

## Up to 77,484,492 Shares of Common Stock Offered by the Selling Stockholders



## InspireMD, Inc.

## Common Stock

This prospectus relates to the resale, from time to time by the selling stockholders named in this prospectus, or the selling stockholders, of up to 77,484,492 shares of our common stock, which consist of (i) 10,266,270 shares of our common stock held by the selling stockholders, or the Shares, (ii) 15,561,894 shares of our common stock, or the Pre-Funded Warrant Shares, issuable upon the exercise of pre-funded warrants, held by the selling stockholders, or the Pre-Funded Warrants, and (iii) 51,656,328 shares of our common stock, or the Warrant Shares, issuable upon the exercise of warrants held by the selling stockholders, or the Warrants, which shall include any shares of common stock issuable upon exercise of pre-funded warrants that the selling stockholder may elect to receive in lieu of shares of common stock under the terms of the Warrants. The Shares, Pre-Funded Warrant Shares, and Warrant Shares shall be collectively referred to as the “Securities”.

Our registration of shares of common stock covered by this prospectus does not mean that the selling stockholders will offer or sell any such shares. The selling stockholders received the Shares, Pre-Funded Warrants and Warrants from us pursuant to a private placement transaction, which was consummated on May 16, 2023. We are registering the offer and resale of the Securities to satisfy a covenant set forth in the registration rights agreement entered into on May 12, 2023 executed concurrently with a securities purchase agreement as of even date thereof with respect to the private placement, pursuant to which we agreed to register the resale of these shares of our common stock within a limited period of time following the date of the registration rights agreement.

We will not receive any of the proceeds from the sale of our common stock by the selling stockholders, although we will receive proceeds from the cash exercise of any Warrants as well as the nominal exercise price upon the exercise of the Pre-Funded Warrants.

Any shares of our common stock subject to resale hereunder will have been issued by us and received by the selling stockholders prior to any resale of such shares pursuant to this prospectus.

The selling stockholders, or its donees, pledgees, transferees or other successors-in-interest, may offer or resell the shares from time to time through public or private transactions at prevailing market prices, at prices related to prevailing market prices or at privately negotiated prices. The selling stockholders will bear all commissions and discounts and similar selling expenses, if any, attributable to the sale of shares. We will bear all costs, expenses and fees (other than commissions and discounts and similar selling expenses) in connection with the registration of the shares. For additional information on the methods of sale that may be used by the selling stockholders, see “Plan of Distribution” beginning on page 13 of this prospectus.

Our common stock is listed on the Nasdaq Capital Market under the symbol “NSPR.” On May 31, 2023, the last reported sale price of our common stock as reported on the Nasdaq Capital Market was \$1.84 per share.

**Investing in our securities involves a high degree of risk. These risks are discussed in this prospectus under “Risk Factors” beginning on page 4 and in our most recent Annual Report on Form 10-K and Quarterly Reports on Form 10-Q, which are incorporated by reference in this prospectus and in any applicable prospectus supplement.**

**Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.**

The date of this prospectus is June 1, 2023

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## ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-3 that we filed with the Securities and Exchange Commission, or the SEC, using a “shelf” registration process. The selling stockholders may resell, from time to time, in one or more offerings, the shares of our common stock offered by this prospectus. Information about the selling stockholders may change over time. When the selling stockholders sell shares of our common stock under this prospectus, we will, if necessary and required by law, provide a prospectus supplement that will contain specific information about the terms of that offering. Any prospectus supplement may also add to, update, modify or replace information contained in this prospectus. If a prospectus supplement is provided and the description of the offering in the prospectus supplement varies from the information in this prospectus, you should rely on the information in the prospectus supplement. You should carefully read this prospectus and the accompanying prospectus supplement, if any, along with all of the information incorporated by reference herein and therein, before making an investment decision.

**You should rely only on the information contained or incorporated by reference in this prospectus or any applicable prospectus supplement. We have not, and the selling stockholders has not, authorized any other person to provide you with different or additional information. If anyone provides you with different or additional information, you should not rely on it. This prospectus is not an offer to sell, nor is the selling stockholders seeking an offer to buy, the shares offered by this prospectus in any jurisdiction where the offer or sale is not permitted. No offers or sales of any of the shares of our common stock are to be made in any jurisdiction in which such an offer or sale is not permitted. You should assume that the information contained in this prospectus or in any applicable prospectus supplement is accurate only as of the date on the front cover thereof or the date of the document incorporated by reference, regardless of the time of delivery of this prospectus or any applicable prospectus supplement or any sales of the shares of our common stock offered hereby or thereby.**

You should read the entire prospectus and any prospectus supplement and any related issuer free writing prospectus, as well as the documents incorporated by reference into this prospectus or any prospectus supplement or any related issuer free writing prospectus, before making an investment decision. Neither the delivery of this prospectus or any prospectus supplement or any issuer free writing prospectus nor any sale made hereunder shall under any circumstances imply that the information contained or incorporated by reference herein or in any prospectus supplement or issuer free writing prospectus is correct as of any date subsequent to the date hereof or of such prospectus supplement or issuer free writing prospectus, as applicable. You should assume that the information appearing in this prospectus, any prospectus supplement or any document incorporated by reference herein or therein is accurate only as of the date of the applicable documents, regardless of the time of delivery of this prospectus or any sale of securities. Our business, financial condition, results of operations and prospects may have changed since that date.

As used in this prospectus, unless the context otherwise indicates, the terms “we,” “our,” “us,” or “the Company” refer to InspireMD, Inc., a Delaware corporation, and its subsidiaries taken as a whole.

## PROSPECTUS SUMMARY

*This summary provides an overview of selected information contained elsewhere or incorporated by reference in this prospectus and does not contain all of the information you should consider before investing in our securities. You should carefully read the prospectus, the information incorporated by reference and the registration statement of which this prospectus is a part in their entirety before investing in our securities, including the information discussed under “Risk Factors” in this prospectus and the documents incorporated by reference and our financial statements and related notes that are incorporated by reference in this prospectus.*

### **Our Business**

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

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

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

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

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

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

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

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

#### **Private Placement**

On May 12, 2023, we entered into a securities purchase agreement, or the Purchase Agreement, pursuant to which we agreed to sell and issue in a private placement, or the Private Placement Offering, an aggregate of our 10,266,270 shares of common stock, Pre-Funded Warrants to purchase up to 15,561,894 of our shares of common stock, and Warrants to purchase up to an aggregate of 51,656,328 of our shares of common stock, consisting of Series H warrants to purchase up to 12,914,086 shares of common stock, Series I warrants to purchase up to 12,914,078 shares of common stock, Series J warrants to purchase up to 12,914,086 shares of common stock and Series K warrants to purchase up to 12,914,078 shares of common stock, at an offering price of \$1.6327 per Share and associated Warrants and an offering price of \$1.6326 per Pre-Funded Warrant and associated Warrants. The Private Placement Offering closed on May 16, 2023. Aggregate gross proceeds to the Company in respect of the Private Placement Offering are approximately \$42.2 million, before deducting fees payable to the placement agent and other offering expenses payable by the Company. If the Warrants are exercised in cash in full this would result in an additional \$71.4 million of gross proceeds.

The Pre-Funded Warrants are immediately exercisable at an exercise price of \$0.0001 per share and will not expire until exercised in full. The Warrants are immediately exercisable upon issuance at an exercise price of \$1.3827 per share, subject to adjustment as set forth therein. The 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 Premarket Approval (PMA) from the Food and Drug Administration, or FDA, for the CGuard Prime Carotid Stent System (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 the SwitchGuard transcarotid system 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 the CGuard Carotid Stent System in the United States begin.

The Warrants may be exercised on a cashless basis if there is no effective registration statement registering the shares underlying the Warrants. Under the terms of the Pre-Funded Warrants and Warrants, certain of the selling stockholders may not exercise the Pre-Funded Warrants or Warrants to the extent such exercise would cause such selling stockholder, together with its affiliates and attribution parties, to beneficially own a number of shares of common stock which would exceed 4.99% or 9.99% of our then outstanding common stock following such exercise, excluding for purposes of such determination common stock issuable upon exercise of the Pre-Funded Warrants or Warrants which have not been exercised. The Warrants may be exercised into pre-funded warrants if the selling stockholder is unable to exercise the Warrant due to the foregoing beneficial ownership limitation or at the selling shareholder's election. The Warrant Shares being registered hereunder include any shares of common stock issuable upon exercise of pre-funded warrants that the selling stockholder may elect to receive in lieu of shares of common stock under the terms of the Warrants.

In connection with the Purchase Agreement, we entered into a registration rights agreement, or the Registration Rights Agreement. Pursuant to the Registration Rights Agreement, we are required to file a resale registration statement, or the Registration Statement, with the SEC to register for resale the Securities within 20 days of the signing date of the Purchase Agreement, or the Signing Date, and to have such Registration Statement declared effective within 45 days after the Signing Date in the event the Registration Statement is not reviewed by the SEC, or 90 days of the Signing Date in the event the Registration Statement is reviewed

by the SEC. We are obligated to pay certain liquidated damages if we fail to file the Registration Statement when required, if we fail to cause the Registration Statement to be declared effective by the SEC when required, or if we fail to maintain the effectiveness of the Registration Statement.

The registration statement of which this prospectus is a part relates to the offer and resale of the Shares and Pre-Funded Warrant Shares and Warrant Shares underlying the Pre-Funded Warrants and Warrants (and pre-funded warrants that the selling stockholder may elect to receive in lieu of shares of common stock under the terms of the Warrant) issued to the selling stockholders pursuant to the Purchase Agreement to fulfill our contractual obligations under the Registration Rights Agreement. When we refer to the selling stockholders in this prospectus, we are referring to the persons names as the selling stockholders in this prospectus and, as applicable, any donees, pledgees, assignees, transferees or other successors-in-interest selling the Securities received after the date of this prospectus from the selling stockholders as a gift, pledge, or other non-sale related transfer.

During the period commencing on the closing of the Private Placement Offering and ending on the earlier of (i) the fifth anniversary of the closing of the Private Placement Offering and (ii) the date that any of OrbiMed Advisors LLC, or OrbiMed, and Soleus Capital Management, L.P. , or Soleus, holds less than 50% of the Private Placement Shares and Pre-Funded Warrants, then OrbiMed and Soleus shall each have the right, subject to certain exceptions, to appoint an independent, non-voting board observer, or a Board Observer, and such Board Observer shall have the right to, among others things, be present and participate at meetings of the board of directors, or any committee thereof, of the Company.

The Company paid LifeSci Capital LLC, a placement fee equal to 5.6% of the aggregate gross proceeds from the closing of the Private Placement Offering, or approximately \$2.4 million, and legal expenses of \$41,600. In addition, the Company paid Piper Sandler & Co. a financial advisory fee of \$1.5 million, AGP/Alliance Global Partners a financial advisory fee of \$250,000 and lead investor counsel expenses of \$125,000.

The foregoing summary descriptions of the Purchase Agreement and the Registration Rights Agreement do not purport to be complete and are qualified in their entirety by reference to the full text of such documents, which are filed as exhibits to the registration statement of which this prospectus is a part and are incorporated by reference herein.

### **Corporate Information**

We were organized in the State of Delaware on February 29, 2008. Our principal executive offices are located at 4 Menorat Hamaor St., Tel Aviv, Israel 6744832. Our telephone number is (888) 776-6804. Our website address is [www.inspiremd.com](http://www.inspiremd.com). Information accessed through our website is not incorporated into this prospectus and is not a part of this prospectus.

## THE OFFERING

Common stock offered by the selling stockholders	Up to 77,484,492 shares of our common stock, par value \$0.0001 per share, which consist of (i) 10,266,270 shares of our common stock held by the selling stockholders, (ii) 15,561,894 shares of our common stock issuable upon the exercise of Pre-Funded Warrants, and (iii) 51,656,328 shares of our common stock issuable upon the exercise of Warrants held by the selling stockholders (which shall include any shares of common stock issuable upon exercise of pre-funded warrants that the selling stockholder may elect to receive in lieu of shares of common stock under the terms of the Warrants) consisting of Series H Warrants to purchase up to 12,914,086 shares of common stock, Series I warrants to purchase up to 12,914,078 shares of common stock, Series J Warrants to purchase up to 12,914,086 shares of common stock and Series K Warrants to purchase up to 12,914,078 shares of common stock.
Common stock currently outstanding	21,192,204 (as of May 19, 2023)
Common Stock to be outstanding assuming exercise of the Pre-Funded Warrants and Warrants	88,410,426
The Pre-Funded Warrants	The Pre-Funded Warrants are immediately exercisable at an exercise price of \$0.0001 per share, and will not expire until exercised in full.
The Warrants	The Warrants are immediately exercisable upon issuance at an exercise price of \$1.3827 per share, subject to adjustment as set forth therein. The 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 our public release of primary and secondary end points related to one year follow up study results from our C-Guardians pivotal trial, (B) in the case of the Series I Warrants, 20 trading days following our announcement of receipt of Premarket Approval (PMA) from the FDA for the CGuard Prime Carotid Stent System (135 cm), (C) in the case of the Series J Warrants, 20 trading days following our announcement of receipt of FDA approval for the SwitchGuard transcrotid system 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 the CGuard Carotid Stent System in the United States begin. The Warrants may be exercised on a cashless basis if there is no effective registration statement registering the shares underlying the warrants. The Warrants may be exercised into pre-funded warrants if the selling stockholder is unable to exercise the Warrant due to certain beneficial ownership limitations, if applicable, or otherwise at the selling stockholder's election.
Selling stockholders	All of the shares of our common stock are being offered by the selling stockholders. See "Selling Stockholder" on page 7 of this prospectus for more information on the selling stockholders.
Use of proceeds	We will not receive any proceeds from the sale of the shares in this offering by the selling stockholders, although we will receive proceeds from the cash exercise of any Warrants as well as the nominal exercise price upon the exercise of the Pre-Funded Warrants. See "Use of Proceeds" beginning on page 6 of this prospectus for additional information.
Registration Rights	Under the terms of the Registration Rights Agreement with the selling stockholders, we have agreed to file the registration statement of which this prospectus forms a part in order to register the resale by the selling stockholders of the shares of our common stock offered hereby. See "Selling Stockholder" on page 7 of this prospectus for additional information.
Plan of Distribution	The selling stockholders, or its pledgees, donees, transferees, distributees, beneficiaries or other successors-in-interest, may offer or sell the shares of our common stock offered under this prospectus from time to time through public or private transactions at our prevailing market prices, at prices related to prevailing market prices or at privately negotiated prices. The selling stockholders may also resell the shares of our common stock offered under this prospectus to or through underwriters, broker-dealers or agents, who may receive compensation in the form of discounts, concessions or commissions. See "Plan of Distribution" beginning on page 13 of this prospectus for additional information on the methods of sale that may be used by the selling stockholders.
Risk factors	

Investing in our common stock involves a high degree of risk. You should carefully read and consider the information beginning on page 4 of this prospectus set forth under the heading “Risk Factors” and all other information set forth in this prospectus and the documents incorporated herein and therein by reference before deciding to invest in our common stock.

Nasdaq symbol for common stock

“NSPR”



## RISK FACTORS

An investment in our securities involves certain risks. Before investing in our securities, you should carefully consider the risk set forth below, as well as the risks described in our most recent Annual Report on Form 10-K, any updates to those risks in our Quarterly Reports on Form 10-Q or Current Reports on Form 8-K, together with all of the other information appearing in this prospectus or incorporated by reference into this prospectus. The risks so described are not the only risks facing our company. Additional risks not presently known to us or that we currently deem immaterial may also impair our business operations. Any of these risks could materially and adversely affect our business, financial condition, results of operations and cash flows and could result in a loss of all or part of your investment. In any case, the value of the securities offered by means of this prospectus could decline due to any of these risks, and you may lose all or part of your investment.

***The sale of a substantial number of shares of our common stock in the public market, including resale of the Securities issued or issuable to the selling stockholders, could adversely affect the prevailing market price for our common stock.***

We are registering for resale up to 77,484,492 shares of our common stock consisting of the Shares and Pre-Funded Warrant Shares and Warrant Shares underlying the Pre-Funded Warrants and Warrants (and pre-funded warrants that the selling stockholder may elect to receive in lieu of shares of common stock under the terms of the Warrant) issued to the selling stockholders pursuant to the Purchase Agreement to fulfill our contractual obligations under the Registration Rights Agreement. Sales of substantial amounts of shares of our common stock in the public market, or the perception that such sales might occur, could adversely affect the market price of our common stock, and the market value of our other securities. We cannot predict if and when the selling stockholders may sell such shares in the public markets. Furthermore, in the future, we may issue additional shares of our common stock or other equity or debt securities exercisable for, or convertible into, shares of our common stock. Any such issuances could result in substantial dilution to our existing stockholders and could cause our stock price to decline.

## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the information incorporated by reference in this prospectus contain “forward-looking statements,” which include information relating to future events, future financial performance, strategies, expectations, competitive environment and regulation. Words such as “may,” “should,” “could,” “would,” “predicts,” “potential,” “continue,” “expects,” “anticipates,” “future,” “intends,” “plans,” “believes,” “estimates,” and similar expressions, as well as statements in future tense, identify forward-looking statements. Forward-looking statements should not be read as a guarantee of future performance or results and will probably not be accurate indications of when such performance or results will be achieved. Forward-looking statements are based on information we have when those statements are made or our management’s good faith belief as of that time with respect to future events, and are subject to risks and uncertainties that could cause actual performance or results to differ materially from those expressed in or suggested by the forward-looking statements. Important factors that could cause such differences include, but are not limited to:

- our history of recurring losses and negative cash flows from operating activities, significant future commitments and the uncertainty regarding the adequacy of our liquidity to pursue our complete business objectives, and substantial doubt regarding our ability to continue as a going concern;
- our need to raise additional capital to meet our business requirements in the future and such capital raising may be costly or difficult to obtain and could dilute out stockholders’ ownership interests;
- an inability to secure and maintain regulatory approvals for the sale of our products;
- negative clinical trial results or lengthy product delays in key markets;
- our ability to maintain compliance with the Nasdaq listing standards;
- our ability to generate revenues from our products and obtain and maintain regulatory approvals for our products;
- our ability to adequately protect our intellectual property;
- our dependence on a single manufacturing facility and our ability to comply with stringent manufacturing quality standards and to increase production as necessary;
- the risk that the data collected from our current and planned clinical trials may not be sufficient to demonstrate that our technology is an attractive alternative to other procedures and products;
- intense competition in our industry, with competitors having substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do;
- entry of new competitors and products and potential technological obsolescence of our products;
- inability to carry out research, development and commercialization plans;
- loss of a key customer or supplier;
- technical problems with our research and products and potential product liability claims;
- product malfunctions;
- price increases for supplies and components;
- adverse economic conditions;
- insufficient or inadequate reimbursement by governmental and other third-party payers for our products;

- adverse federal, state and local government regulation, in the United States, Europe or Israel and other foreign jurisdictions;
- the fact that we conduct business in multiple foreign jurisdictions, exposing us to foreign currency exchange rate fluctuations, logistical and communications challenges, burdens and costs of compliance with foreign laws and political and economic instability in each jurisdiction;
- the escalation of hostilities in Israel, which could impair our ability to manufacture our products; and
- current or future unfavorable economic and market conditions and adverse developments with respect to financial institutions and associated liquidity risk.

The foregoing does not represent an exhaustive list of matters that may be covered by the forward-looking statements contained herein or risk factors that we are faced with that may cause our actual results to differ from those anticipated in our forward-looking statements. You should review carefully the risks and uncertainties described under the heading “Item 1A. Risk Factors” in our recently filed 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 prospectus are based on information available to us on the date of this prospectus. 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 prospectus.

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.

#### **USE OF PROCEEDS**

We will not receive any proceeds from the sale of shares of our common stock by the selling stockholders.

We may receive proceeds from the exercise of the Warrants as well as the nominal exercise price upon the exercise of the Pre-Funded Warrants to the extent the Warrants and Pre-Funded Warrants are exercised. We can make no assurances that any of the Warrants or Pre-Funded Warrants will be exercised, or if exercised, the quantity that will be exercised or the period in which such Warrants or Pre-Funded Warrants will be exercised.

We intend to use the net proceeds from any exercise of the Warrants and Pre-Funded Warrants for product and clinical development, obtaining regulatory approvals, expansion of manufacturing capabilities, commercial readiness activities to support potential new product launches including CGuard Prime and SwitchGuard in the US and EU as well as for working capital and general corporate purposes.

## SELLING STOCKHOLDERS

The shares of common stock being offered by the selling stockholders consisting of the Shares and Pre-Funded Warrant Shares and Warrant Shares underlying the Pre-Funded Warrants and Warrants (and pre-funded warrants that the selling stockholder may elect to receive in lieu of shares of common stock under the terms of the Warrant) issued to the selling stockholders pursuant to the Purchase Agreement to fulfill our contractual obligations under the Registration Rights Agreement. See “Prospectus Summary – Private Placement.”

The following table sets forth the number and percentage of shares of our common stock beneficially owned by the selling stockholders as of May 19, 2023, taking into account number of shares that may be offered under this prospectus and the number and percentage of our common stock beneficially owned by the selling stockholders assuming all of the shares offered under this prospectus are sold. Beneficial ownership is determined in accordance with the rules of the SEC and includes voting or investment power with respect to shares of our common stock. Generally, a person “beneficially owns” shares of our common stock if the person has or shares with others the right to vote those shares or to dispose of them, or if the person has the right to acquire voting or disposition rights within 60 days.

All information contained in the table below and the footnotes thereto is based upon information provided to us by the selling stockholders. The information in the table below and the footnotes thereto regarding shares of our common stock to be beneficially owned after the offering under this prospectus assumes the sale of all shares of our common stock being offered by the selling stockholders under this prospectus. The percentage of shares of our common stock owned prior to and after the offering under this prospectus is based on 21,192,204 shares of our common stock outstanding as of May 19, 2023. Unless otherwise indicated in the footnotes to this table, we believe that the selling stockholders has sole voting and investment power with respect to the shares of our common stock indicated as beneficially owned.

To our knowledge, except for Gary Roubin, Michael Berman and Thomas J. Kester, our directors, and Paul Stuka, who is the Chairman of the Board of Directors, and except as described above, neither the selling stockholders nor any of their affiliates, officers, directors or principal equity holders have held any position or office or had any other material relationship with us or our affiliates within the past three years.

As used in this prospectus, the term “selling stockholder” includes the selling stockholders named below and any donees, pledgees, transferees or other successors-in-interest selling shares of our common stock received after the date of this prospectus from the selling stockholders as a gift, pledge, or other non-sale related transfer.

The number of shares in the column “Maximum Number of Common Stock Offered” represents all of the shares of our common stock that the selling stockholders may offer under this prospectus. The fourth column assumes the sale of all the shares of our common stock offered by the selling stockholders under this prospectus and that the selling stockholder does not acquire any additional shares of our common stock before the completion of the offering under this prospectus. However, because the selling stockholders may sell all or some of the shares offered under this prospectus from time to time, or in another permitted manner, we cannot assure you as to the actual number of shares of our common stock that will be sold by the selling stockholders or that will be held by the selling stockholders after completion of any sales. The selling stockholders may sell some, all or none of the shares of our common stock offered under this prospectus. We do not know how long the selling stockholders will hold the Shares, Pre-Funded Warrants or Warrants (and pre-funded warrants that the selling stockholder may elect to receive in lieu of shares of common stock under the terms of the Warrant), whether any will exercise the Pre-Funded Warrants or Warrants, and upon such exercise, how long such selling stockholders will hold the shares of common stock before selling them, and we currently have no agreements, arrangements or understandings with the selling stockholders regarding the sale of any of the shares of common stock.

Under the terms of the Pre-Funded Warrants and Warrants, certain of the selling stockholders may not exercise the Pre-Funded Warrants or Warrants (and pre-funded warrants that the selling stockholder may elect to receive in lieu of shares of common stock under the terms of the Warrant) to the extent such exercise would cause such selling stockholder, together with its affiliates and attribution parties, to beneficially own a number of shares of common stock which would exceed 4.99% or 9.99% of our then outstanding common stock following such exercise, excluding for purposes of such determination common stock issuable upon exercise of the Pre-Funded Warrants or Warrants which have not been exercised. The number of shares in the second column does not reflect this limitation.

<b>Selling Stockholder</b>	<b>Ownership Before Offering</b>		<b>Maximum number of shares of common stock offered</b>	<b>Ownership After Offering</b>	
	<b>Number of shares of common stock beneficially owned</b>	<b>Percentage of common stock beneficially owned</b>		<b>Number of shares of common stock beneficially owned</b>	<b>Percentage of common stock beneficially owned</b>
MW XO Health Innovations Fund, LP	26,037,498 <sup>(1)</sup>	9.99%	26,037,498	-	-
Entities affiliated with OrbiMed	17,141,214 <sup>(2)</sup>	9.99%	17,141,214	-	-
Soleus Private Equity Fund III, L.P.	8,268,768 <sup>(3)</sup>	9.99%	8,268,768	-	-
Nantahala Capital Partners Limited Partnership	1,106,568 <sup>(4)</sup>	5.01%	1,106,568	-	-
Nantahala Capital Partners II Limited Partnership	499,038 <sup>(5)</sup>	2.31%	499,038	-	-
NCP RFM LP	1,898,523 <sup>(6)</sup>	8.34%	1,898,523	-	-
Blackwell Partners LLC - Series A	5,955,948 <sup>(7)</sup>	9.99%	5,955,948	-	-
Pinehurst Partners, L.P.	1,388,646 <sup>(8)</sup>	6.22%	1,388,646	-	-
Entities affiliated with Rosalind	10,848,723 <sup>(9)</sup>	9.99%	10,848,723	-	-
Velan Capital Master Fund, LP	2,712,087 <sup>(10)</sup>	4.99%	2,712,087	-	-
Gary Roubin, M.D.	536,973 <sup>(11)</sup>	2.52%	183,747 <sup>(12)</sup>	353,226 <sup>(13)</sup>	1.65%
Michael Berman Revocable Trust	389,311 <sup>(14)</sup>	1.82%	367,491 <sup>(15)</sup>	21,820 <sup>(16)</sup>	*
Osiris Investment Partners, L.P.	872,960 <sup>(17)</sup>	4.05%	525,000 <sup>(18)</sup>	347,960 <sup>(19)</sup>	1.61%
Thomas J Kester	388,641 <sup>(20)</sup>	1.81%	183,747 <sup>(21)</sup>	204,894 <sup>(22)</sup>	*
Barer & Son Capital, LLC	183,747 <sup>(23)</sup>	*	183,747	-	-
Sol J Barer	391,301 <sup>(24)</sup>	2.12%	183,747 <sup>(25)</sup>	207,554 <sup>(26)</sup>	1.26%

\* Represents ownership of less than one percent.

(1) Represents (i) 1,860,405 shares of common stock issued in our May 2023 financing, (ii) 6,818,761 shares of common stock issuable upon the exercise of pre-funded warrants issued in our May 2023 financing, (iii) 4,339,583 shares of common stock issuable upon the exercise of Series H Warrants issued in our May 2023 financing, (iv) 4,339,583 shares of common stock issuable upon the exercise of Series I Warrants issued in our May 2023 financing, (v) 4,339,583 shares of common stock issuable upon the exercise of Series J Warrants issued in our May 2023 financing, and (vi) 4,339,583 shares of common stock issuable upon the exercise of Series K Warrants issued in our May 2023 financing. The exercise of the foregoing warrants is subject to a 9.99% blocker. Marshall Wace, LLC, as general partner of Marshall Wace North America, LP, is the investment manager of MW XO Health Innovations Fund, LP. No individual has ultimate beneficial ownership of the shares owned by MW XO Health Innovations Fund, LP. The address of the selling stockholder is 350 Park Ave, New York, NY 10022.

- (2) Represents (i) 1,638,304 shares of common stock issued in our May 2023 financing issued to OrbiMed Private Investments IX, LP, or OPI IX, (ii) 3,393,310 shares of common stock issuable upon the exercise of pre-funded warrants issued to OPI IX in our May 2023 financing, (iii) 2,515,807 shares of common stock issuable upon the exercise of Series H Warrants issued to OPI IX in our May 2023 financing, (iv) 2,515,807 shares of common stock issuable upon the exercise of Series I Warrants issued to OPI IX in our May 2023 financing, (v) 2,515,807 shares of common stock issuable upon the exercise of Series J Warrants issued to OPI IX in our May 2023 financing, (vi) 2,515,807 shares of common stock issuable upon the exercise of Series K Warrants issued to OPI IX in our May 2023 financing, (vii) 222,101 shares of common stock issued in our May 2023 financing issued to OrbiMed Genesis Master Fund, L.P., or Genesis Master Fund, (viii) 460,023 shares of common stock issuable upon the exercise of pre-funded warrants issued to Genesis Master Fund in our May 2023 financing, (ix) 341,062 shares of common stock issuable upon the exercise of Series H Warrants issued to Genesis Master Fund in our May 2023 financing, (x) 341,062 shares of common stock issuable upon the exercise of Series I Warrants issued to Genesis Master Fund in our May 2023 financing, (xi) 341,062 shares of common stock issuable upon the exercise of Series J Warrants issued to Genesis Master Fund in our May 2023 financing, and (xii) 341,062 shares of common stock issuable upon the exercise of Series K Warrants issued to Genesis Master Fund in our May 2023 financing. The exercise of the foregoing warrants is subject to a 9.99% blocker. OrbiMed Capital GP IX LLC, or GP IX, is the general partner of OPI IX and OrbiMed Advisors LLC, or OrbiMed Advisors, is the managing member of GP IX. By virtue of such relationships, GP IX and OrbiMed Advisors may be deemed to have voting power and investment power over the securities held by OPI IX and as a result, may be deemed to have beneficial ownership over such securities. OrbiMed Genesis GP LLC, or Genesis GP, is the general partner of Genesis Master Fund and OrbiMed Advisors is the managing member of Genesis GP. By virtue of such relationships, Genesis GP and OrbiMed Advisors may be deemed to have voting power and investment power over the securities held by Genesis Master Fund and as a result, may be deemed to have beneficial ownership over such securities. OrbiMed Advisors exercises voting and investment power through a management committee comprised of Carl L. Gordon, Sven H. Borho, and W. Carter Neild, each of whom disclaims beneficial ownership of the shares held by OPI IX and Genesis Master Fund. The business address of the entities is c/o OrbiMed Advisors LLC, 601 Lexington Avenue, 54th Floor, New York, NY 10022.
- (3) Represents (i) 1,378,128 shares of common stock issued in our May 2023 financing, (ii) 1,378,128 shares of common stock issuable upon the exercise of pre-funded warrants issued in our May 2023 financing, (iii) 1,378,128 shares of common stock issuable upon the exercise of Series H Warrants issued in our May 2023 financing, (iv) 1,378,128 shares of common stock issuable upon the exercise of Series I Warrants issued in our May 2023 financing, (v) 1,378,128 shares of common stock issuable upon the exercise of Series J Warrants issued in our May 2023 financing, and (vi) 1,378,128 shares of common stock issuable upon the exercise of Series K Warrants issued in our May 2023 financing. The exercise of the foregoing warrants is subject to a 9.99% blocker. Soleus Private Equity GP III, LLC is the sole general partner of the selling stockholder. Soleus PE GP III, LLC is the sole manager of Soleus Private Equity GP III, LLC. Mr. Guy Levy is the sole managing member of Soleus PE GP III, LLC. Each of Mr. Guy Levy, Soleus PE GP III, LLC and Soleus Private Equity GP III, LLC disclaims beneficial ownership of the securities held by the selling stockholder, except to the extent of their respective pecuniary interests therein. The address of the selling stockholder is 104 Field Point Road, Second Floor, Greenwich, CT 06830.
- (4) Represents (i) 189,761 shares of common stock issued in our May 2023 financing, (ii) 179,095 shares of common stock issuable upon the exercise of pre-funded warrants issued in our May 2023 financing, (iii) 184,428 shares of common stock issuable upon the exercise of Series H Warrants issued in our May 2023 financing, (iv) 184,428 shares of common stock issuable upon the exercise of Series I Warrants issued in our May 2023 financing, (v) 184,428 shares of common stock issuable upon the exercise of Series J Warrants issued in our May 2023 financing, and (vi) 184,428 shares of common stock issuable upon the exercise of Series K Warrants issued in our May 2023 financing. The exercise of the foregoing warrants is subject to a 9.99% blocker. The above shall not be deemed to be an admission by any selling stockholder that it is itself a beneficial owner of any these securities for purposes of Section 13(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, or any other purpose. Nantahala Capital Management, LLC, a Registered Investment Adviser, has the power to vote and/or direct the disposition of the securities held by the selling stockholder, either as a General Partner, Investment Manager, or Sub-Advisor, and may be deemed the beneficial owner of the shares of common stock held by such selling stockholder. Further, these selling stockholders may exercise certain rights to acquire shares of common stock disclosed above only if such acquisition would not cause the total number of shares of common stock beneficially owned by it and its affiliates to exceed 9.99% of the shares of common stock then outstanding. Wilmot Harkey and Daniel Mack are managing members of Nantahala Capital Management, LLC and may be deemed to have voting and dispositive power over the shares held by the selling stockholder. The address of the selling stockholder is 130 Main St., 2nd Floor, New Canaan, Connecticut 06840.
- (5) Represents (i) 85,578 shares of common stock issued in our May 2023 financing, (ii) 80,768 shares of common stock issuable upon the exercise of pre-funded warrants issued in our May 2023 financing, (iii) 83,173 shares of common stock issuable upon the exercise of Series H Warrants issued in our May 2023 financing, (iv) 83,173 shares of common stock issuable upon the exercise of Series I Warrants issued in our May 2023 financing, (v) 83,173 shares of common stock issuable upon the exercise of Series J Warrants issued in our May 2023 financing, and (vi) 83,173 shares of common stock issuable upon the exercise of Series K Warrants issued in our May 2023 financing. The exercise of the foregoing warrants is subject to a 9.99% blocker. The above shall not be deemed to be an admission by any selling stockholder that it is itself a beneficial owner of any these securities for purposes of Section 13(d) of the Exchange Act, or any other purpose. Nantahala Capital Management, LLC, a Registered Investment Adviser, has the power to vote and/or direct the disposition of the securities held by the selling stockholder, either as a General Partner, Investment Manager, or Sub-Advisor, and may be deemed the beneficial owner of the shares of common stock held by such selling stockholder. Further, these selling stockholders may exercise certain rights to acquire shares of common stock

disclosed above only if such acquisition would not cause the total number of shares of common stock beneficially owned by it and its affiliates to exceed 9.99% of the shares of common stock then outstanding. Wilmot Harkey and Daniel Mack are managing members of Nantahala Capital Management, LLC and may be deemed to have voting and dispositive power over the shares held by the selling stockholder. The address of the selling stockholder is 130 Main St., 2nd Floor, New Canaan, Connecticut 06840.

- (6) Represents (i) 325,570 shares of common stock issued in our May 2023 financing, (ii) 307,271 shares of common stock issuable upon the exercise of pre-funded warrants issued in our May 2023 financing, (iii) 316,421 shares of common stock issuable upon the exercise of Series H Warrants issued in our May 2023 financing, (iv) 316,420 shares of common stock issuable upon the exercise of Series I Warrants issued in our May 2023 financing, (v) 316,421 shares of common stock issuable upon the exercise of Series J Warrants issued in our May 2023 financing, and (vi) 316,420 shares of common stock issuable upon the exercise of Series K Warrants issued in our May 2023 financing. The exercise of the foregoing warrants is subject to a 9.99% blocker. The above shall not be deemed to be an admission by any selling stockholder that it is itself a beneficial owner of any these securities for purposes of Section 13(d) of the Exchange Act, or any other purpose. Nantahala Capital Management, LLC, a Registered Investment Adviser, has the power to vote and/or direct the disposition of the securities held by the selling stockholder, either as a General Partner, Investment Manager, or Sub-Advisor, and may be deemed the beneficial owner of the shares of common stock held by such selling stockholder. Further, these selling stockholders may exercise certain rights to acquire shares of common stock disclosed above only if such acquisition would not cause the total number of shares of common stock beneficially owned by it and its affiliates to exceed 9.99% of the shares of common stock then outstanding. Wilmot Harkey and Daniel Mack are managing members of Nantahala Capital Management, LLC and may be deemed to have voting and dispositive power over the shares held by the selling stockholder. The address of the selling stockholder is 130 Main St., 2nd Floor, New Canaan, Connecticut 06840.
- (7) Represents (i) 1,021,363 shares of common stock issued in our May 2023 financing, (ii) 963,953 shares of common stock issuable upon the exercise of pre-funded warrants issued in our May 2023 financing, (iii) 992,658 shares of common stock issuable upon the exercise of Series H Warrants issued in our May 2023 financing, (iv) 992,658 shares of common stock issuable upon the exercise of Series I Warrants issued in our May 2023 financing, (v) 992,658 shares of common stock issuable upon the exercise of Series J Warrants issued in our May 2023 financing, and (vi) 992,658 shares of common stock issuable upon the exercise of Series K Warrants issued in our May 2023 financing. The exercise of the foregoing warrants is subject to a 9.99% blocker. The above shall not be deemed to be an admission by any selling stockholder that it is itself a beneficial owner of any these securities for purposes of Section 13(d) of the Exchange Act, or any other purpose. Nantahala Capital Management, LLC, a Registered Investment Adviser, has the power to vote and/or direct the disposition of the securities held by the selling stockholder, either as a General Partner, Investment Manager, or Sub-Advisor, and may be deemed the beneficial owner of the shares of common stock held by such selling stockholder. Further, these selling stockholders may exercise certain rights to acquire shares of common stock disclosed above only if such acquisition would not cause the total number of shares of common stock beneficially owned by it and its affiliates to exceed 9.99% of the shares of common stock then outstanding. Wilmot Harkey and Daniel Mack are managing members of Nantahala Capital Management, LLC and may be deemed to have voting and dispositive power over the shares held by the selling stockholder. The address of the selling stockholder is 280 South Mangum Street, Suite 210 Durham, NC 27701.

- (8) Represents (i) 238,133 shares of common stock issued in our May 2023 financing, (ii) 224,749 shares of common stock issuable upon the exercise of pre-funded warrants issued in our May 2023 financing, (iii) 231,441 shares of common stock issuable upon the exercise of Series H Warrants issued in our May 2023 financing, (iv) 231,441 shares of common stock issuable upon the exercise of Series I Warrants issued in our May 2023 financing, (v) 231,441 shares of common stock issuable upon the exercise of Series J Warrants issued in our May 2023 financing, and (vi) 231,441 shares of common stock issuable upon the exercise of Series K Warrants issued in our May 2023 financing. The exercise of the foregoing warrants is subject to a 9.99% blocker. The above shall not be deemed to be an admission by any selling stockholder that it is itself a beneficial owner of any these securities for purposes of Section 13(d) of the Exchange Act, or any other purpose. Nantahala Capital Management, LLC, a Registered Investment Adviser, has the power to vote and/or direct the disposition of the securities held by the selling stockholder, either as a General Partner, Investment Manager, or Sub-Advisor, and may be deemed the beneficial owner of the shares of common stock held by such selling stockholder. Further, these selling stockholders may exercise certain rights to acquire shares of common stock disclosed above only if such acquisition would not cause the total number of shares of common stock beneficially owned by it and its affiliates to exceed 9.99% of the shares of common stock then outstanding. Wilmot Harkey and Daniel Mack are managing members of Nantahala Capital Management, LLC and may be deemed to have voting and dispositive power over the shares held by the selling stockholder. The address of the selling stockholder is c/o Corporation Trust Center, 1209 Orange Street Wilmington, DE 19801.
- (9) Represents (i) 1,575,531 shares of common stock issued to Rosalind Master Fund L.P. in our May 2023 financing, (ii) 1,488,710 shares of common stock issuable upon the exercise of pre-funded warrants issued to Rosalind Master Fund L.P. in our May 2023 financing, (iii) 1,532,121 shares of common stock issuable upon the exercise of Series H Warrants issued to Rosalind Master Fund L.P. in our May 2023 financing, (iv) 1,532,120 shares of common stock issuable upon the exercise of Series I Warrants issued to Rosalind Master Fund L.P. in our May 2023 financing, (v) 1,532,121 shares of common stock issuable upon the exercise of Series J Warrants issued to Rosalind Master Fund L.P. in our May 2023 financing, (vi) 1,532,120 shares of common stock issuable upon the exercise of Series K Warrants issued to Rosalind Master Fund L.P. in our May 2023 financing, (vii) 284,874 shares of common stock issued to Rosalind Opportunities Fund I L.P. in our May 2023 financing, (viii) 267,126 shares of common stock issuable upon the exercise of pre-funded warrants issued to Rosalind Opportunities Fund I L.P. in our May 2023 financing, (ix) 276,000 shares of common stock issuable upon the exercise of Series H Warrants issued to Rosalind Opportunities Fund I L.P. in our May 2023 financing, (x) 276,000 shares of common stock issuable upon the exercise of Series I Warrants issued to Rosalind Opportunities Fund I L.P. in our May 2023 financing, (xi) 276,000 shares of common stock issuable upon the exercise of Series J Warrants issued to Rosalind Opportunities Fund I L.P. in our May 2023 financing, and (xii) 276,000 shares of common stock issuable upon the exercise of Series K Warrants issued to Rosalind Opportunities Fund I L.P. in our May 2023 financing. The exercise of the foregoing warrants is subject to a 4.99% blocker, except that the exercise of the pre-funded warrants mentioned in (ii) above is subject to a 9.99% blocker. Rosalind Advisors, Inc., or the Advisor, is the investment advisor to Rosalind Master Fund L.P., or RMF, and may be deemed to be the beneficial owner of shares held by RMF. Steven Salamon is the portfolio manager of the Advisor and may be deemed to be the beneficial owner of shares held by RMF. Notwithstanding the foregoing, the Advisor and Mr. Salamon disclaim beneficial ownership of the shares. The address of the selling stockholder is c/o TDWaterhouse, 77 Bloor St W, 3<sup>rd</sup> Floor, Toronto, Ontario M5S 1M2.
- (10) Represents (i) 904,029 shares of common stock issued in our May 2023 financing, (ii) 452,015 shares of common stock issuable upon the exercise of Series H Warrants issued in our May 2023 financing, (iii) 452,014 shares of common stock issuable upon the exercise of Series I Warrants issued in our May 2023 financing, (iv) 452,015 shares of common stock issuable upon the exercise of Series J Warrants issued in our May 2023 financing, and (v) 452,014 shares of common stock issuable upon the exercise of Series K Warrants issued in our May 2023 financing. The exercise of the foregoing warrants is subject to a 4.99% blocker. Securities beneficially owned directly by Velan Capital Master Fund LP, or Velan Master. As the general partner of Velan Master, Velan Capital Holdings LLC, or Velan GP, may be deemed to beneficially own the securities owned directly by Velan Master. As the investment manager of Velan Master, Velan Capital Investment Management LP, or Velan Capital, may be deemed to beneficially own the securities owned directly by Velan Master. As the general partner of Velan Capital, Velan Capital Management LLC, or Velan IM GP, may be deemed to beneficially own the securities owned directly by Velan Master. As the managing members of Velan GP and Velan IM GP, Adam Morgan and Balaji Venkataraman may be deemed to beneficially own the securities owned directly by Velan Master. The address of the selling stockholder is 1055 Powers Place, Suite B, Alpharetta, Georgia, 30009.
- (11) Represents (i) 61,249 shares of common stock issued in our May 2023 financing, (ii) 30,625 shares of common stock issuable upon the exercise of Series H Warrants issued in our May 2023 financing, (iii) 30,624 shares of common stock issuable upon the exercise of Series I Warrants issued in our May 2023 financing, (iv) 30,625 shares of common stock issuable upon the exercise of Series J Warrants issued in our May 2023 financing, (v) 30,624 shares of common stock issuable upon the exercise of Series K Warrants issued in our May 2023 financing, (vi) 155,487 shares of common stock previously acquired, (vii) 5,310 shares of restricted stock granted under the InspireMD, Inc. 2013 Long-Term Incentive Plan, (viii) 160,759 shares of restricted stock granted under the 2021 Equity Incentive Plan, and (ix) 22,880 previously acquired warrants to purchase shares of common stock that are currently exercisable, and (x) options to purchase 8,790 shares of common stock that are currently exercisable or exercisable within 60 days of May 19, 2023. The address of the selling stockholder is 4300 Rockmore Rd Jackson Wyoming 83001.
- (12) Represents (i) 61,249 shares of common stock issued in our May 2023 financing, (ii) 30,625 shares of common stock issuable upon the exercise of Series H Warrants issued in our May 2023 financing, (iii) 30,624 shares of common stock issuable upon the exercise



of Series I Warrants issued in our May 2023 financing, (iv) 30,625 shares of common stock issuable upon the exercise of Series J Warrants issued in our May 2023 financing, and (v) 30,624 shares of common stock issuable upon the exercise of Series K Warrants issued in our May 2023 financing.

(13) Represents (i) 155,487 shares of common stock previously acquired, (ii) 5,310 shares of restricted stock granted under the InspireMD, Inc. 2013 Long-Term Incentive Plan, (iii) 160,759 shares of restricted stock granted under the 2021 Equity Incentive Plan, and (iv) 22,880 previously acquired warrants to purchase shares of common stock that are currently exercisable and (v) options to purchase 8,790 shares of common stock that are currently exercisable or exercisable within 60 days of May 19, 2023.

- (14) Represents (A) the following securities held by the Michael Berman Revocable Trust of which Michael Berman, has sole voting and investment power: (i) 122,497 shares of common stock issued in our May 2023 financing, (ii) 61,249 shares of common stock issuable upon the exercise of Series H Warrants issued in our May 2023 financing, (iii) 61,248 shares of common stock issuable upon the exercise of Series I Warrants issued in our May 2023 financing, (iv) 61,249 shares of common stock issuable upon the exercise of Series J Warrants issued in our May 2023 financing, (v) 61,248 shares of common stock issuable upon the exercise of Series K Warrants issued in our May 2023 financing, (vi) 14,869 shares of common stock previously acquired, and (B) the following securities held by Michael Berman, a member of our board of directors: (i) previously acquired warrants to purchase 2,688 shares of common stock that are currently exercisable or exercisable within 60 days of May 19, 2023, and (ii) options to purchase 4,263 shares of common stock that are currently exercisable or exercisable within 60 days of May 19, 2023. Excludes 10,710 shares of restricted stock granted under the Israeli Appendix of InspireMD, Inc. 2013 Long-Term Incentive Plan and 166,508 shares of restricted stock granted under the 2021 Equity Incentive Plan held in trust, with respect to which the trustee has a proxy with the right to vote such shares at his discretion. The address of the selling stockholder is c/o InspireMD, Inc., 4 Menorat Hamor St., Tel Aviv, Israel 6744832.
- (15) Represents the following securities held by the Michael Berman Revocable Trust: (i) 122,497 shares of common stock issued in our May 2023 financing, (ii) 61,249 shares of common stock issuable upon the exercise of Series H Warrants issued in our May 2023 financing, (iii) 61,248 shares of common stock issuable upon the exercise of Series I Warrants issued in our May 2023 financing, (iv) 61,249 shares of common stock issuable upon the exercise of Series J Warrants issued in our May 2023 financing, and (v) 61,248 shares of common stock issuable upon the exercise of Series K Warrants issued in our May 2023 financing.
- (16) Represents the following securities held by Michael Berman, a member of our board of directors: (i) 14,869 shares of common stock previously acquired, (ii) previously acquired warrants to purchase 2,688 shares of common stock that are currently exercisable or exercisable within 60 days of May 19, 2023, and (iii) options to purchase 4,263 shares of common stock that are currently exercisable or exercisable within 60 days of May 19, 2023. Excludes 10,710 shares of restricted stock granted under the Israeli Appendix of InspireMD, Inc. 2013 Long-Term Incentive Plan and 166,508 shares of restricted stock granted under the 2021 Equity Incentive Plan held in trust, with respect to which the trustee has a proxy with the right to vote such shares at his discretion.
- (17) Paul Stuka, chairman of our board of directors, is the principal and managing member of Osiris Investment Partners, L.P., and, as such, has beneficial ownership of (A) (i) 73,534 shares of common stock previously acquired, (ii) 175,000 shares of common stock issued in our May 2023 financing, (iii) 87,500 shares of common stock issuable upon the exercise of Series H Warrants issued in our May 2023 financing, (iv) 87,500 shares of common stock issuable upon the exercise of Series I Warrants issued in our May 2023 financing, (v) 87,500 shares of common stock issuable upon the exercise of Series J Warrants issued in our May 2023 financing, (vi) 87,500 shares of common stock issuable upon the exercise of Series K Warrants issued in our May 2023 financing, (B) personally holding (i) options to purchase 6,443 shares of common stock that are currently exercisable or exercisable within 60 days of May 19, 2023, (ii) 5,310 shares of restricted stock granted under the InspireMD, Inc. 2013 Long-Term Incentive Plan, (iii) 243,066 shares of restricted stock granted under the 2021 Equity Incentive Plan, and (iv) 19,607 shares of common stock previously acquired. The address of the selling stockholder is 70 Colonial Drive, Chatham, MA 02633.
- (18) Represents the following securities held by Osiris Investment Partners, L.P.: (i) 175,000 shares of common stock issued in our May 2023 financing, (ii) 87,500 shares of common stock issuable upon the exercise of Series H Warrants issued in our May 2023 financing, (iii) 87,500 shares of common stock issuable upon the exercise of Series I Warrants issued in our May 2023 financing, (iv) 87,500 shares of common stock issuable upon the exercise of Series J Warrants issued in our May 2023 financing, and (v) 87,500 shares of common stock issuable upon the exercise of Series K Warrants issued in our May 2023 financing.
- (19) Paul Stuka, a member of our board of directors, is the principal and managing member of Osiris Investment Partners, L.P., and, as such, has beneficial ownership of (A) 73,534 shares of common stock previously acquired (B) personally holding (i) options to purchase 6,443 shares of common stock that are currently exercisable or exercisable within 60 days of May 19, 2023, (ii) 5,310 shares of restricted stock granted under the InspireMD, Inc. 2013 Long-Term Incentive Plan, (iii) 243,066 shares of restricted stock granted under the 2021 Equity Incentive Plan, and (iv) 19,607 shares of common stock previously acquired.

- (20) Represents (i) 61,249 shares of common stock issued in our May 2023 financing, (ii) 30,625 shares of common stock issuable upon the exercise of Series H Warrants issued in our May 2023 financing, (iii) 30,624 shares of common stock issuable upon the exercise of Series I Warrants issued in our May 2023 financing, (iv) 30,625 shares of common stock issuable upon the exercise of Series J Warrants issued in our May 2023 financing, (v) 30,624 shares of common stock issuable upon the exercise of Series K Warrants issued in our May 2023 financing, (vi) 27,063 shares of common stock previously acquired, (ii) 8,780 shares of restricted stock granted under the InspireMD, Inc. 2013 Long-Term Incentive Plan, (vii) 160,759 shares of restricted stock granted under the 2021 Equity Incentive Plan, (viii) 4,032 warrants to purchase shares of common stock that are currently exercisable, and (ix) options to purchase 4,260 shares of common stock that are currently exercisable or exercisable within 60 days of May 19, 2023. The address of the selling stockholder is 1 Liberty Square, Fifth Floor, Boston, Massachusetts 02109.
- (21) Represents (i) 61,249 shares of common stock issued in our May 2023 financing, (ii) 30,625 shares of common stock issuable upon the exercise of Series H Warrants issued in our May 2023 financing, (iii) 30,624 shares of common stock issuable upon the exercise of Series I Warrants issued in our May 2023 financing, (iv) 30,625 shares of common stock issuable upon the exercise of Series J Warrants issued in our May 2023 financing, and (v) 30,624 shares of common stock issuable upon the exercise of Series K Warrants issued in our May 2023 financing.
- (22) Represents of (i) 27,063 shares of common stock previously acquired, (ii) 8,780 shares of restricted stock granted under the InspireMD, Inc. 2013 Long-Term Incentive Plan, (iii) 160,759 shares of restricted stock granted under the 2021 Equity Incentive Plan, (iv) 4,032 previously acquired warrants to purchase shares of common stock that are currently exercisable, and (v) options to purchase 4,260 shares of common stock that are currently exercisable or exercisable within 60 days of May 19, 2023.
- (23) Represents (i) 61,249 shares of common stock issued in our May 2023 financing, (ii) 30,625 shares of common stock issuable upon the exercise of Series H Warrants issued in our May 2023 financing, (iii) 30,624 shares of common stock issuable upon the exercise of Series I Warrants issued in our May 2023 financing, (iv) 30,625 shares of common stock issuable upon the exercise of Series J Warrants issued in our May 2023 financing, and (v) 30,624 shares of common stock issuable upon the exercise of Series K Warrants issued in our May 2023 financing. The address of the selling stockholder is 2 Barer Lane, Mendham, New Jersey 07945.
- (24) Represents (i) 61,249 shares of common stock issued in our May 2023 financing, (ii) 30,625 shares of common stock issuable upon the exercise of Series H Warrants issued in our May 2023 financing, (iii) 30,624 shares of common stock issuable upon the exercise of Series I Warrants issued in our May 2023 financing, (iv) 30,625 shares of common stock issuable upon the exercise of Series J Warrants issued in our May 2023 financing, (v) 30,624 shares of common stock issuable upon the exercise of Series K Warrants issued in our May 2023 financing, and (vi) 207,554 shares of common stock previously acquired. The address of the selling stockholder is 2 Barer Lane, Mendham, New Jersey 07945.
- (25) Represents (i) 61,249 shares of common stock issued in our May 2023 financing, (ii) 30,625 shares of common stock issuable upon the exercise of Series H Warrants issued in our May 2023 financing, (iii) 30,624 shares of common stock issuable upon the exercise of Series I Warrants issued in our May 2023 financing, (iv) 30,625 shares of common stock issuable upon the exercise of Series J Warrants issued in our May 2023 financing, (v) and 30,624 shares of common stock issuable upon the exercise of Series K Warrants issued in our May 2023 financing
- (26) Represents 207,554 shares of common stock previously acquired.

## PLAN OF DISTRIBUTION

The selling stockholders, including its pledgees, donees, transferees, distributees, beneficiaries or other successors in interest, may from time to time offer some or all of the shares of our common stock offered under this prospectus. We will not receive any of the proceeds from the sale of the shares of our common stock offered under this prospectus by the selling stockholders. We will bear all fees and expenses incident to our obligation to register the shares of our common stock offered under this prospectus.

The selling stockholders may sell all or a portion of the shares of our common stock beneficially owned by it and offered hereby from time to time directly or through one or more underwriters, broker-dealers or agents. If the shares of our common stock are sold through underwriters or broker-dealers, The selling stockholders will be responsible for underwriting discounts or commissions or agent's commissions. The shares of our common stock may be sold on any national securities exchange or quotation service on which the securities may be listed or quoted at the time of sale, in the over-the-counter market or in transactions otherwise than on these exchanges or systems or in the over-the-counter market and in one or more transactions at fixed prices, at prevailing market prices at the time of the sale, at varying prices determined at the time of sale, or at privately negotiated prices. These sales may be effected in transactions, which may involve crosses or block transactions.

The selling stockholders may use any one or more of the following methods when disposing of shares of our common stock or interests therein:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell shares of our common stock as agent, but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an over-the-counter distribution;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- short sales effected after the effective date of the registration statement of which this prospectus forms a part;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The selling stockholders may, from time to time, pledge or grant a security interest in some or all of the shares of our common stock owned by it and, if it defaults in the performance of its secured obligations, the pledgees or secured parties may offer and sell the shares of our common stock, from time to time, under this prospectus, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending the list of The selling stockholders to include the pledgee, transferee, or other successors in interest as selling stockholder under this prospectus. The selling stockholders also may transfer the shares of our common stock in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

In connection with the sale of shares of our common stock or interests therein, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of shares of our common stock in the course of hedging the positions it assumes. The selling stockholders may also sell shares of our common stock short and deliver these securities to close out its short positions, or loan or pledge the shares of our common stock to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares of our common stock offered under this prospectus, which shares of our common stock such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

Broker-dealers engaged by the selling stockholders may arrange for other broker-dealers to participate in sales. If the selling stockholders effects certain transactions by selling shares of our common stock to or through underwriters, broker-dealers or agents, such underwriters, broker-dealers or agents may receive commissions in the form of discounts, concessions or commissions from the selling stockholders or commissions from purchasers of the shares of our common stock for whom they may act as agent or to whom they may sell as principal. Such commissions will be in amounts to be negotiated, but, except as set forth in a supplement to this prospectus, in the case of an agency transaction will not be in excess of a customary brokerage commission in compliance with applicable rules of the Financial Industry Regulatory Authority, Inc., or FINRA; and in the case of a principal transaction a markup or markdown in compliance with applicable FINRA rules.

The aggregate proceeds to the selling stockholders from the sale of the shares of our common stock offered under this prospectus will be the purchase price of the shares of common stock less discounts or commissions, if any. The selling stockholders reserves the right to accept and, together with its agents from time to time, to reject, in whole or in part, any proposed purchase of shares of our common stock to be made directly or through agents. We will not receive any of the proceeds from the offering under this prospectus.

The selling stockholders also may resell all or a portion of the shares of our common stock offered under this prospectus in open market transactions in reliance upon Rule 144 under the Securities Act, provided that it meets the criteria and conforms to the requirements of that rule.

The selling stockholders and any underwriters, broker-dealers or agents that participate in the sale of the shares of our common stock or interests therein may be deemed to be "underwriters" within the meaning of Section 2(a)(11) of the Securities Act. Any discounts, commissions, concessions or profit they earn on any resale of the shares of our common stock may be underwriting discounts and commissions under the Securities Act. Each selling stockholder has informed us that it does not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the securities. The selling stockholders is subject to the prospectus delivery requirements of the Securities Act.

To the extent required pursuant to Rule 424(b) under the Securities Act, the shares of our common stock to be sold, the name of The selling stockholders, the purchase price and public offering price, the names of any agents, dealer or underwriter, and any applicable commissions or discounts with respect to a particular offer will be set forth in an accompanying prospectus supplement or, if appropriate, a post-effective amendment to the registration statement that includes this prospectus.

We have agreed to keep this prospectus effective until the earlier of (i) the date on which the securities may be resold by the selling stockholders without registration and without regard to any volume or manner-of-sale limitations by reason of Rule 144, or (ii) all of the securities have been sold pursuant to this prospectus or Rule 144 under the Securities Act or any other rule of similar effect. In order to comply with the securities laws of some states, if applicable, the shares of our common stock may be sold in these jurisdictions only through registered or licensed brokers or dealers. In addition, in some states the shares of our common stock may not be sold unless the shares been registered or qualified for sale or an exemption from registration or qualification requirements is available and is complied with.

The selling stockholders and any other person participating in a sale of shares of our common stock registered under this prospectus will be subject to applicable provisions of the Exchange Act, and the rules and regulations thereunder, including, without limitation, to the extent applicable, Regulation M of the Exchange Act, which may limit the timing of purchases and sales of any of the shares of our common stock by the selling stockholders and any other participating person. All of the foregoing may affect the marketability of the shares of our common stock and the ability of any person or entity to engage in market-making activities with respect to the shares of our common stock. In addition, we will make copies of this prospectus (as it may be supplemented or amended from time to time) available to the selling stockholders for the purpose of satisfying the prospectus delivery requirements of the Securities Act. The selling stockholders may indemnify any broker-dealer that participates in transactions involving the sale of the shares of our common stock against certain liabilities, including liabilities arising under the Securities Act.

## LEGAL MATTERS

The validity of the securities offered by this prospectus will be passed upon by Greenberg Traurig, LLP, New York, New York.

## EXPERTS

The financial statements incorporated in this prospectus by reference to the Annual Report on Form 10-K for the year ended December 31, 2022 have been so incorporated in reliance on the report, which contains an explanatory paragraph relating to the Company's ability to continue as a going concern as described in Note 1b to the financial statements, of Kesselman & Kesselman, an independent registered public accounting firm and a member firm of PricewaterhouseCoopers International Limited, given on the authority of said firm as experts in auditing and accounting.

## WHERE YOU CAN FIND MORE INFORMATION

We are subject to the informational requirements of the Exchange Act and in accordance therewith file annual, quarterly and current reports, proxy statements and other information with the SEC. In addition, the SEC maintains a website that contains reports, proxy and information statements and other information regarding registrants that file electronically with the SEC. The address of the SEC's website is [www.sec.gov](http://www.sec.gov).

We make available free of charge on or through our website at [www.inspire-md.com](http://www.inspire-md.com), our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with or otherwise furnish it to the SEC.

We have filed with the SEC a registration statement under the Securities Act, relating to the securities offered under this prospectus. The registration statement, including the attached exhibits, contains additional relevant information about us and the securities. This prospectus does not contain all of the information set forth in the registration statement. You can obtain a copy of the registration statement for free at [www.sec.gov](http://www.sec.gov). The registration statement and the documents referred to below under "Incorporation of Certain Information by Reference" are also available on our website, [www.inspire-md.com](http://www.inspire-md.com).

We have not incorporated by reference into this prospectus the information on our website, and you should not consider it to be a part of this prospectus.

## INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to “incorporate by reference” the information we have filed with it, which means that we can disclose important information to you by referring you to those documents. The information we incorporate by reference is an important part of this prospectus, and later information that we file with the SEC will automatically update and supersede this information. We incorporate by reference the documents listed below and any future documents (excluding information furnished pursuant to Items 2.02 and 7.01 of Form 8-K) we file with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act subsequent to the date of this prospectus and prior to the termination of the offering:

- Our Annual Report on [Form 10-K](#) for the fiscal year ended December 31, 2022, as filed with the Commission on March 30, 2023;
- Our Quarterly Reports on [Form 10-Q](#) for the quarter ended March 31, 2023, filed with the SEC on May 15, 2023;
- Our Current Reports on Form 8-K (other than portions thereof furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits accompanying such reports that relate to such items), filed with the SEC on the following dates: [March 20, 2023](#) and [May 15, 2023](#); and
- The description of the Company’s Common Stock in [Exhibit 4.1](#) to our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, filed with the SEC on March 30, 2023, and as may be further updated or amended in any amendment or report filed for such purpose.

All filings filed by us pursuant to the Exchange Act of 1934 after the date of the initial filing of the registration statement of which this prospectus forms a part and prior to the effectiveness of such registration statement (excluding information furnished pursuant to Items 2.02 and 7.01 of Form 8-K) shall also be deemed to be incorporated by reference into this prospectus.

You should rely only on the information incorporated by reference or provided in this prospectus. We have not authorized anyone else to provide you with different information. Any statement contained in a document incorporated by reference into this prospectus will be deemed to be modified or superseded for the purposes of this prospectus to the extent that a later statement contained in this prospectus or in any other document incorporated by reference into this prospectus modifies or supersedes the earlier statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus. You should not assume that the information in this prospectus is accurate as of any date other than the date of this prospectus or the date of the documents incorporated by reference in this prospectus.

We will provide without charge to each person to whom a copy of this prospectus is delivered, upon written or oral request, a copy of any or all of the reports or documents that have been incorporated by reference in this prospectus but not delivered with this prospectus (other than an exhibit to these filings, unless we have specifically incorporated that exhibit by reference in this prospectus). Any such request should be addressed to us at: 4 Menorat Hamaor St., Tel Aviv, Israel 6744832, Attention: Craig Shore, Chief Financial Officer, or made by phone at (888) 776-6804. You may also access the documents incorporated by reference in this prospectus through our website at [www.inspire-md.com](http://www.inspire-md.com). Except for the specific incorporated documents listed above, no information available on or through our website shall be deemed to be incorporated in this prospectus or the registration statement of which it forms a part.

Up to 77,484,492 Shares of Common Stock Offered by the Selling Stockholders



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PROSPECTUS

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**June 1, 2023**

We have not authorized any dealer, salesperson or other person to give any information or represent anything not contained in this prospectus. You must not rely on any unauthorized information. If anyone provides you with different or inconsistent information, you should not rely on it. This prospectus does not offer to sell any securities in any jurisdiction where it is unlawful. Neither the delivery of this prospectus, nor any sale made hereunder, shall create any implication that the information in this prospectus is correct after the date hereof.

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