanctions, including dismissal for cause, whether or not the employee's failure to comply results in a violation of law. Needless to say, a violation of law, or even an SEC investigation that does not result in prosecution, can tarnish a person's reputation and irreparably damage a career.

4.15 Company Assistance

Any person who has a question about this Policy or its application to any proposed transaction may obtain additional guidance from the Compliance Officer, who can be reached by telephone at +1 786-425-3292 ext. 125 or by e-mail at mikel@inspiremd.com.

4.16 Certification

All persons subject to this Policy must certify their understanding of, and intent to comply with, this Policy.

5 Responsibility

The Finance Controllers have the overall responsibility for implementing the Insider Trading Policy, ensuring that all employees sign the Insider Trading Form.

The CEO has final approval over any future changes to the Policy.

Appendix 1 - GUIDELINES FOR RULE 10B5-1 PLANS

Rule 10b5-1 under the Securities Exchange Act of 1934, as amended (the "***Exchange Act***"), provides a defense from insider trading liability under Rule 10b-5. In order to be eligible to rely on this defense, a person subject to this Policy must enter into a Rule 10b5-1 plan for transactions in Company Securities (as defined in the Insider Trading Policy) that meets certain conditions specified in the Rule (a "***Rule 10b5-1 Plan***"). If the plan meets the requirements of Rule 10b5-1, Company Securities may be purchased or sold without regard to certain insider trading restrictions. In general, a Rule 10b5-1 Plan must be entered into at a time when the person entering into the plan is not aware of material nonpublic information. Once the plan is adopted, the person must not exercise any influence over the amount of securities to be traded, the price at which they are to be traded or the date of the trade. The plan must either specify the amount, pricing and timing of transactions in advance or delegate discretion on these matters to an independent third party.

As specified in the Company's Insider Trading Policy, a Rule 10b5-1 Plan must be approved by the Compliance Officer and meet the requirements of Rule 10b5-1 and these guidelines. Any Rule 10b5-1 Plan must be submitted for approval five days prior to the entry into the Rule 10b5-1 Plan. No further pre-approval of transactions conducted pursuant to the Rule 10b5-1 Plan will be required.

The following guidelines apply to all Rule 10b5-1 Plans:

- You may not enter into, modify or terminate a trading program during a blackout period or while in possession of material nonpublic information. Entering into, modifying, revoking, or early termination of a Rule 10b5-1 Plan must be approved in advance by the Compliance Officer.
- Rule 10b5-1 Plans must include a representation certifying that at the time of the adoption or modification: (1) you are not aware of material, nonpublic information about the Company or its securities; and (2) you are adopting the plan in good faith and not as part of a plan or scheme to evade the prohibitions of Rule 10b-5.
- All Rule 10b5-1 Plans must have a duration of at least 61 months and no more than 12 years.
- If a Rule 10b5-1 Plan is terminated, you must wait at least 30 days before trading outside of the Rule 10b5-1 Plan.
- If a trading program is terminated, you must wait until the end of the current or next Blackout Period (as defined in the Insider Trading Policy), whichever is sooner, before a new Rule 10b5-1 plan may be adopted.
- You may not commence sales under a trading program until (i) for directors, officers and other Section 16 insiders, the later of: (1) 90 days after plan adoption; or (2) two (2) business days following the public disclosure of the Company's annual financial results in a Form 10-K or quarterly financial results in a Form 10-Q (but not to exceed 120 days following plan adoption); and (ii) for individuals not covered by (i), at least 30 days following the date of establishment of a trading program.
- The waiting period requirement described above will apply to any modification to the amount, price or timing of a purchase or sale (including changes to related formulae) under an existing Rule 10b5-1 Plan. Trading under your Rule 10b5-1 Plan will continue pursuant to the original terms of your Rule 10b5-1 Plan until this waiting period has elapsed, at which time the modified Rule 10b5-1 Plan will become effective or the revocation or termination of the plan (as applicable).
- Following any permitted revocation or early termination of a Rule 10b5-1 Plan, you may not establish a new Rule 10b5-1 Plan until the commencement of the next open trading window.

- You may not have more than one Rule 10b5-1 Plan in effect at any given time (i.e. "***multiple overlapping plans***"), subject to certain limited exceptions that comport with the requirements of Rule 10b5-1 relating to multiple or overlapping plans.
    - This restriction on multiple overlapping plans will not apply to a plan adopted solely and exclusively for the purpose of selling Company Securities in the open market or through a broker to satisfy a person's tax obligations through a "sell-to-cover" method in connection with the vesting of equity awards ("***Sell-to-Cover Plans***"). Sales under Sell-to-Cover Plans must be strictly limited to the number of securities needed to cover such person's tax obligations and the award holder may not be permitted to exercise control over the timing of such sales. This exemption does not apply to plans for sales incident to the exercise of option awards.
- You may not adopt more than one Rule 10b5-1 Plan to execute a single trade during any consecutive 12-month period, subject to certain limited exceptions that comport with the requirements of Rule 10b5-1. This restriction does not apply to Sell-to-Cover Plans.
- If you are director, officer and other Section 16 insider, you must also confirm that all trades made pursuant to the Rule 10b5-1 Plan will be made in accordance with Rule 144 under the Securities Act of 1933, as amended.
- You may not engage in any trades of the Company's securities outside of the Rule 10b5-1 Plan while a plan is in effect.

Each director, officer and other Section 16 insider understands that the approval or adoption of a pre-planned selling program in no way reduces or eliminates such person's obligations under Section 16 of the Exchange Act, including such person's disclosure and short-swing trading liabilities thereunder. If any questions arise, such person should consult with their own counsel in implementing a Rule 10b5-1 Plan. Each director, officer and other Section 16 insider seeking to establish a new Rule 10b5-1 Plan, or amend or modify an existing Rule 10b5-1 Plan, will be required to provide a written representation to the Company certifying that such director or officer (i) will deliver a copy of any such Rule 10b5-1 Plan, including any amendments or modifications thereto, to the Compliance Officer and (ii) consents to the disclosure of the material terms of any such Rule 10b5-1 Plan, including any amendments or modifications thereto, in the Company's Exchange Act reports.

None of the requirements or plan terms currently contemplated by this Appendix to the Company's Insider Trading Policy are exhaustive or limiting on the Company. The Company has the right to require the inclusion of additional provisions in your Rule 10b5-1 Plan designed to protect you and/or the Company, whether before or after the Rule 10b5-1 Plan has been approved by the Compliance Officer, or to delete or amend existing provisions.

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, 333-215682, 333-252199), Form S-3 (Nos. 333-272149, 333-265409, 333-255038, 333-223530, 333-286309, 333-289292) and Form S-8 (Nos. 333-248837, 333-249320, 333-232348, 333-218499, 333-196533, 333-188839, 333-260216, 333-272003, 333-274890, 333-276349, 333-282441, 333-291617) of InspireMD Inc. of our report dated March 18, 2026 relating to the financial statements, which appears in this Form 10-K.

Tel-Aviv, Israel
March 18, 2026

/s/ Kesselman & Kesselman
Certified Public Accountants (Isr.)
A member firm 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 18, 2026

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, Michael Lawless, 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 18, 2026

By: */s/ Michael Lawless*
Name: Michael Lawless
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, 2025 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 18, 2026

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, 2025 of InspireMD, Inc. (the "Company"). I, Michael Lawless, 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 18, 2026

By: */s/ Michael Lawless*
Name: Michael Lawless
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.