

Up to 16,556,184 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 16,556,184 shares of our common stock, which consist of (i) 6,791,380 shares of our common stock held by the selling stockholders, or the Shares, and (ii) 9,764,804 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. The Shares and Pre-Funded 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 and Pre-Funded Warrants from us pursuant to a private placement transaction, which was consummated on July 31, 2025. We are registering the offer and resale of the Securities to satisfy a covenant set forth in the registration rights agreement entered into on July 30, 2025 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 the Securities 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 the Securities by the selling stockholders, although we will receive the nominal exercise price upon the exercise of the Pre-Funded Warrants.

Any Securities 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 Securities 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 Securities. For additional information on the methods of sale that may be used by the selling stockholders, see "Plan of Distribution" beginning on page 14 of this prospectus.

Our common stock is listed on The Nasdaq Capital Market under the symbol "NSPR." On August 13, 2025, the last reported sale price of our common stock as reported on The Nasdaq Capital Market was \$2.50 per share.

Investing in our securities involves risks. You should carefully read and consider the risk factors included in our periodic reports filed with the Securities and Exchange Commission (the "SEC"), which are incorporated by reference in this prospectus and the section entitled "Risk Factors" on page 6 of this prospectus.

We are a "smaller reporting company" under applicable SEC rules and, as such, are eligible for reduced public company reporting requirements. See "Prospectus Summary—Implications of Being a Smaller Reporting Company" for more information.

Neither the SEC nor any state securities commission has approved or disapproved of these securities, passed upon the accuracy or adequacy of this prospectus, or determined if this prospectus or any prospectus supplement is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is August 14, 2025

TABLE OF CONTENTS

	<u>Page</u>
ABOUT THIS PROSPECTUS	1
PROSPECTUS SUMMARY	2
RISK FACTORS	6
SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS	7
USE OF PROCEEDS	8
SELLING STOCKHOLDERS	9
PLAN OF DISTRIBUTION	14
LEGAL MATTERS	16
EXPERTS	16
WHERE YOU CAN FIND MORE INFORMATION	16
INCORPORATION OF CERTAIN INFORMATION BY REFERENCE	17

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 Securities 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.

Overview

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

Our CGuard™ carotid embolic prevention system (“CGuard EPS”) combines MicroNet and a unique self-expandable nitinol stent in a single device for use in carotid artery revascularization. Our CGuard EPS originally received CE mark approval under Medical Device Directive 93/42/EEC (“MDD”) in the European Union (“EU”) in March 2013 and was fully launched in Europe in September 2015. Subsequently, we launched CGuard EPS in over 30 countries and on February 3, 2021, we executed a distribution agreement with Chinese partners for the purpose of expanding our presence in the Asian markets. In January 2024, we received CE mark recertification under the EU’s Medical Device Regulation regulatory framework.

On September 8, 2020, we received approval from the U.S. Food and Drug Administration (“FDA”) of our Investigation Device Exemption (“IDE”), thereby allowing us to proceed with a pivotal study of our CGuard™ Carotid Stent System, C-GUARDIANS, for prevention of stroke in patients in the United States. C-GUARDIANS is a prospective, multicenter, single-arm, pivotal study to evaluate the safety and efficacy of the CGuard™ Carotid Stent System when used to treat symptomatic and asymptomatic carotid artery stenosis in patients undergoing carotid artery stenting (“CAS”). The study, which completed enrollment in June 2023, enrolled 316 patients across 24 trial sites in the U.S. and Europe and from April 2023 included deployment of the CGuard stent using CGuard Prime, our next generation CAS stent platform.

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 are 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.

In November 2023, we announced positive 30-day follow up results from the C-GUARDIANS trial in which stenting with the CGuard Carotid Stent System in patients with carotid artery stenosis and at high risk for carotid endarterectomy had a DSMI rate of 0.95%, measured from the date of the procedure through 30 days follow-up post-procedure. In May 2024, we announced positive one-year follow up results from the C-GUARDIANS trial, with a rate of 30-day DSMI and ipsilateral stroke between 31 and 365 days of 1.95%.

These data were used to support the premarket approval (“PMA”) submission in September 2024 with a view to potential FDA approval of the CGuard Prime carotid stent system in the first half of 2025.

In October 2024, the FDA approved the Company's IDE to initiate the CGUARDIANS II pivotal study of its CGuard Prime 80cm Carotid Stent System during transcatheter revascularization (TCAR) procedures.

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

We continue to invest in current and future potential new indications, products and manufacturing enhancements for CGuard that are expected to reduce cost of goods and/or provide the best-in-class performing delivery systems, such as CGuard Prime. In furtherance of our strategy that focuses on establishing the CGuard Carotid Stent System as a viable alternative to vascular surgery, we are developing a new transcatheter artery revascularization (TCAR) system, SwitchGuard™ neuroprotection system ("SwitchGuard NPS"), for transcatheter access and neuro protection. In addition, we intend to explore new indications for CGuard 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 Carotid Stent System 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 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, we estimate that the addressable market for CGuard Carotid Stent System 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 Carotid Stent System and SwitchGuard NPS to be approximately \$9.3 billion, which may grow over time if expanded treatment options such as CGuard Carotid Stent System and SwitchGuard NPS lead to increased patient screening for carotid artery disease.

Recent Developments

PMA Approval for CGuard Prime carotid stent system

As previously disclosed, on September 16, 2024, the Company submitted a PMA application for its the CGuard Prime carotid stent system to the FDA. On June 23, 2025, the Company received PMA approval of the CGuard Prime Carotid Stent System in the United States from the FDA, and on July 9, 2025, the Company announced the official commercial launch of the CGuard Prime carotid stent system in the United States. On June 13, 2025, the Company announced that it received CE Mark approval under the European Medical Device Regulation (MDR) for the CGuard® Prime EPS.

Private Placement

On July 30, 2025, 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 6,791,380 of our shares our common stock, and Pre-Funded Warrants to purchase up to 9,764,804 of our shares of common stock, at an offering price of \$2.42 per Share and \$2.4199 per Pre-Funded Warrant. The Private Placement Offering closed on July 31, 2025. Aggregate gross proceeds to the Company in respect of the Private Placement Offering are approximately \$40.1 million, before deducting fees payable to the placement agent and other offering expenses payable by the Company.

The Pre-Funded Warrants are immediately exercisable at an exercise price of \$0.0001 per share and will not expire until exercised in full.

Under the terms of the Pre-Funded Warrants, certain of the selling stockholders may not exercise the Pre-Funded 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 which have not been exercised.

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 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.

The Company paid BofA Securities, Inc., a placement fee equal to 6.0% of the aggregate gross proceeds from the closing of the Private Placement Offering, subject to the exclusion of certain Securities, or approximately \$2.4 million, and expense reimbursements of up to \$75,000.

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. In October 2024, we established our global headquarters in Miami, Florida to support the anticipated U.S. launch and commercialization of the CGuard Prime carotid stent system.

Our principal executive offices are located at 6303 Waterford District Drive, Suite 215, Miami, Florida 33126, and our telephone number is (888) 776-6804. Our website address is <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 prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

Our common stock is listed on The Nasdaq Capital Market under the symbol “NSPR.”

Implications of Being a Smaller Reporting Company

We qualify as a “smaller reporting company,” as defined by applicable rules of the SEC. As a result, we are permitted to take advantage of certain exemptions available to smaller reporting companies, including the exemption from the auditor attestation requirements of Section 404(b) of the Sarbanes-Oxley Act as long as we do not otherwise also qualify as an “accelerated filer” or “large accelerated filer” for SEC reporting purposes, and reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements. In addition, as a smaller reporting company, we may choose to present only the two most recent fiscal years of audited financial statements in our Annual Report on Form 10-K.

THE OFFERING

Common stock offered by the selling stockholders	Up to 16,556,184 shares of our common stock, par value \$0.0001 per share, which consist of (i) 6,791,380 shares of our common stock held by the selling stockholders, and (ii) 9,764,804 shares of our common stock issuable upon the exercise of Pre-Funded Warrants.
Common stock currently outstanding	41,720,662 (as of August 1, 2025)
Common Stock to be outstanding assuming exercise of the Pre-Funded Warrants	51,485,466
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.
Selling stockholders	All of the Securities are being offered by the selling stockholders. See “Selling Stockholder” on page 9 of this prospectus for more information on the selling stockholders.
Use of proceeds	We will not receive any proceeds from the sale of the Securities in this offering by the selling stockholders, although we will receive the nominal exercise price upon the exercise of the Pre-Funded Warrants. See “Use of Proceeds” beginning on page 8 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 Securities offered hereby. See “Selling Stockholder” on page 9 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 Securities 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 Securities 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 14 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 6 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. See also “Special Note Regarding Forward-Looking Statements” in this prospectus.

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 16,556,184 shares of our common stock consisting of the Shares and Pre-Funded Warrant Shares 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, including the information incorporated by reference into this prospectus, contains, may contain statements that are forward-looking statements about our expectations, beliefs or intentions regarding, among other things, our product development efforts, business, financial condition, results of operations, strategies, plans and prospects. In addition, from time to time, we or our representatives have made or may make forward-looking statements, orally or in writing. Forward-looking statements can be identified by the use of forward-looking words such as “believe,” “expect,” “intend,” “plan,” “may,” “should,” “would,” “anticipate,” “could,” “might,” “seek,” “target,” “will,” “project,” “predict,” “forecast,” “potential,” “continue” or their negatives or variations of these words or other comparable words or by the fact that these statements do not relate strictly to historical matters. These forward-looking statements may be included in, among other things, various filings made by us with the SEC, press releases or oral statements made by or with the approval of one of our authorized executive officers. Forward-looking statements relate to anticipated or expected events, activities, trends or results as of the date they are made. Because forward-looking statements relate to matters that have not yet occurred, these statements are inherently subject to risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements. Many factors could cause our actual activities or results to differ materially from the activities and results anticipated in forward-looking statements, including, but not limited to:

- our history of recurring losses and negative cash flows from operating activities, significant future commitments and the uncertainty regarding the adequacy of our liquidity to pursue our complete business objectives, and substantial doubt regarding our ability to continue as a going concern;
- our need to raise additional capital to meet our business requirements in the future and such capital raising may be costly or difficult to obtain and could dilute out stockholders’ ownership interests;
- market acceptance of our products;
- an inability to secure and maintain regulatory approvals for the sale of our products;
- negative clinical trial results or lengthy product delays in key markets;
- our ability to maintain compliance with the Nasdaq listing standards;
- our ability to generate significant revenues from 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;
- insufficient or inadequate reimbursement by governmental and other third-party payers for our products;
- our efforts to successfully obtain and maintain intellectual property protection covering our products, which may not be successful;
- adverse federal, state and local government regulation, in the United States, Europe or Israel and other foreign jurisdictions;
- the fact that we conduct business in multiple foreign jurisdictions, exposing us to foreign currency exchange rate fluctuations, logistical and communications challenges, burdens and costs of compliance with foreign laws and political and economic instability in each jurisdiction;
- security, political and economic instability in the Middle East that could harm our business, including due to the current security situation in Israel; 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 the Securities by the selling stockholders.

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

We intend to use the net proceeds from any exercise of the Pre-Funded Warrants for our operations, including, but not limited to, research and development, sales and marketing, and working capital and other general corporate purposes.

SELLING STOCKHOLDERS

The Securities being offered by the selling stockholders consisting of the Shares and Pre-Funded Warrant Shares 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 August 1, 2025, 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 41,720,662 shares of our common stock outstanding as of August 1, 2025. 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. Shares issuable pursuant to the exercise of stock options and warrants exercisable within 60 days are deemed outstanding and held by the holder of such options or warrants for computing the percentage of outstanding common stock beneficially owned by such person but are not deemed outstanding for computing the percentage of outstanding common stock beneficially owned by any other person.

To our knowledge, except for Tom Kester, Gary Ruben, our directors, Paul Stuka, our Chairman of the Board of Directors, and Marvin Slosman, our Chief Executive Officer and a director, 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 or Pre-Funded Warrants, whether any will exercise the Pre-Funded 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, certain of the selling stockholders may not exercise the Pre-Funded 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 which have not been exercised. The number of shares in the second column does not reflect this limitation.

Selling Stockholder	Ownership Before Offering		Maximum number of shares of common stock offered	Ownership After Offering	
	Number of shares of common stock beneficially owned	Percentage of common stock beneficially owned		Number of shares of common stock beneficially owned	Percentage of common stock beneficially owned
Entities affiliated with Marshall Wace ⁽¹⁾	28,103,699	9.99%	2,066,201	26,037,498	9.99%
Entities affiliated with OrbiMed ⁽²⁾	23,612,817	9.99%	6,198,603	17,414,214	9.99%
Nantahala Capital Partners Limited Partnership (3)	2,418,016	5.3%	826,446	1,591,570	3.5%
Entities affiliated with Rosalind Advisors, Inc. ⁽⁴⁾	10,987,104	9.99%	2,066,177	8,920,927	9.99%
Velan Capital Master Fund LP ⁽⁵⁾	3,951,756	5.1%	1,239,669	2,712,087	4.99%
Entities affiliated with Aberdeen Investments ⁽⁶⁾	2,066,115	5.0%	2,066,115	-	-
Ghisallo Master Fund LP ⁽⁷⁾	1,239,669	3.0%	1,239,669	-	-
Entities affiliated with Parkman Healthcare Partners LLC ⁽⁸⁾	1,520,478	3.6%	750,000	770,478	1.8%
Gary Roubin, M.D. ⁽⁹⁾	752,878	1.8%	41,322	711,556	1.7%
Paul Stuka ⁽¹⁰⁾	1,060,281	2.5%	20,661	1,039,620	2.5%
Thomas Kester ⁽¹¹⁾	539,567	1.3%	30,991	508,576	1.2%
Marvin Slosman ⁽¹²⁾	1,566,529	3.6%	10,330	1,556,199	3.6%

* Represents ownership of less than one percent.

- (1) The shares of common stock registered for resale relate to the shares of common stock underlying 2,066,201 Pre-Funded Warrants purchased by Marshall Wace Investment Strategies – Eureka Fund (“MW Eureka Fund”). Beneficial ownership represents (i) 1,860,405 shares of common stock held by MW XO Health Innovations Fund, L.P. (“MW Innovations Fund”), (ii) subject to a 9.99% blocker, the Pre-Funded Warrants issued to MW Eureka Fund in the Private Placement Offering and (iii) subject to a 9.99% blocker, (A) 15,497,927 shares of common stock issuable upon the exercise of pre-funded warrants issued to MW Innovations Fund in a prior private placement offering of the Company (the “2023 Private Placement Offering”) and issued upon the exercise and conversion of Series H Warrants and Series I Warrants into pre-funded warrants in 2024 and 2025, respectively, (B) 4,339,583 shares of common stock issuable upon the exercise of Series J Warrants issued to MW Innovations Fund in the 2023 Private Placement Offering, and (C) 4,339,583 shares of common stock issuable upon the exercise of Series K Warrants issued to MW Innovations Fund in the 2023 Private Placement Offering. Marshall Wace, LLP is the investment manager of MW Eureka Fund, and Marshall Wace North America L.P. is the investment manager of MW Innovations Fund. No individual has ultimate beneficial ownership of the shares owned by such stockholders. The address of Marshall Wace LLP is George House, 131 Sloane Street, London SW1X 9AT, United Kingdom and the address of Marshall Wace North America L.P. is 350 Park Avenue, New York, NY 10022.
- (2) The shares of common stock registered for resale relate to the shares of common stock underlying (i) 5,165,503 Pre-Funded Warrants purchased by OrbiMed Private Investments IX, LP (“OPI IX”) and (ii) 1,033,100 Pre-Funded Warrants purchased by OrbiMed Genesis Master Fund, L.P. (“Genesis Master Fund”), in each case, in the Private Placement Offering. Beneficial ownership represents: (i) 1,878,704 shares of common stock held by OPI IX; (ii) 254,701 shares of common stock held by Genesis Master Fund; (iii) subject to a 9.99% blocker, (A) 8,424,924 shares of common stock issuable upon the exercise of pre-funded warrants issued to OPI IX in the 2023 Private Placement Offering and issued upon the exercise and conversion of Series H Warrants and Series I Warrants into pre-funded warrants in 2024 and 2025, respectively, (B) 2,515,807 shares of common stock issuable upon the exercise of Series J Warrants issued to OPI IX in the 2023 Private Placement Offering, (C) 2,515,807 shares of common stock issuable upon the exercise of Series K Warrants issued to OPI IX in the 2023 Private Placement Offering, (D) 1,142,147 shares of common stock issuable upon the exercise of pre-funded warrants issued to Genesis Master Fund in the 2023 Private Placement Offering and issued upon the exercise and conversion of Series H Warrants and Series I into pre-funded warrants in 2024 and 2025, respectively, (E) 341,062 shares of common stock issuable upon the exercise of Series J Warrants issued to Genesis Master Fund in the 2023 Private Placement Offering, and (F) 341,062 shares of common stock issuable upon the exercise of Series K Warrants issued to Genesis Master Fund in the 2023 Private Placement Offering; and (iv) subject to a 9.99% blocker, 5,165,503 and 1,033,100 shares of common stock issuable upon the exercise of the Pre-Funded Warrants issued to OPI IX and Genesis Master Fund, respectively, in the Private Placement Offering. OrbiMed Capital GP IX LLC, or GP IX, is the general partner of OPI IX and OrbiMed Advisors LLC (“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 (“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) The shares of common stock registered for resale relate to 826,446 shares of common stock purchased by Nantahala Capital Partners Limited Partnership (“Nantahala Capital Partners”) in the Private Placement Offering. Beneficial ownership represents (i) 1,882,814 shares of common stock, including the 826,446 shares of common stock purchased in the Private Placement Offering and (ii) subject to a 9.99% blocker: (A) 267,601 shares of common stock issuable upon the exercise of Series J Warrants issued to Nantahala Capital Partners in the 2023 Private Placement Offering, and (C) 267,601 shares of common stock issuable upon the exercise of Series K Warrants issued to Nantahala Capital Partners in the 2023 Private Placement Offering. Nantahala Capital Management, LLC, a Registered Investment Adviser, has the power to vote and/or direct the disposition of the securities held by Nantahala Capital Partners, 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 stockholder. Further, Nantahala Capital Partners 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 stockholder. The address of Nantahala Capital Partners is 130 Main St., 2nd Floor, New Canaan, Connecticut 06840.
- (4) The shares of common stock registered for resale relate to (i) 566,177 shares of common stock and (ii) 1,500,000 Pre-Funded Warrants purchased by Rosalind Master Fund L.P. (“Rosalind Master Fund”) in the Private Placement Offering. Beneficial ownership represents (i) 3,508,336 shares of common stock held by Rosalind Master Fund, (ii) 397,407 shares of common stock held by Rosalind Opportunities Fund I L.P. (“Rosalind Opportunities”), (iii) subject to a 9.99% blocker: (A) 1,413,120 shares of common stock issuable upon the exercise of pre-funded warrants issued to Rosalind Master Fund in the 2023 Private Placement Offering and issued upon the exercise and conversion of Series H Warrants and Series I into pre-funded warrants in 2024 and 2025, respectively; (B) 1,532,121 shares of common stock issuable upon the exercise of Series J Warrants issued to Rosalind Master Fund in the 2023 Private Placement Offering; (C) 1,532,120 shares of common stock issuable upon the exercise of Series K Warrants issued to Rosalind Master Fund in the 2023 Private Placement Offering; (D) 552,000 shares of common stock issuable upon the exercise of pre-funded warrants issued to Rosalind Opportunities in the 2023 Private Placement Offering and issued upon the exercise and conversion of Series H Warrants and Series I into pre-funded warrants in 2024 and 2025, respectively; (E) 276,000 shares of common stock issuable upon the exercise of Series J Warrants issued to Rosalind Opportunities in the 2023 Private Placement Offering and (F) 276,000 shares of common stock issuable upon the exercise of Series K Warrants issued to Rosalind Opportunities in the 2023 Private Placement Offering; and (iv) subject to a 9.99% blocker, the exercise of the Pre-Funded Warrants issued to Rosalind Master Fund in the Private Placement Offering. 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 stockholder is c/o TDWaterhouse, 77 Bloor St W, 3rd Floor, Toronto, Ontario M5S 1M2.

- (5) The shares of common stock registered for resale relate to 1,239,669 shares of common stock purchased by Velan Capital Master Fund LP (“Velan Master”). Beneficial ownership includes (i) 2,143,698 shares of common stock, including the 1,239,669 shares of common stock purchased in the Private Placement Offering and (ii) subject to a 4.99% blocker: (A) 904,029 shares of common stock issuable upon the exercise of pre-funded warrants that were issued upon the exercise and conversion of Series H Warrants and Series I into pre-funded warrants in 2024 and 2025, respectively; (B) 452,015 shares of common stock issuable upon the exercise of Series J Warrants issued in the 2023 Private Placement Offering; (C) 452,014 shares of common stock issuable upon the exercise of Series K Warrants issued in the 2023 Private Placement Offering. As the general partner of Velan Master, Velan Capital Holdings LLC (“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 (“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 (“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 100 North Main Street, Suite 301, Alpharetta, Georgia, 30009.
- (6) The shares of common stock registered for resale and the beneficial ownership set forth above relate to (i) 804,958 shares of common stock purchased by Abrdn Healthcare Investors, (ii) 451,033 shares of common stock purchased by Abrdn World Healthcare Fund and (iii) 810,124 shares of common stock purchased by Abrdn Healthcare Opportunities Fund. The securities held by the foregoing stockholders may be deemed to be beneficially owned by Aberdeen Investments, which acts as each stockholders’ appointed advisor, and/or Jason Akus, the portfolio manager of such fund. Notwithstanding the foregoing, Aberdeen Investments, as advisor, and Mr. Akus disclaim beneficial ownership of the shares except to the extent of their respective pecuniary interest therein. The address of the selling stockholders is 28 State Street, 17th Floor, Boston MA 02110.
- (7) The shares of common stock registered for resale and the beneficial ownership set forth above relate to 1,239,669 shares purchased by Ghisallo Master Fund LP (“Ghisallo Master Fund”) in the Private Placement Offering. The securities held by Ghisallo Master Fund may be deemed to be beneficially owned by Ghisallo Capital Management LLC (Ghisallo Master Fund’s investment advisor), and Michael Germino. Notwithstanding the foregoing, Mr. Germino disclaims beneficial ownership of the shares except to the extent of his pecuniary interest therein. The address of the selling stockholder is 190 Elgin Avenue, George Town, Grand Cayman, CI KY1-9008.
- (8) The shares of common stock registered for resale relate to (i) 61,739 shares of common stock purchased by Blackstone CSP-MST FMAP Fund (“FMAP Fund”), (ii) 201,203 shares of common stock purchased by BEMAP Master Fund Ltd. (“BEMAP”), (iii) 63,211 shares of common stock purchased by 360 North Partners LP (“360 North”), and (iv) 423,847 shares of common stock purchased by Parkman HP Master Fund LP (“Parkman HP”), in each case, in the Private Placement Offering. Beneficial ownership represents (i) 125,450 shares of common stock held by FMPA Fund, (ii) 408,219 shares of common stock held by BEMAP, (iii) 126,343 shares of common stock held by 360 North, and (iv) 860,466 shares of common stock held by Parkman HP, in each case, inclusive of the shares purchased by such stockholders in the Private Placement Offering. The securities held by the foregoing stockholders may be deemed to be beneficially owned by Parkman Healthcare Partners LLC (“Parkman Healthcare”), which is the investment advisor of each of the foregoing stockholders, and/or Gregory Martinez, the portfolio manager of Parkman Healthcare. Notwithstanding the foreign, Parkman Healthcare and Mr. Martinez disclaim beneficial ownership of the shares except to the extent of their pecuniary interest, if any, therein. The business address of the entities is c/o Parkman Healthcare, 700 Canal Street, 2nd Floor, Stamford, CT 06902.

- (9) The shares of common stock registered for resale relate to 41,322 shares of common stock purchased by Gary Roubin, one of our directors, in the Private Placement Offering. Beneficial ownership includes (i) 608,425 shares, which includes (A) the 41,322 shares purchased in the Private Placement Offering and (B) 82,244 shares of restricted stock granted under the Company's 2021 Equity Incentive Plan, (ii) 84,129 shares of common stock issuable upon exercise of warrants that are currently exercisable and (iii) 60,324 shares of common stock issuable upon exercise of options that are currently exercisable or exercisable within 60 days of August 1, 2025.
- (10) The shares of common stock registered for resale relate to 20,661 shares of common stock purchased by Paul Stuka, our Chairman of the Board of Directors, in the Private Placement Offering. Beneficial ownership includes (i) 804,479 shares, which includes (A) the 20,661 shares purchased in the Private Placement Offering and (B) 123,963 shares of restricted stock granted under the Company's 2021 Equity Incentive Plan, (ii) 175,000 shares of common stock issuable upon exercise of warrants that are currently exercisable and (iii) 80,802 shares of common stock issuable upon exercise of options that are currently exercisable or exercisable within 60 days of August 1, 2025. Such securities are held either personally or Osiris Investment Partners, L.P., of which Mr. Stuka is the principal and managing member.
- (11) The shares of common stock registered for resale relate to 30,991 shares of common stock purchased by Thomas Kester, one of our directors, in the Private Placement Offering. Beneficial ownership includes (i) 420,758 shares, which includes (A) the 30,991 shares purchased in the Private Placement Offering and (B) 82,244 shares of restricted stock granted under the Company's 2021 Equity Incentive Plan, (ii) 65,281 shares of common stock issuable upon exercise of warrants that are currently exercisable and (iii) 53,528 shares of common stock issuable upon exercise of options that are currently exercisable or exercisable within 60 days of August 1, 2025.
- (12) The shares of common stock registered for resale relate to 10,330 shares of common stock purchased by Marvin Slosman, our Chief Executive Officer and one of our directors, in the Private Placement Offering. Beneficial ownership includes (i) 16,722 shares, including the 10,330 shares purchased in the Private Placement Offering, (ii) 1,121,678 shares underlying restricted stock units granted to Mr. Slosman that have vested or vest within 60 days of August 1, 2025 and may be issued to Mr. Slosman solely upon a change of control, termination by the Company or a resignation by Mr. Slosman for "good reason," (iii) 5,048 shares of common stock issuable upon exercise of warrants that are currently exercisable and (iv) 423,081 shares of common stock issuable upon exercise of options that are currently exercisable or exercisable within 60 days of August 1, 2025.

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 Securities offered under this prospectus. We will not receive any of the proceeds from the sale of the Securities offered under this prospectus by the selling stockholders. We will bear all fees and expenses incident to our obligation to register the Securities offered under this prospectus.

The selling stockholders may sell all or a portion of the Securities beneficially owned by it and offered hereby from time to time directly or through one or more underwriters, broker-dealers or agents. If the Securities are sold through underwriters or broker-dealers, the selling stockholders will be responsible for underwriting discounts or commissions or agent's commissions. The Securities 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 Securities owned by it and, if it defaults in the performance of its secured obligations, the pledgees or secured parties may offer and sell the Securities, 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 Securities 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 Securities 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 Securities 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 Securities offered under this prospectus will be the purchase price of the Securities 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 Securities to be made directly or through agents. We will not receive any of the proceeds from the offering of the Securities under this prospectus.

The selling stockholders also may resell all or a portion of the Securities 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 Securities 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 Securities 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 Securities may be sold in these jurisdictions only through registered or licensed brokers or dealers. In addition, in some states the Securities 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 the Securities 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 Securities 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 Securities 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, Miami, Florida.

EXPERTS

The financial statements incorporated in this prospectus by reference to the Annual Report on Form 10-K for the year ended December 31, 2024 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 1.b to the financial statements), of Kesselman & Kesselman, Certified Public Accountants (Isr.), a member firm of PricewaterhouseCoopers International Limited, an independent registered public accounting firm, 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.

We make available free of charge on or through our website at www.inspiremd.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. The registration statement and the documents referred to below under "Incorporation of Certain Information by Reference" are also available on our website, www.inspiremd.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” into this prospectus the information we file with them, which means that we can disclose important information to you by referring you to those documents. Any statement contained or incorporated by reference in this prospectus shall be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained herein, or in any subsequently filed document which also is incorporated by reference herein, modifies or supersedes such earlier statement. Any such statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus. We incorporate into this prospectus by reference the following documents that we previously filed with the SEC (other than any document or portion of any document furnished or deemed furnished and not filed in accordance with the SEC’s rules, including Items 2.02 and 7.01 of Form 8-K and Item 9.01 of Form 8-K related thereto):

- our Annual Report on [Form 10-K](#) for the year ended December 31, 2024, filed with the SEC on March 12, 2025;
- our Quarterly Reports on Form 10-Q for the quarters ended [March 31, 2025](#) and [June 30, 2025](#), filed with the SEC on May 8, 2025 and August 4, 2025, respectively;
- our Definitive Proxy Statement on [Schedule 14A](#) filed on April 15, 2025, to the extent specifically incorporated by reference into Part III of the Annual Report on [Form 10-K](#) for the fiscal year ended December 31, 2024, filed with the SEC on March 12, 2025;
- our Current Reports on Form 8-K (other than the information furnished pursuant to Item 2.02 or 7.01 thereof or related exhibits furnished pursuant to Item 9.01 thereof) filed with the SEC on [June 3, 2025](#), [June 3, 2025](#), [June 13, 2025](#), [June 24, 2025](#) and [July 31, 2025](#); 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, 2024, filed with the SEC on March 12, 2025, and as may be further updated or amended in any amendment or report filed for such purpose.

All documents that we file (but not those that we furnish or that are deemed furnished and not filed in accordance with the SEC’s rules, including Items 2.02 and 7.01 of Form 8-K and Item 9.01 of Form 8-K related thereto) with the SEC pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act (i) after the date of the initial registration statement of which this prospectus forms a part and prior to the effectiveness of such registration statement and (ii) after the date of this prospectus and before all of the securities offered by this prospectus are sold are incorporated by reference in this prospectus from the date of filing of the documents, unless we specifically provide otherwise. Information that we file with the SEC will automatically update and may replace information previously filed with the SEC.

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: 6303 Waterford District Drive, Suite 215, Miami, Florida 33126, Attention: 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.inspiremd.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 16,556,184 Shares of Common Stock Offered by the Selling Stockholders



PROSPECTUS

August 14, 2025

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.