As filed with the Securities and Exchange Commission on May 4, 2026

Registration No. 333-295160

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

AMENDMENT NO. 2
TO
FORM S-1
REGISTRATION STATEMENT
Under
The Securities Act of 1933

MOBIA MEDICAL, INC.
(Exact name of Registrant as specified in its charter)

Delaware	**3841**	**20-8573833**
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification Number)

2802 Flintrock Trace, Suite 226
Austin, TX 78738
(855) 628-9375
(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

Richard Foust
President and Chief Executive Officer
Mobia Medical, Inc.
2802 Flintrock Trace, Suite 226
Austin, TX 78738
(855) 628-9375
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

B. Shayne Kennedy **J. Ross McAloon** **Latham & Watkins LLP** **650 Town Center Drive, 20th Floor** **Costa Mesa, California 92626** **(714) 755-8181**	**Chase Leavitt** **Mobia Medical, Inc.** **2802 Flintrock Trace, Suite 226** **Austin, Texas 78738** **(855) 628-9375**	**Ilir Mujalovic** **Lesley Janzen** **Cleary Gottlieb Steen & Hamilton LLP** **One Liberty Plaza** **New York, New York 10006** **(212) 225-2000**

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☐

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☐

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to Completion, dated May 4, 2026
Preliminary Prospectus

10,000,000 Shares

Common Stock

This is Mobia Medical, Inc.'s initial public offering. We are offering 10,000,000 shares of our common stock.

We expect the public offering price to be between $14.00 and $16.00 per share. Currently, no public market exists for the shares. After pricing of the offering, we expect that the shares will trade on the Nasdaq Global Select Market under the symbol "MOBI."

We are an "emerging growth company" and a "smaller reporting company" as defined under federal securities laws and are subject to reduced public company disclosure standards. Please see the section titled "Prospectus Summary—Implications of Being an Emerging Growth Company and a Smaller Reporting Company."

Investing in our common stock involves a high degree of risk. Please see section titled "Risk Factors" starting on page 18 of this prospectus.

	Per Share	Total
Initial public offering price	$	$
Underwriting discounts and commissions [(1)]	$	$
Proceeds, before expenses, to us	$	$

(1) See the section titled "Underwriting" for a description of the underwriting discounts and commissions and offering expenses.

The underwriters may also exercise their option to purchase up to an additional 1,500,000 shares from us, at the public offering price, less the underwriting discounts and commissions, for 30 days after the date of this prospectus.

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

The shares will be ready for delivery on or about , 2026.

BofA Securities **J.P. Morgan** **Goldman Sachs & Co. LLC**

BTIG

Wolfe | Nomura Alliance

The date of this prospectus is , 2026.

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Unless the context otherwise requires, all references in this prospectus to "Mobia," "Mobia Medical," the "Company," "we," "us," or "our" refers to Mobia Medical, Inc., a Delaware corporation.

We have not, and the underwriters have not, authorized anyone to provide any information or to make any representation other than those contained in this prospectus, any amendment or supplement to this prospectus, or any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We and the underwriters take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares of common stock offered hereby, and only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus, any amendment or supplement to this prospectus, or any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of shares of our common stock. Our business, financial condition, results of operations, and prospects may have changed since that date.

For investors outside the United States: We have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside the United States.

GENERAL INFORMATION

Industry, Market and Other Data

This prospectus contains estimates, projections, and other information concerning our industry and our business, as well as data regarding market research, estimates, and forecasts prepared by our management and third parties. Information that is based on estimates, forecasts, projections, market research, or similar methodologies is inherently subject to uncertainties, and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. While we believe the market and industry data included in this prospectus are reliable and are based on reasonable assumptions, these data and the industry in which we operate are subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section titled "Risk Factors." These and other factors could cause results to differ materially from those expressed in these estimates, publications, and reports made by third parties or us.

Unless otherwise expressly stated, we obtained such industry, business, market, and other data from reports, research surveys, studies, and similar data prepared by market research firms and other third parties, industry and general publications, government data, and similar sources. For example, information regarding the timing and number of strokes in the United States annually, the percentage of ischemic strokes, stroke prevalence in the United States, number of stroke survivors, and estimated annual healthcare burden of ischemic stroke is based on information in 2025 Heart Disease and Stroke Statistics: A Report of US and Global Data From the American Heart Association, published in *Circulation*, a peer-reviewed medical journal published by the American Heart Association, in 2025. In some cases, we do not expressly refer to the sources from which this data is derived. The content of these third-party sources, except to the extent specifically set forth in this prospectus, does not constitute a portion of this prospectus and is not incorporated herein.

Forecasts and other forward-looking information with respect to industry, business, market, and other data are subject to the same qualifications and additional uncertainties regarding the other forward-looking statements in this prospectus. See "Special Note Regarding Forward-Looking Statements."

Trademarks, Trade Names and Service Marks

"Mobia," "Mobia Medical," "MicroTransponder," "Vivistim," "Paired VNS," and the Mobia, Mobia Medical, Vivistim and Paired VNS logos and our other registered or common law trademarks appearing in this prospectus are the property of Mobia Medical, Inc. This prospectus contains references to our trademarks and service marks and to those belonging to other entities. Solely for convenience, trademarks and trade names referred to in this prospectus, including logos, artwork and other visual displays, may appear without the ® or TM symbols, but the omission of such references is not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights or the rights of the applicable licensor to these trademarks and trade names. We do not intend our use or display of other entities' trade names, trademarks, or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other entity.

Basis of Presentation

Certain monetary amounts, percentages and other figures included elsewhere in this prospectus have been subject to rounding adjustments. Percentage amounts included in this prospectus have not in all cases been calculated on the basis of such rounded figures, but on the basis of such amounts prior to rounding. For this reason, percentage amounts in this prospectus may vary from those obtained by performing the same calculations using the figures in our financial statements included elsewhere in this prospectus. Accordingly, certain other figures and amounts that appear as totals in this prospectus may not be the arithmetic aggregation of the figures or amounts that precede them, and figures or amounts expressed as a percentage may not total 100% or be the arithmetic aggregation of the percentages that precede them.

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus and is qualified in its entirety by the more detailed information and financial statements included elsewhere in this prospectus. It does not contain all of the information that may be important to you and your investment decision. You should carefully read this entire prospectus, including the sections titled "Risk Factors," "Special Note Regarding Forward-Looking Statements," "Business," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes included elsewhere in this prospectus.

Overview

We are a commercial-stage medical device company redefining stroke recovery for survivors living with life-altering motor impairments. Our Vivistim Paired Vagus Nerve Stimulation (Paired VNS) System is the first and only clinically-validated, FDA-approved solution for chronic ischemic stroke survivors with moderate to severe upper extremity impairments. Stroke is one of the leading causes of long-term disability in the United States. While advancements in acute stroke care over the past decade have significantly reduced mortality, innovation for chronic stroke recovery has lagged, resulting in a growing number of stroke survivors living with meaningful impairments. Our breakthrough Vivistim Paired VNS System (Vivistim System) addresses this unmet need. The Vivistim System includes an implanted pulse generator and lead that deliver stimulation to the vagus nerve when activated. During treatment (Vivistim Therapy), intentional bursts of stimulation are delivered during functional movement to increase neuroplasticity and durably restore motor function. Clinical data has demonstrated that Vivistim Therapy delivers meaningful improvements in upper limb function, which can help stroke survivors regain critical capabilities and independence and restore quality of life, regardless of the time elapsed since the patient's stroke. We believe we are setting a new standard of care in chronic stroke recovery, facilitating a new treatment pathway for chronic ischemic stroke survivors with moderate to severe upper extremity impairments. We have experienced rapid growth since our full commercial launch in 2023, and physicians have performed over 1,000 implants, including approximately 700 in 2025.

In the United States, a stroke occurs every 40 seconds and approximately 800,000 strokes occur annually, according to a report published by the American Heart Association (AHA) in 2025. Stroke occurs when blood flow to a region of the brain is suddenly interrupted, either because an artery becomes blocked in the case of an ischemic stroke, or because a weakened blood vessel ruptures in the case of a hemorrhagic stroke. For stroke survivors, the interruption of blood flow to the brain can result in lasting motor, cognitive, visual, and language impairments, including weakness or hemiparesis affecting the extremities. Based on a report published by the AHA in 2025, we estimate that there are currently approximately 10 million stroke survivors in the United States, the majority of whom are living with chronic impairments.

Chronic ischemic stroke is a serious medical condition characterized by physical and cognitive impairments that persist beyond the first three to six months post-stroke. These impairments can materially diminish a patient's independence and quality of life. According to a report published by the AHA in 2025, ischemic stroke is a leading cause of serious long-term impairment for adults in the United States and has an estimated annual healthcare burden of more than $25 billion.

Chronic stroke recovery presents a significant market opportunity. According to the AHA, approximately 87% of the strokes in the United States are ischemic. This equates to approximately 9 million ischemic stroke survivors in the United States, of which we estimate that more than 4 million are chronic ischemic stroke survivors living with moderate to severe upper extremity impairment. This population falls within the current on-label indication for the Vivistim System. We believe that an initial market opportunity comprises approximately 1 million of those survivors that demonstrate the requisite overall health, cognition and motivation to participate in therapy and have received some amount of post-stroke therapy, which we estimate represents an initial market opportunity of over $30 billion based on the average selling price of the Vivistim System. Vivistim Therapy is effective for recent stroke survivors as well as patients who initiate treatment many years post-stroke. Based on a report published by the AHA in 2025, we estimate that each year approximately 200,000 new stroke survivors in the United States meet our indication for use, with 50,000 of these survivors representative of our initial market opportunity.

There is no standard of care for motor recovery in the chronic stage of stroke. After the initial three- to six-month sub-acute phase post-stroke, patients typically reach a functional plateau with conventional physical rehabilitation and have limited options to continue improving. As a result, we believe that there is a large population of highly motivated stroke survivors who have few proven options.

Our breakthrough Vivistim System is the first and only FDA-approved solution for chronic ischemic stroke survivors with moderate to severe upper extremity impairments. The Vivistim System facilitates Vivistim Therapy, which has been clinically proven to significantly improve upper limb function and help patients regain critical capabilities and independence. Vivistim Therapy leverages neuroplasticity – the ability of the nervous system to adapt and reorganize its connections – to improve upper limb function in patients with chronic stroke. The Vivistim System includes an implantable device that stimulates the vagus nerve only when intentionally activated, triggering the release of neuromodulators. These neuromodulators create a heightened state of plasticity in the brain, such that neural networks can more readily adapt and reform in response to stimuli. When functional movements, such as goal- or task-oriented exercises and movements, are performed in the presence of these increased neuromodulators, the brain can create new neural connections and strengthen existing connections to a degree that would otherwise not be possible, enabling lasting improvements in motor pathways and creating greater potential for recovery.

Shortly after device implantation, patients begin Vivistim Therapy with a physical or occupational therapist. This therapy does not require patient-specific programming. In the clinic, the therapist uses a remote to activate the Vivistim System during task-specific practice, such as reaching for and grasping objects. Patients continue Vivistim Therapy at home, both during their in-clinic therapy protocol and, if desired, in the months and years that follow. At home, patients easily activate stimulation sessions by swiping the Vivistim magnet over the Vivistim implanted pulse generator (IPG) implant site, which initiates 30 minutes of periodic stimulation pulses. Patients can perform this therapy at home or during their activities of daily living to further reinforce their neural retraining. We believe the ability for patients to observe real, tangible improvements in their ability to perform activities of daily living can encourage ongoing engagement with at-home therapy, helping patients to sustain their efforts and achieve meaningful, lasting functional improvement over time.

We believe we are setting a new standard of care in chronic stroke recovery, facilitating a new treatment pathway for chronic ischemic stroke patients with moderate to severe upper extremity impairment. We believe Vivistim Therapy offers these patients a number of key benefits, including the first and only FDA-approved device clinically proven to deliver significant improvements in upper limb function; significant clinical improvement even for patients who initiate treatment many years post-stroke; durable improvements underpinned by a clinically proven mechanism of action; high patient and therapist satisfaction; and a safe and minimally invasive outpatient procedure.

We are building a robust body of clinical evidence supporting the safety, efficacy, durability, and well-understood mechanism of action of Vivistim Therapy, with additional trials ongoing and planned in 2026 and beyond. In our pivotal, triple-blind, randomized, sham-controlled VNS-REHAB trial, Vivistim Therapy resulted in an approximately two-times greater, as measured by Fugl-Meyer Assessment of Upper Extremity (FMA-UE), and approximately three-times greater, as measured by Wolf Motor Function Test (WMFT), improvement in hand and arm function compared to intensive rehabilitation alone, at the end of the in-clinic and at-home therapy protocol. Data from the trial also demonstrated a favorable safety profile, with no severe adverse events, serious adverse events or unanticipated adverse events associated with the Vivistim System. While implantation can result in procedure-related complications, such as post-operative pain and infection, the rate of surgical complications that did not resolve within a few weeks was less than 1% in the VNS-REHAB trial. These results highlight Vivistim Therapy's distinctive ability to drive substantial neuroplastic adaptations and functional gains, which we believe sets it apart as the only therapy with robust clinical evidence for effective post-stroke motor recovery. Looking ahead, our GRASP registry is collecting real-world evidence to reinforce the durable benefits of Vivistim Therapy. We believe patient access is key to gaining market acceptance, and we remain committed to expanding patient access by developing additional evidence that further validates the benefits of Vivistim Therapy, accelerates market adoption, strengthens proof of its clinical utility, and supports broader reimbursement coverage decisions.

We continue to optimize our commercial model to support the adoption of Vivistim Therapy and gain further market acceptance. Our strategy is tailored to our unique patient and customer dynamics. Stroke survivors living with life-altering functional impairment can self-identify and are highly motivated to seek effective, long-lasting

solutions. These patients are often supported by dedicated advocates who create a strong network of care and commitment. Our target customer base consists of a highly concentrated group of approximately 1,500 primary and comprehensive stroke centers in the United States, which are hospitals that have cross-functional teams with the capabilities to treat acute stroke at the highest level of care and in compliance with AHA guidelines. These stroke centers, which are typically surrounded by a network of therapy sites with neurorehabilitation capabilities, provide the infrastructure for efficient implementation of Vivistim Therapy.

As a novel treatment, expanding market acceptance depends in part upon our ability to educate healthcare providers and others as to the distinctive characteristics, clinical and benefits, safety, durability and ease of use of Vivistim Therapy. We believe we have implemented highly effective initiatives for generating a consistent funnel of Vivistim Therapy candidates through physician and therapist referrals, as well as direct patient engagement. Stroke survivors interact with a diverse network of care providers who help identify and evaluate candidates. We directly engage each of these stakeholders through specialized events, summits, and conferences as well as through our field-based commercial team. Our commercial organization is responsible for driving adoption of the Vivistim System through customer outreach, education, and relationship management activities. Our team includes Territory Managers (TMs), who support initial customer onboarding efforts at stroke centers and maintain commercial relationships with physicians and administrators, and Therapy Development Specialists (TDSs), who focus on outreach to therapy sites and provide general educational information regarding the clinical use of the Vivistim System. These activities are intended to facilitate customer adoption and utilization of the Vivistim System.

Our commitment to offering life-changing treatments drives our passion for innovation through continuous research and development. We commenced development efforts in 2007 with an aim to pursue initial research from the University of Texas regarding the effects of vagus nerve stimulation. By early 2013, we began focusing on paired vagus nerve stimulation therapy for stroke recovery, working with a small team of fewer than ten engineers, clinicians and scientists. Over several years, this work led to the development and clinical testing of our Vivistim System, including through our feasibility, pilot and pivotal trials from 2014 to 2021. Following the results of our pivotal trial, we submitted a premarket approval (PMA) application to the FDA in March 2021. The Vivistim System received PMA approval from the FDA in 2021 and is classified by the FDA as a Class III device. In 2021, the Vivistim System was granted breakthrough device status under the FDA's Breakthrough Devices Program. We aim to build upon these development efforts and leverage our internal expertise, clinical insights and experience gained from developing the Vivistim System to assess and prioritize research and development initiatives.

The Vivistim System implantation procedure falls under a long-established Category 1 CPT code. Effective January 1, 2026, this CPT code was assigned to a New Technology Ambulatory Payment Classification (APC) by the Centers for Medicare and Medicaid Services (CMS), establishing an elevated payment level that we believe will support sustainable access for Medicare beneficiaries. Coverage for Vivistim Therapy varies by payor. As there are currently no national coverage determinations or local coverage determinations specific to Vivistim Therapy, coverage for Medicare fee-for-service patients is made on a case-by-case basis and patients are typically able to access Vivistim Therapy when medically necessary, without prior authorization. Currently, most commercial insurers have determined that Vivistim Therapy is experimental or investigational and therefore, not covered. To that end, commercial insurance, Medicaid and Medicare Advantage generally require prior authorization. Our in-house market access team supports providers by facilitating administrative aspects of the prior authorization process, including assisting with documentation and submissions to payors in advance of implantation. As part of our longer term strategy, our market access team plans to continue to engage with payors to communicate clinical and health economic data which may impact coverage policies. We believe that expanded payor coverage will facilitate broader patient access to Vivistim Therapy.

We have experienced rapid growth since our full commercial launch in 2023. We recognized revenue of $32.0 million for the year ended December 31, 2025, compared to revenue of $15.6 million for the year ended December 31, 2024, representing 104.8% year-over-year growth. For the year ended December 31, 2025, we recognized a gross margin of 81.1% and a net loss of $46.5 million, compared to a gross margin of 79.6% and a net loss of $24.6 million for the year ended December 31, 2024. As of December 31, 2025, we had an accumulated deficit of approximately $157.8 million.

Overview of Chronic Stroke Impairment

In the United States, a stroke occurs every 40 seconds and approximately 800,000 strokes occur annually, according to a report published by the AHA in 2025. Based on the same report, we estimate that there are approximately 10 million stroke survivors in the United States, the majority of whom are living with chronic impairments. Chronic ischemic stroke is a serious medical condition characterized by physical and cognitive impairments that persist beyond the first three to six months post-stroke. The first three to six months after a stroke are commonly referred to as the sub-acute phase. These impairments can materially diminish a patient's independence and quality of life. According to a report published by the AHA in 2025, ischemic stroke is a leading cause of serious long-term impairment for adults in the United States and has an estimated annual healthcare burden of more than $25 billion.

Chronic upper extremity impairment is among the most common and disabling consequences of stroke, with millions of survivors experiencing weakness, loss of coordination, reduced dexterity, and impaired function in the arm and hand, persisting for more than three to six months post-stroke. These impairments significantly limit the patients' ability to perform activities of daily living, such as eating, dressing, bathing, and personal care, can impede a survivor's ability to return to their profession, and can have a profound impact on functional independence and quality of life.

While advancements in acute stroke care have helped to significantly reduce the stroke mortality rate in the United States over time, effective therapeutic options for post-stroke recovery have not advanced, and there is no standard of care for motor recovery in the chronic stage of stroke. The standard of care for post-stroke recovery in the sub-acute phase consists of several weeks or months of conventional occupational or physical rehabilitation therapy, although many patients do not receive any rehabilitation therapy at all due to lack of access or motivation. While stroke patients can, and often do, make some physical and cognitive improvements during the acute and sub-acute phases when neuroplasticity is the highest, a substantial proportion of patients continue living with long-term motor impairments and associated complications. We believe there is limited data demonstrating the clinical efficacy of conventional rehabilitation therapy beyond the sub-acute phase, leaving many patients with chronic deficits in functionality. In addition, we believe that conventional rehabilitation therapy has experienced limited adoption or continuation in the chronic phase and that these patients have generally not had an effective therapeutic option for continued recovery.

Our Market Opportunity

Based on a report published by the AHA in 2025, we estimate that there are currently approximately 10 million stroke survivors in the United States. According to the AHA, approximately 87% of strokes are ischemic. This equates to approximately 9 million ischemic stroke survivors in the United States. Based on our analysis of third-party publications, we estimate that more than 4 million of these survivors are chronic ischemic stroke survivors living with moderate to severe upper extremity impairment. For example, according to several third-party publications, up to two-thirds of stroke survivors continue to experience upper extremity disability at six months post-stroke (*e.g.*, Lang CE, et al., *Observation of amounts of movement practice provided during stroke rehabilitation*, Arch Phys Med Rehabil. 2009 Oct;90(10):1692-8; and Kwakkel G, Kollen BJ, van der Grond J, Prevo AJ., *Probability of regaining dexterity in the flaccid upper limb: impact of severity of paresis and time since onset in acute stroke*, Stroke, Volume 34, Number 9, 2181-6 (2003), and approximately 81% of stroke survivors with upper extremity disability after six months post-stroke have moderate to severe upper extremity impairment (Woytowicz E, et al., *Determining Levels of Upper Extremity Movement Impairment by Applying a Cluster Analysis to the Fugl-Meyer Assessment of the Upper Extremity in Chronic Stroke*, Archives of Physical Medicine and Rehabilitation, 2016; 98, 456-462). We expect this large prevalence population to continue to grow over time, driven by, among others, increasing stroke survival rates due to improvements in acute thrombectomy therapies and increasing stroke incidence rates among young adults.

Based on our FDA-approved, on-label indication for the Vivistim System, we estimate that our total addressable market opportunity in the United States consists of the approximately 4 million chronic ischemic stroke survivors living with moderate to severe upper extremity impairment. While we are pursuing this total addressable market, we believe an initial market opportunity comprises stroke survivors that demonstrate the requisite overall health,

cognition and motivation to participate in therapy and have received some amount of post-stroke therapy. According to the AHA, two-thirds of stroke survivors receive rehabilitation therapy following a stroke. This rate of therapy generally decreases over time, with one study published in *Stroke* in 2023 concluding that the rate of conventional occupational therapy decreases to 21% in the three to six months following a stroke (Young, Bittany et al., *Rehabilitation Therapy Doses Are Low After Stroke and Predicted by Clinical Factors*, Stroke, Volume 54, Number 3, 831-839 (2023)). Based on these patient factors and post-stroke therapy rates, we estimate that this initial market opportunity comprises approximately 1 million stroke survivors within our total addressable market. We believe this patient population represents an initial market opportunity of over $30 billion based on the average selling price of the Vivistim System.

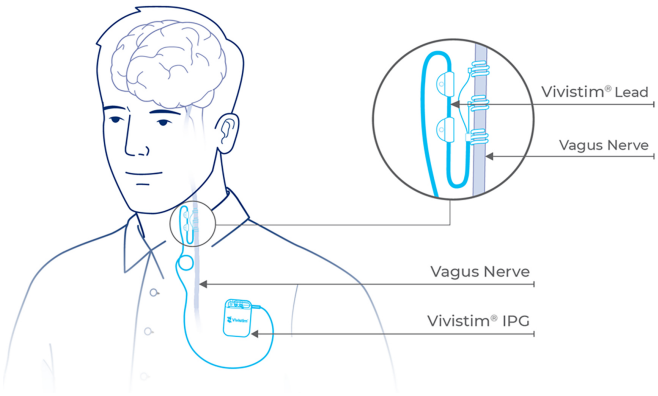
Vivistim Therapy has demonstrated meaningful clinical improvements in upper extremity function independent of the time elapsed since stroke. As such, Vivistim Therapy is appropriate for patients who initiate treatment many years post-stroke as well as more recent stroke survivors. Based on a report published by the AHA in 2025, we estimate that each year approximately 200,000 new stroke survivors in the United States meet our indication for use, with 50,000 of these survivors representative of our initial market opportunity.

The market share we ultimately achieve is subject to a number of assumptions, risks and uncertainties, including the market acceptance of Vivistim Therapy and our ability to execute on our commercial strategy. As a novel treatment, market acceptance depends, in part, on our ability to raise awareness, the adoption of Vivistim Therapy by hospitals, healthcare providers, therapists, patients, caregivers and adequate payor coverage and reimbursement, and the acceptance of Vivistim Therapy as safe, effective and cost-effective. We may be unsuccessful in attaining significant market acceptance or such acceptance may take longer or be more costly than anticipated. For more information, please see the section titled "*Risk Factors — Risks Related to Our Business and Industry — The commercial success of Vivistim Therapy depends upon attaining significant market acceptance of our products by hospitals, healthcare providers, therapists, patients, caregivers and payors" and " — The size of our market opportunity has not been established with precision and may be smaller than we estimate, possibly materially.*"

Our Solution

Our breakthrough Vivistim System is the first and only FDA-approved solution for chronic ischemic stroke survivors with moderate to severe upper extremity impairments. The Vivistim System facilitates Vivistim Therapy, which has been clinically proven to significantly improve upper limb function and help patients regain critical capabilities and independence. Vivistim Therapy leverages neuroplasticity – the ability of the nervous system to adapt and reorganize its connections – to improve upper limb function in patients with chronic stroke. The Vivistim System includes an implantable device that stimulates the vagus nerve only when intentionally activated, triggering the release of neuromodulators, including acetylcholine, norepinephrine, and serotonin. These neuromodulators create a heightened state of plasticity in the brain, such that neural networks can more readily adapt and reform in response to stimuli. When functional movements, such as goal- or task-oriented exercises and movements, are performed in the presence of these increased neuromodulators, the brain can create new neural connections and strengthen existing connections to a degree that would otherwise not be possible, enabling lasting improvements in

motor pathways and creating greater potential for recovery. The image below depicts the placement of the Vivistim System, including the IPG and lead.



Shortly after device implantation, patients begin Vivistim Therapy with a physical or occupational therapist. In the clinic, the therapist uses a remote to activate the Vivistim System during task-specific practice, such as reaching for and grasping objects. Patients can continue Vivistim Therapy at home, both during their in-clinic therapy protocol and, if desired, in the months and years that follow. At home, patients easily activate stimulation sessions by swiping the Vivistim magnet over the Vivistim IPG implant site, which initiates 30 minutes of periodic stimulation pulses.

We believe Vivistim Therapy offers the first effective therapeutic option for these patients, with the following key benefits:

- **First and only FDA-approved device clinically proven to deliver significant improvements in upper limb function.** In our pivotal, triple-blind, randomized, sham-controlled VNS-REHAB trial, Vivistim Therapy resulted in an approximately two-times greater, as measured by FMA-UE, and approximately three-times greater, as measured by WMFT, improvement in hand and arm function compared to intensive rehabilitation alone, at the end of the in-clinic and at-home therapy protocol. At such time, the FMA-UE score increased by 5.8 points in the treatment group. These results highlight Vivistim Therapy's distinctive ability to drive substantial neuroplastic adaptations and functional gains, which we believe sets it apart as the only therapy with robust clinical evidence for effective post-stroke motor recovery. Based on published case studies involving patients that received Vivistim Therapy, improvements in upper limb function following Vivistim Therapy can further enable patients to perform activities of daily living, such as dressing independently, preparing meals, folding laundry, and eating (Saylor A, Patrick L, Reddy CG, Gandhi R., *Vagus Nerve Stimulation Paired With Upper Extremity Rehabilitation for Chronic Stroke: Real-World Implementation and Outcomes*. Arch Rehabil Res Clin Transl. (2026)). Even modest gains – particularly in wrist, hand, and finger function – can impact dignity, independence, and quality of life.
- **Significant clinical improvement even for patients who initiate treatment many years post-stroke.** Unlike conventional rehabilitation therapies, which have shown benefits during the sub-acute phase of stroke recovery but not in the chronic phase, Vivistim Therapy has demonstrated clinically meaningful improvements for patients even years after their stroke. We observed significant functional improvements in all cohorts of our pivotal clinical trial, with participants averaging 3.3 years post-stroke at the time of treatment and a range from nine months to 10 years into their recovery. Commercially, we have treated patients many years post-stroke, including up to 45 years, who have achieved meaningful clinical benefit,

demonstrating that improvement with Vivistim Therapy is possible regardless of time elapsed since stroke and offering hope to a large population of chronic stroke survivors.

- **Durable improvements underpinned by a clinically proven mechanism of action.** The functional gains achieved with Vivistim Therapy are long-lasting, providing durable, life-changing outcomes for stroke survivors. Clinical data has demonstrated sustained motor improvements, measured out to one year in our pivotal trial and three years in our pilot trial. This lasting effect is enabled by the unique mechanism of action underlying Vivistim Therapy, which creates durable neural pathways that enable motor improvements.
- **High patient and therapist satisfaction, with consistently positive feedback.** Based on a survey we conducted in connection with our VNS-REHAB trial, 98% of patients that received Vivistim Therapy were satisfied with their experience. In addition, based on a commercial survey conducted by us, 98% of therapists would recommend Vivistim Therapy to suitable candidates. We believe the high satisfaction rate reflects the profound impact of these functional gains on patients' lives, and the differentiation of functional gains enabled by Vivistim Therapy.
- **Safe and minimally invasive outpatient procedure.** The IPG and lead are placed via a simple, 60-minute procedure using two small incisions, allowing patients to return home on the same day and quickly resume activities of daily living. This type of procedure has been safely performed by neurosurgeons, who are trained on it in their residency programs, and other qualified surgeons for over 25 years to treat other medical conditions and is considered safe and reliable. Our clinical results have validated the safety of the system and therapy, with no severe adverse events, serious adverse events or unanticipated adverse events associated with the Vivistim System in our VNS-REHAB trial. Our clinical results have also validated the safety of the procedure with a low complication rate. In our VNS-REHAB trial, the rate of surgical complications that did not resolve within a few weeks was less than 1%. The IPG battery has an indicated service life under continuous use conditions of five years. After its end of service, the IPG can be surgically replaced for continued use. For more information, please see the section titled "*Risk Factors — Risks Related to Our Business and Industry — Adverse events, product recalls, or other complications or customer satisfaction issues associated with Vivistim Therapy, including regarding the finite IPG battery life, could limit its adoption.*"

The Vivistim System received PMA approval from the FDA in 2021 and is classified by the FDA as a Class III device. Class III devices require approval of a PMA and are devices deemed by the FDA to pose the greatest risks, such as implantable devices, devices that have a new intended use, or devices that use advanced technology that is not substantially equivalent to that of a legally marketed device. The Vivistim System was granted breakthrough device status under the FDA's Breakthrough Devices Program in 2021, because it is intended to provide more effective treatment of a life-threatening or irreversibly debilitating condition. For more information, please see the section titled "Business — Government Regulation" for a discussion on the FDA's classification system of medical devices and the Breakthrough Devices Program.

Our Success Factors

We believe the continued growth of our company will be driven by the following success factors:

- ***First and only FDA-approved solution establishing a new standard of care in chronic stroke recovery.***
- ***Large and untapped market opportunity with significant unmet need.***
- ***Compelling body of clinical data demonstrating the significant and sustained benefits of Vivistim Therapy.***
- ***Unique customer and patient dynamics to support a scalable commercial model.***
- ***Favorable coding and payment dynamics with dedicated in-house market access team supporting patients and providers.***

- ***Differentiated purpose-built technology for Vivistim Therapy protected by robust IP portfolio.***
- ***Seasoned executives with extensive Med Tech commercialization expertise and a proven track record of value creation.***

Our Growth Strategies

Our mission is to redefine stroke recovery for survivors living with life-altering functional impairments by establishing Vivistim Therapy as the standard of care for chronic stroke. The key elements of our growth strategy include:

- ***Expand our market development efforts to broaden awareness and access to Vivistim Therapy.***
- ***Driving utilization of Vivistim Therapy by promoting awareness among patients, caregivers and healthcare providers.***
- ***Building upon our strong base of clinical evidence to support adoption and expand payor coverage.***
- ***Investing in research and development to drive continuous innovation, better outcomes, and improved user experience.***
- ***Expanding clinical indications to benefit a broader patient population.***
- ***Continue to evaluate expansion into geographies outside of the United States.***

Recent Developments

2026 Convertible Notes

From January 30, 2026 through February 11, 2026, we issued convertible promissory notes to certain investors in an aggregate principal amount of $40.0 million (2026 Convertible Notes). The 2026 Convertible Notes mature on January 30, 2028 (Maturity Date). The 2026 Convertible Notes bear no interest for the first six months following the date of issuance (Interest Free Period). Following such Interest Free Period, the 2026 Convertible Notes accrue interest at a rate of 7.0% per annum through the Maturity Date, which interest payments shall be paid in kind. Immediately prior to the closing of this offering, the 2026 Convertible Notes and any accrued interest will automatically convert into shares of our common stock at the applicable conversion price. The conversion price is the lower of (a) 80% of the initial public offering price per share in this offering and (b) the valuation of the Company immediately prior to the closing of this offering divided by the number of fully diluted shares of capital stock (on an as-converted basis) outstanding immediately prior to this offering but excluding the 2026 Convertible Notes (Fully Diluted Capitalization), provided, that in no event shall such conversion price be less than the quotient obtained by dividing $226.0 million by the Fully Diluted Capitalization or greater than the quotient obtained by dividing $750.0 million by the Fully Diluted Capitalization. Based on an assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and without giving effect to accrued interest (if any), the 2026 Convertible Notes will automatically convert into an aggregate of 3,333,324 shares of our common stock immediately prior to the closing of this offering. Each $1.00 increase in the assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would decrease the shares of common stock issued in the Notes Conversion by 208,333 shares, and each $1.00 decrease in the assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase the shares of common stock issued in the Notes Conversion by 238,095 shares, in each case without giving effect to accrued interest (if any).

Preliminary Estimated Selected Financial Results for the Three Months Ended March 31, 2026

Our financial results for the three months ended March 31, 2026 are not yet complete and will not be available until after the completion of this offering. Accordingly, set forth below are certain preliminary estimated selected unaudited financial results for the three months ended March 31, 2026 and the corresponding period of the prior

fiscal year. We have provided ranges, rather than specific amounts, for the three months ended March 31, 2026, because our closing procedures for the quarter-end financial closing process are not yet complete. These ranges are based on the information available to us as of the date of this prospectus. These preliminary estimated results for the three months ended March 31, 2026 are derived from our preliminary internal financial records and are subject to revisions based on our procedures and controls associated with the completion of our financial reporting process, including all the customary reviews and approvals. As a result, actual results may vary from the preliminary estimated results presented below, and it is possible that actual results will not be within the currently estimated ranges. These preliminary estimates are not necessarily indicative of any future period and should be read together with "Risk Factors," "Special Note Regarding Forward-Looking Statements," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our audited financial statements and related notes included elsewhere in this prospectus.

The preliminary unaudited financial data included in this prospectus has been prepared by, and is the responsibility of, our management. PricewaterhouseCoopers LLP has not audited, reviewed, examined, compiled, nor applied agreed-upon procedures with respect to the preliminary financial data. Accordingly, PricewaterhouseCoopers LLP does not express an opinion or any other form of assurance with respect thereto.

	Three Months Ended March 31,		
	2026 (estimated low)	2026 (estimated high)	2025 (actual)
	(unaudited) (in thousands)		
Preliminary estimated financial results:			
Revenue	$ 11,850	$ 12,050	$ 5,661
Cost of goods sold	2,130	2,230	1,015
Total operating expenses	$ 26,800	$ 27,000	$ 14,950
Net loss attributable to common stockholders	$ (17,720)	$ (18,120)	$ (10,653)

For the three months ended March 31, 2026, we expect revenue to be between $11.9 million and $12.1 million, compared to $5.7 million for the three months ended March 31, 2025. The expected increase in revenue was driven entirely by higher adoption of the Vivistim System. Units of IPGs, a primary component of the Vivistim System, sold during the period increased by 108.9%. Average selling prices of the Vivistim System remained consistent period over period.

For the three months ended March 31, 2026, we expect cost of goods sold to be between $2.1 million and $2.2 million, compared to $1.0 million for the three months ended March 31, 2025. The expected increase in cost of goods sold is primarily due to a higher sales volume of Vivistim Systems, as well as an increase in incoming freight and product warranty costs. Cost per unit of the underlying product remained relatively consistent year over year.

For the three months ended March 31, 2026, we expect total operating expenses to be between $26.8 million and $27.0 million, compared to $15.0 million for the three months ended March 31, 2025. The expected increase in total operating expenses is primarily due to higher personnel-related expenses as a result of increased headcount, particularly within the commercial organization, as well as higher commissions driven by increased sales of Vivistim Systems. Additional contributing factors include higher audit, legal, and other professional fees, increased travel and meeting expenses related to expanded staffing, increased marketing and branding costs, including those associated with the Company's name change, and expenses related to the post-market GRASP clinical study.

For the three months ended March 31, 2026, we expect net loss attributable to common stockholders to be between $17.7 million and $18.1 million, compared to $10.7 million for the three months ended March 31, 2025. The expected increase in net loss is due to higher operating expenses, which more than offset the increase in revenue. The increase in net loss also reflects an increase in other expense of $0.7 million related to the change in the fair value of our 2026 Convertible Notes payable.

As of March 31, 2026, our cash and cash equivalents balance is expected to be approximately $55.7 million as compared to $33.6 million at December 31, 2025. The increase is primarily due to net proceeds from the issuance of $40.0 million of 2026 Convertible Notes during the quarter, partially offset by cash used in operating activities.

Risks Related to our Business

Our ability to execute our business strategy is subject to numerous risks, as more fully described in the section titled "Risk Factors" immediately following this prospectus summary. These risks include, among others:

- We have a history of net losses, and we expect to continue to incur losses for the foreseeable future. If we ever achieve profitability, we may not be able to sustain it.
- Our recurring losses from operations and financial condition raise substantial doubt about our ability to continue as a going concern.
- If we fail to manage our growth effectively, our business could be materially and adversely affected.
- The commercial success of Vivistim Therapy depends upon attaining significant market acceptance of our products by hospitals, healthcare providers, therapists, patients, caregivers and payors.
- Our success depends entirely on our currently marketed Vivistim Therapy. If we are unable to successfully market and sell Vivistim Therapy, our business prospects will be materially and adversely affected, and we may be unable to achieve revenue growth and to fund our operations.
- If we fail to effectively hire, train, and retain our direct sales force, increase our sales capabilities, or develop broad brand awareness in a cost-effective manner, our growth will be materially and adversely affected, and our business will suffer.
- Coverage and adequate reimbursement may not be available or may be subject to change for our Vivistim System, including any future products we commercialize, which could diminish our sales, increase our competition, or affect our ability to sell our currently marketed Vivistim Therapy and any future products profitably.
- We depend on a small number of third-party contract manufacturers and suppliers, some of which are single source, to produce and package all elements comprising our Vivistim System as well as certain implantation tools, and if these suppliers and manufacturers fail to supply our Vivistim System or its components or subcomponents in sufficient quantities or at all, it will have a material adverse effect on our business, financial condition, and results of operations.
- The size of our market opportunity has not been established with precision and may be smaller than we estimate, possibly materially.
- Adverse events, product recalls, or other complications or customer satisfaction issues associated with Vivistim Therapy, including regarding the finite IPG battery life, could limit its adoption.
- We have limited clinical data, evidence and experience regarding the safety and efficacy of Vivistim Therapy.
- If we are unable to maintain existing, and obtain additional, patent and other intellectual property protection for our technology and products, or if the scope of the patent protection we obtained is not sufficiently broad, we may not be able to compete effectively in our markets.
- Our products and operations are subject to extensive government regulation and oversight in the United States, and our failure to comply with applicable requirements could materially and adversely affect our business.

- Failure to maintain marketing authorizations for our products, or to timely obtain necessary marketing authorizations for our future products, may have a material and adverse effect on our business, financial condition and results of operations.
- We have identified a material weakness in our internal control over financial reporting.

Corporate Information

We were incorporated in Delaware on March 5, 2007 as MicroTransponder, Inc. Effective February 23, 2026, we changed our name to "Mobia Medical, Inc." Our principal executive offices are located at 2802 Flintrock Trace, Suite 226, Austin, TX 78738. Our telephone number is (855) 628-9375. Our website address is www.mobia.com. Information contained on the website is not incorporated by reference into this prospectus and the inclusion of our website address in this prospectus is an inactive textual reference only.

Implications of Being an Emerging Growth Company and a Smaller Reporting Company

We are an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012 (the JOBS Act). We will remain an emerging growth company until the earliest of: (i) the last day of the fiscal year following the fifth anniversary of the consummation of this offering; (ii) the last day of the fiscal year in which we have total annual gross revenue of at least $1.235 billion; (iii) the last day of the fiscal year in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Securities Exchange Act of 1934, as amended (the Exchange Act), which would occur if the market value of our common stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year; or (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period. An emerging growth company may take advantage of specified reduced reporting requirements and is relieved of certain other significant requirements that are otherwise generally applicable to public companies. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

As an emerging growth company, we have elected to take advantage of certain reduced disclosure obligations in the registration statement that this prospectus is a part of, and may elect to take advantage of other reduced reporting requirements in future filings. In particular:

- we will present in this prospectus only two years of audited financial statements, plus any required unaudited financial statements, and related section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations;"
- we will avail ourselves of the exemption from the requirement to obtain an attestation and report from our independent registered public accounting firm on the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act of 2002, as amended (the Sarbanes-Oxley Act);
- we will avail ourselves of relief from compliance with the requirements of the Public Company Accounting Oversight Board regarding the communication of critical audit matters in the auditor's report on the financial statements;
- we will provide less extensive disclosure about our executive compensation arrangements; and
- we will not be required to hold stockholder non-binding advisory votes on executive compensation or golden parachute arrangements.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of some accounting standards until those standards would otherwise apply to private companies. We have elected to use the extended transition period for any other new or revised accounting standards during the period in which we remain an emerging growth company; however, we may adopt certain new or revised accounting standards early.

We are also a “smaller reporting company” as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as the market value of our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

THE OFFERING

Common stock offered by us	10,000,000 shares.
Option to purchase additional shares	We have granted the underwriters an option for a period of 30 days to purchase up to 1,500,000 additional shares of our common stock at the public offering price, less the underwriting discounts and commissions.
Common stock to be outstanding immediately after this offering	33,085,391 shares (or 34,585,391 shares if the underwriters exercise their option to purchase additional shares in full).
Use of proceeds	We estimate that the net proceeds to us from the sale of shares of our common stock in this offering will be approximately $134.5 million (or approximately $155.4 million if the underwriters exercise their option to purchase additional shares in full), based upon the assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page on this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. We currently intend to use the net proceeds from this offering to expand our direct sales force and commercial organization, continue our research and development activities and our clinical studies and trials, and for working capital and other general corporate purposes. We may use a portion of the net proceeds we receive from this offering to acquire businesses, products, services, or technologies. We periodically evaluate strategic opportunities; however, we do not have agreements or commitments for any material acquisitions or investments at this time. See the section titled "Use of Proceeds" for additional information.
Risk Factors	Investing in our common stock involves a high degree of risk. See the section of this prospectus titled "Risk Factors" beginning on page 18 and other information included in this prospectus for a discussion of factors you should carefully consider before deciding to invest in shares of our common stock.
Reserved share program	At our request, the underwriters have reserved for sale, at the initial public offering price, up to 5% of the shares offered by this prospectus for sale to some of our directors, officers, employees, distributors, dealers, business associates and related persons. If these persons purchase reserved shares, this will reduce the number of shares available for sale to the general public. Any reserved shares that are not so purchased will be offered by the underwriters to the general public on the same terms as the other shares offered by this prospectus.
Proposed Nasdaq Global Select Market trading symbol	"MOBI"

The number of shares of our common stock to be outstanding immediately after this offering is based on 23,085,391 shares of our common stock outstanding as of December 31, 2025, which reflects (i) the Preferred Stock Conversion described below, (ii) the issuance of the 2026 Convertible Notes and the related Notes Conversion (as defined below) and (iii) the Warrant Exercises described below, and excludes the following:

- 29,622 shares of our common stock issuable upon the exercise of warrants to purchase shares of our redeemable convertible preferred stock outstanding as of December 31, 2025, which will convert into warrants to purchase shares of our common stock immediately prior to the completion of this offering with an exercise price of $8.8618 per share of common stock (the Warrant Conversion);

- 4,046,266 shares of common stock issuable upon exercise of options to purchase shares of our common stock outstanding as of December 31, 2025, at a weighted-average exercise price of $3.51 per share;
- 524,180 shares of common stock issuable upon exercise of options to purchase shares of our common stock granted after December 31, 2025, at a weighted-average exercise price of $7.91 per share;
- 523,613 shares of common stock reserved for future issuance under our 2022 Equity Incentive Plan, as amended (the 2022 Plan), as of December 31, 2025, provided that we will cease granting awards under our 2022 Plan upon the effectiveness of the 2026 Incentive Award Plan (the 2026 Plan);
- 2,680,780 shares of common stock issuable upon the exercise of stock options (the IPO Options) to be granted in connection with this offering under the 2026 Plan (based upon an assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover of this prospectus), which will become effective on the business day immediately prior to the date of effectiveness of the registration statement of which this prospectus forms a part, to our non-employee directors and certain of our employees at an exercise price equal to the initial public offering price in this offering;
- 181,810 shares of common stock issuable upon the vesting of restricted stock units (the IPO RSUs and, together with the IPO Options, the IPO Grants) to be granted in connection with this offering under the 2026 Plan (based upon an assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover of this prospectus), which will become effective immediately following the effectiveness of the applicable Form S-8 registration statement, to certain of our employees;
- a number of shares of our common stock reserved for future issuance under the 2026 Plan (which number includes the IPO Grants), which will become effective on the business day immediately prior to the date of effectiveness of the registration statement of which this prospectus forms a part, equal to the sum of (1) a number of shares equal to 14% of the number of fully-diluted shares of our common stock upon the closing of this offering (calculated on an as-converted basis after giving effect to the number of shares of common stock to be sold in this offering and assuming the exercise in full of the underwriters' over-allotment option and including shares subject to outstanding equity awards and the share reserve under the 2026 Plan and the 2026 Employee Stock Purchase Plan (the ESPP)), plus (2) any shares of common stock remaining available for future issuance under our 2022 Plan as of the effectiveness of the 2026 Plan, which shares will be added to the share reserve under the 2026 Plan upon its effectiveness; and
- a number of shares of common stock reserved for issuance under our ESPP, which will become effective on the business day immediately prior to the date of effectiveness of the registration statement of which this prospectus forms a part, equal to a number of shares equal to 1% of the number of fully-diluted shares of our common stock upon the closing of this offering (calculated on an as-converted basis after giving effect to the number of shares of common stock to be sold in this offering and assuming the exercise in full of the underwriters' over-allotment option and including shares subject to outstanding equity awards and the share reserves under the 2026 Plan and the ESPP).

Each of the 2026 Plan and the ESPP provides for annual automatic increases in the number of shares reserved thereunder, and the 2026 Plan also provides for increases to the number of shares that may be granted thereunder based on awards under the 2022 Plan that expire, are forfeited, or otherwise repurchased by us, as more fully described in the section titled "Executive and Director Compensation—Equity Incentive Plans."

In addition, unless otherwise indicated, all information in this prospectus assumes or gives effect to:

- the filing and effectiveness of our amended and restated certificate of incorporation and the effectiveness of our amended and restated bylaws, which will occur immediately prior to the completion of this offering;
- the conversion of all outstanding shares of our redeemable convertible preferred stock as of December 31, 2025 into an aggregate of 18,831,868 shares of our common stock, which will occur immediately prior to the completion of this offering (the Preferred Stock Conversion);

- the issuance of 34,455 shares of our common stock upon the net exercise of warrants to purchase 908,000 shares of our Series B redeemable convertible preferred stock outstanding as of December 31, 2025, which exercise will occur immediately prior to the completion of this offering at an exercise price of $3.73744 per share (based upon an assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover of this prospectus) (the Series B Warrant Exercise);
- the issuance of 1,714 shares of our common stock upon the net exercise of warrants to purchase 258,000 shares of our Series D redeemable convertible preferred stock outstanding as of December 31, 2025, which exercise will occur immediately prior to the completion of this offering at an exercise price of $4.207 per share (based upon an assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover of this prospectus) (together with the Series B Warrant Exercise, the Warrant Exercises);
- the issuance of 3,333,324 shares of our common stock upon the conversion of the 2026 Convertible Notes, based on an assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, which conversion will occur immediately prior to the closing of this offering (the Notes Conversion);
- a 1-for-3.483 reverse split of our capital stock, which was effected on May 1, 2026;
- no exercise of outstanding options or warrants after December 31, 2025; and
- no exercise of the underwriters' option to purchase additional shares of common stock from us.

SUMMARY FINANCIAL DATA

The following tables summarize our financial data for the periods and as of the dates indicated. Except for pro forma and pro forma adjusted amounts, we have derived the statements of operations data for the years ended December 31, 2025 and 2024, and the selected balance sheet data as of December 31, 2025 from our audited financial statements and related notes included elsewhere in this prospectus. Our historical results are not necessarily indicative of results that may be expected in the future. You should read the following summary financial data together with our financial statements and the related notes appearing elsewhere in this prospectus and the information in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations." The summary financial data included in this section are not intended to replace the financial statements and related notes thereto included elsewhere in this prospectus and are qualified in their entirety by such financial statements and related notes thereto.

Statements of Operations Data

	Years ended December 31,	
(in thousands, except share and per share amounts)	**2025**	**2024**
Revenue	$ 32,041	$ 15,644
Cost of goods sold	6,066	3,193
Gross profit	25,975	12,451
Operating expenses:		
Research and development costs	$ 6,515	$ 4,243
Selling, general and administrative expenses	65,828	32,444
Total operating expenses	72,343	36,687
Loss from operations	(46,368)	(24,236)
Other income (expense):		
Interest expense	(967)	(970)
Other income, net	842	617
Total other expense, net	(125)	(353)
Loss before provision for income taxes	(46,493)	(24,589)
Provision for income taxes	(5)	(14)
Net loss attributable to common stockholders	$ (46,498)	$ (24,603)
Net loss per share attributable to common stockholders, basic and diluted[1]	$ (54.78)	$ (42.82)
Weighted-average number of shares used in computing net loss per share attributable to common stockholders, basic and diluted[1]	848,812	574,632
Pro forma net loss per share attributable to common stockholders, basic and diluted[2]	$ (2.02)	$ (1.08)
Weighted-average number of shares used in computing pro forma net loss per share attributable to common stockholders, basic and diluted[2]	23,050,173	22,775,993

(1) Basic and diluted net loss per share attributable to common stockholders and weighted-average number of shares used in computing basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2025 has been revised to correct an error in our previously issued financial statements and recasted to reflect the reverse stock split, as more fully described in Note 3, "Summary of Significant Accounting and Reporting Policies and Basis of Presentation—Revision of previously issued financial statements and recast to reflect the reverse stock split" to our audited financial statements. For the calculation of our basic and diluted net loss per share attributable to common stockholders and weighted-average number of shares used in the computation of the per share amounts, see Note 14 to our audited financial statements included elsewhere in this prospectus.

(2) The unaudited pro forma net loss per share attributable to common stockholders, basic and diluted for the year ended December 31, 2025 was computed using the weighted-average number of shares of common stock outstanding, including the pro forma effect of the Preferred Stock Conversion, the issuance of the 2026 Convertible Notes and the related Notes Conversion, the Warrant Exercises and the Warrant Conversion, as if such conversions and exercises had occurred at the beginning of the period, or their issuance dates, if later. Unaudited pro forma net loss per share attributable to common stock does not include the shares expected to be sold and related proceeds to be received in this offering.

Balance Sheet Data

(in thousands)	As of December 31, 2025		
	Actual	Pro forma [1]	Pro forma as adjusted [2][3]
Cash and cash equivalents	$ 33,587	$ 73,500	$ 208,000
Working capital[4]	36,151	76,064	210,564
Total assets	48,149	88,061	221,626
Notes payable, net of discount and deferred financing costs	7,130	7,130	7,130
Warrant liabilities	865	—	—
Redeemable convertible preferred stock	179,773	—	—
Additional paid-in capital	6,985	227,421	361,821
Accumulated deficit	(157,789)	(157,875)	(157,875)
Total stockholders' deficit	$ (150,774)	$ 69,777	$ 204,277

(1) The pro forma balance sheet data gives effect: (i) to the Preferred Stock Conversion, (ii) the issuance of the 2026 Convertible Notes and the related Notes Conversion, (iii) the Warrant Exercises, (iv) the Warrant Conversion and (v) the filing and effectiveness of our amended and restated certificate of incorporation, which will become effective immediately upon the closing of this offering.

(2) Reflects the pro forma adjustments described in footnote (1) above and the issuance and sale of 10,000,000 shares of common stock in this offering at the assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

(3) The pro forma information discussed above is illustrative only and will be adjusted based on the actual initial public offering price and other terms of our initial public offering determined at pricing. Each $1.00 increase (decrease) in the assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted amount of each of cash and cash equivalents, total assets, additional paid-in capital, and total stockholders' equity by approximately $9.3 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1.0 million shares in the number of shares offered by us at the assumed initial public offering price after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us would increase (decrease) each of cash and cash equivalents, total assets, additional paid-in capital, and total stockholders' equity by approximately $14.0 million.

(4) We define working capital as current assets less current liabilities. See our audited financial statements and the related notes included elsewhere in this prospectus for further details regarding our current assets and current liabilities.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this prospectus, including our financial statements and the related notes and the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could harm our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline if one or more of these risks or uncertainties actually occur, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations and the market price of our common stock. Certain statements below are forward-looking statements. See the section titled "Special Note Regarding Forward-Looking Statements" appearing elsewhere in this prospectus.

Risks Related to Our Business and Industry

We have a history of net losses, and we expect to continue to incur losses for the foreseeable future. If we ever achieve profitability, we may not be able to sustain it.

We have incurred losses since our inception and expect to continue to incur losses for the foreseeable future. We reported net losses of $46.5 million and $24.6 million for the years ended December 31, 2025 and 2024, respectively. As a result of these losses, as of December 31, 2025, we had an accumulated deficit of approximately $157.8 million. We expect to continue to incur significant sales and marketing, research and development, clinical and regulatory, and other expenses as we expand our commercial organization, increase marketing efforts to drive adoption of Vivistim Therapy, expand existing relationships with our customers, conduct clinical trials on our existing and future products and develop new products or add new features to our existing products, pursue any required regulatory clearances or approvals, and seek to establish broader commercial coverage. In addition, we expect our general and administrative expenses to increase following this offering due to the additional costs associated with being a public company. Additionally, we may encounter unforeseen expenses, difficulties, complications, delays, and other known and unknown obstacles as we continue to build and scale our business. The net losses that we incur may fluctuate significantly from period to period. We will need to generate significant additional revenue in order to achieve and sustain profitability. Even if we achieve profitability, we cannot be sure that we will remain profitable for any period of time.

Our recurring losses from operations and financial condition raise substantial doubt about our ability to continue as a going concern.

In Note 2 to our financial statements for the fiscal year ended December 31, 2025 included elsewhere in this prospectus, we concluded that our history of continued operating losses and negative operating cash flows raise substantial doubt about our ability to continue as a going concern. Similarly, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements as of and for the fiscal year ended December 31, 2025, describing the existence of substantial doubt about our ability to continue as a going concern.

Our future viability is dependent on our ability to generate cash from our operating activities or to raise additional capital to finance our operations. There is no assurance that we will succeed in obtaining sufficient funding on terms acceptable to us to fund continuing operations, if at all. The perception that we might be unable to continue as a going concern may also make it more difficult to obtain financing for the continuation of our operations on terms that are favorable to us, or at all, and could result in the loss of confidence by investors, suppliers and employees. Our financial statements do not include any adjustments that might result from the outcome of this uncertainty. If we are unable to continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our financial statements, and it is likely that our investors will lose all or a part of their investment.

If we fail to manage our growth effectively, our business could be materially and adversely affected.

We have experienced recent rapid growth and anticipate further growth. For example, for the year ended December 31, 2025, our revenue was $32.0 million compared to revenue of $15.6 million for the year ended December 31, 2024, an increase of 104.8% year-over-year. This growth has placed significant demands on our management, financial, operational, technological and other resources, and we expect that our future growth will continue to place significant demands on our management and other resources and will require us to continue developing and improving our operational, financial and other internal controls. In particular, continued growth increases the challenges involved in a number of areas, including managing our third-party manufacturers and supplier relationships and ensuring adequate inventory is available, recruiting and retaining sufficient skilled personnel for leadership positions, sales force and other functions, providing adequate training and supervision to maintain our high-quality standards and preserving our culture and values. We may not be able to address these challenges in a cost-effective manner, or at all.

To achieve our business objectives, we must also successfully increase our supply of products and components from third-party manufacturers to meet expected demand. If demand decreases, we will need to implement capacity and cost reduction measures involving restructuring costs. If demand increases, we will be required to make capital expenditures related to increased production. This would also put pressure on our third-party manufacturing capabilities. For example, a sudden increase in demand could require increased production of components, such as the implantable pulse generator (IPG) or stimulation lead. Adapting to changes in demand inherently involves a delay because it takes time to identify the change the market is undergoing and to implement any measures to take as a result. Finally, capacity adjustments are inherently risky because there is imperfect information, and sales trends may rapidly intensify, ebb, or even reverse. We may be unable to accurately or timely predict trends in demand and customer behavior or to take appropriate measures to mitigate risks and react to opportunities resulting from such trends. Any inability in the future to identify or to adequately and effectively react to changes in demand could have a material adverse effect on our business, financial condition and results of operations.

In addition, we may experience challenges managing the inventory of components of our Vivistim System, which can lead to excess inventory. Inventory levels in excess of customer demand may result in inventory obsolescence or expiration, which could potentially result in inventory write-downs or write-offs, which could be substantial and could impact our gross margins. Actual future demand could be less than our forecast, which may result in additional reserves and write-downs in the future, or actual demand could be stronger than our forecast, which may result in a reduction to previously recorded reserves and write-downs in the future and increase the volatility of our operating results.

In the future, we may also experience difficulties with quality control, component supply and shortages of qualified personnel, among other problems. These problems could result in delays in product availability, product quality issues, delays in our ability to reach our sales potential delays in the development and launch of new products and increases in expenses. Any such delays, issues or increased expenses could adversely affect our business, financial condition and results of operations. In addition, rapid and significant growth will place a strain on our administrative and operational infrastructure, particularly as we transition to being a public company. In order to manage our operations and growth, we will need to continue to improve our operational and management controls, hiring process, reporting and information technology systems and financial internal control procedures. If we do not effectively manage our growth, we may not be able to execute on our business plan, respond to competitive pressures, take advantage of market opportunities, reach our sales potential, satisfy customer requirements or maintain high-quality product offerings, which could have a material adverse effect on our business, financial condition and results of operations.

Our success depends entirely on our currently marketed Vivistim Therapy. If we are unable to successfully market and sell Vivistim Therapy, our business prospects will be materially and adversely affected, and we may be unable to achieve revenue growth and to fund our operations.

To date, all of our revenue has been derived, and we expect it to continue to be derived, from sales of our Vivistim System. Our future financial success will depend entirely on our ability to effectively and profitably market

and sell Vivistim Therapy. The commercial success of Vivistim Therapy and any of our future products we develop will depend on a number of factors, including the following:

- our revenue growth;
- the market awareness and adoption of Vivistim Therapy, including by patients and our customers;
- the scope, timing and costs of supporting the growth and expansion of our commercial organization and efforts;
- the availability and amount of reimbursement for procedures using our products;
- the adoption of private payor coverage of our products;
- changes in the acquisition costs of finished goods and components used in our products;
- the costs associated with securing additional suppliers and service providers;
- the timing and costs of our research and development efforts;
- the scope, rate of progress and costs of our current or future clinical and registries as well as costs associated with complying with regulatory requirements;
- the cost and timing of additional regulatory clearances or approvals;
- the costs of attaining, defending, and enforcing our intellectual property rights;
- whether we acquire third-party products or technologies;
- litigation or other claims against us for intellectual property infringement or otherwise;
- the emergence of competing or complementary technologies;
- our ability to raise additional funds to finance our operations;
- debt service requirements;
- our need to implement additional infrastructure and internal systems;
- general economic, industry and market conditions or extraordinary external events, such as a recession;
- the rate at which we expand internationally;
- the cost associated with being a public company;
- our reputation among physicians, hospitals and therapists; and
- whether we are required by the FDA or comparable non-U.S. regulatory authorities to conduct additional clinical trials for future or current indications.

If we fail to successfully market and sell our products, we will not be able to achieve profitability, which will have a material adverse effect on our business, financial condition and results of operations.

If we fail to effectively hire, train, and retain our direct sales force, increase our sales capabilities, or develop broad brand awareness in a cost-effective manner, our growth will be materially and adversely affected, and our business will suffer.

As of December 31, 2025, we had a direct sales team consisting of approximately 83 sales professionals, inclusive of approximately 40 Territory Managers (TMs) and 43 Therapy Development Specialists (TDSs) with substantial applicable medical device and clinical experience, as well as sales management. In order to generate

future growth, we must continue to add highly qualified personnel to our commercial organization, with a strategic mix of TMs and TDSs, to drive further awareness and penetration within healthcare providers that interact with stroke survivors. Identifying and recruiting qualified commercial personnel and training them on our product, applicable federal and state laws and regulations, and on our internal policies and procedures requires significant time, expense, and attention. Once hired, the training process is lengthy because it requires significant education for new TMs and TDSs to achieve the level of clinical competency with our products expected by physicians and therapists. Upon completion of the training, our TMs and TDSs typically require lead time in the field to grow their network of accounts and achieve the productivity levels we expect them to reach in any individual territory. Furthermore, the use of our products may involve limited, non-contractual support activities provided in connection with initial education and setup prior to or at the time of implantation. The Company does not have an ongoing obligation to provide programming, reprogramming, or customer or technical support after implantation, and any such activities, if performed, are incidental and not considered significant. Also, to the extent we hire personnel from our competitors, we may have to wait until applicable non-competition or non-solicitation provisions have expired before deploying such personnel in restricted territories or incur costs to relocate personnel outside of such territories, and we may be subject to future allegations that these new hires have been improperly solicited, or that they have divulged to us proprietary or other confidential information of their former employers. Our business may be harmed if our efforts to expand and train our sales force and any future efforts to engage in direct-to-patient programs and direct-to-consumer marketing do not generate a corresponding increase in revenue, and our higher fixed costs may slow our ability to reduce costs in the face of a sudden decline in demand for our products. Moreover, the members of our direct sales force are at-will employees. The loss of these personnel to competitors or otherwise could have a material adverse effect on our business, financial condition, and results of operations. If we are unable to attract, train and retain our direct sales force personnel or replace them with individuals of equivalent technical expertise and qualifications, if we are unable to successfully instill technical expertise in replacement personnel, or if our direct sales force personnel are unable to reach the productivity levels we expect on the timeline we expect for any reason, our revenue and results of operations could be materially and adversely affected.

The commercial success of Vivistim Therapy depends upon attaining significant market acceptance of our products by hospitals, healthcare providers, therapists, patients, caregivers and payors.

Our success depends, in part, on the acceptance of Vivistim Therapy as safe, effective and cost-effective. We cannot predict how quickly, if at all, hospitals, healthcare providers, therapists, patients, caregivers or payors will adopt Vivistim Therapy or, if adopted, how frequently Vivistim Therapy will be used. Vivistim Therapy and any future products we may develop or market may never gain broad market acceptance for some or all of our targeted indications. It is important to our success, future growth, and profitability that we are able to increase healthcare provider awareness of Vivistim Therapy and that hospitals, healthcare providers, therapists, patients, caregivers and payors believe that our products offer benefits over alternative treatment methods, and that they adopt our products. These parties may not adopt our products unless they are able to determine, based on experience, clinical data, medical society recommendations, and other analyses, that our products are safe, effective and cost-effective on a stand-alone basis and relative to competitors' products. If physicians or payors do not find our body of published clinical evidence and data compelling or wish to wait for additional studies, they may choose not to use or provide coverage and reimbursement for or prescribe our product. Currently, there are a number of large third-party payers that have determined that our Vivistim Therapy is experimental or investigational and therefore do not cover it at this time. In addition, the long-term effects of our Vivistim Therapy beyond our current clinical trials are not yet known. Certain physicians, hospitals, therapists and payers may prefer to see longer-term safety and efficacy data than we have produced. Even if we are able to raise awareness, physicians and therapists may be slow in changing their medical treatment practices and may be hesitant to select our products for recommendation to their patients for a variety of reasons, including:

- long-standing relationships with competing companies and distributors that sell other products;
- competitive responses from competing companies and distributors that sell alternative products;
- lack or perceived lack of sufficient clinical evidence, including long-term data, supporting reliability, safety, clinical or economic benefits;

- lack of third-party coverage or adequate reimbursement, particularly from private payors;
- lack of experience with our products and concerns that we are relatively new to market; and
- time commitment and skill development that may be required to gain familiarity and proficiency with our products and implantation procedures.

Stroke survivors interact with a diverse network of care providers, including stroke interventionalists, neurosurgeons, neurologists, physical medicine and rehabilitation physicians, occupational and physical therapists, stroke coordinators and nurses. Each of these providers can play a role in identifying and evaluating potential Vivistim Therapy candidates. We directly engage each of these stakeholders through our field-based commercial team, as well as through specialized events, summits, and conferences. As a result, our success depends, in large part, on effectively marketing Vivistim Therapy to these healthcare providers. We aim to educate these healthcare providers regarding the patient population that would benefit from Vivistim Therapy. Acceptance of Vivistim Therapy depends upon our education of healthcare providers as to the distinctive characteristics, clinical and benefits, safety, durability and ease of use of Vivistim Therapy as compared to other therapy options and any future competitor VNS devices and upon our effective communication to healthcare providers of the proper use of Vivistim Therapy as well as our ability to provide effective and timely physician, therapist and patient support, including in connection with device education and addressing any technical, quality or other concerns. However, we cannot assure you that we will achieve broad market acceptance among these practitioners. Healthcare providers may be reluctant or unwilling to invest time to learn about the benefits of Vivistim Therapy, and to deviate from practices or therapy programs which they consider to be more established. If we are not able to effectively demonstrate that the use of Vivistim Therapy is beneficial in a broad range of patients, some healthcare providers may choose to utilize Vivistim Therapy on only a subset of their total eligible patient population or not at all, and adoption of our product will be limited and may not occur as rapidly as we anticipate or at all, which would have a material adverse effect on our business, financial condition and results of operations.

Most of our customers are hospitals, which may require us to enter into contracts regarding our devices. This process can be lengthy and time-consuming and may require extensive negotiations and management time with an uncertain degree of success. If we do not receive access to hospital facilities via these contracting processes or otherwise, or if we are unable to secure contracts or tender successful bids, we may not achieve our sales and revenues goals, and our results of operations may be harmed. Furthermore, we may expend significant effort in these time-consuming processes and still may not obtain a purchase contract from such hospitals.

In addition, certain characteristics and features of Vivistim Therapy may prevent widespread market adoption. For example, some patients have reported pain, discomfort, bruising, swelling and infection after implantation as well as device related issues, such as low or high impedance (a measure of the lead's resistance to current), which have led to explant or revision requests. These and any similar future explants or revisions could deter potential candidates from pursuing treatment or prompt physicians to favor alternative therapies. Even if physicians recommend Vivistim Therapy to patients, patients may not adopt it for a variety of reasons, including because they do not want to or are unable to undergo the implantation procedure (which involves typical risks associated with such procedures, including infection), do not perceive our device as safe, effective or cost-effective, prefer any future competitive devices or therapies (including as a result of competitive patient marketing) or because Vivistim Therapy is not reimbursed by their health insurance provider.

Also, screening patients for Vivistim Therapy requires a clinical assessment of a patient's motor impairments, which is typically done based on the Fugl-Meyer Assessment of Upper Extremity (FMA-UE) score. The FMA-UE assessment can take about 30 minutes or more to complete, which can be longer than other clinical assessments. Follow-up assessments take about the same time. Vivistim Therapy Healthcare providers that use other clinical assessments that are shorter may not want to learn how to use the FMA-UE scoring system or invest the time in a longer assessment process generally, which may impact adoption of Vivistim Therapy.

Additionally, even if our products achieve market acceptance, they may not maintain that market acceptance over time if competing products, therapies or technologies are considered safer, more effective, more cost-effective or otherwise superior. Any failure of our products to generate sufficient demand or to achieve meaningful market

acceptance and penetration will harm our future prospects and have a material adverse effect on our business, financial condition, and results of operations.

Coverage and adequate reimbursement may not be available or may be subject to change for our Vivistim System, including any future products we commercialize, which could diminish our sales, increase our competition, or affect our ability to sell our currently marketed Vivistim Therapy and any future products profitably.

Our customers are generally reimbursed by third-party payors for the procedures that are required to implant our device. Because there is no separate reimbursement for supplies used in surgical procedures, including our device, the additional cost associated with the use of our products can affect the profit margin of the hospital where the procedure is performed. Some of our target customers may be unwilling to adopt our products in light of potential additional associated cost. In addition, customers that perform the procedure may be subject to reimbursement claim denials upon submission of the claim. These events, or any other decline in the amount payors are willing to reimburse our customers, could make it difficult for existing customers to continue using or to adopt our products and could create additional pricing pressure for us. If we are forced to lower the price we charge for our products, our gross margins will decrease, which could have a material adverse effect on our business, financial condition and results of operations and impair our ability to grow our business.

Based on our experience to date, third-party payors generally reimburse for the surgical procedures in which our products are used only if the patient meets the established medical necessity criteria for surgery. Some payors are moving toward a managed care system and control their healthcare costs by limiting authorizations for surgical procedures, including elective procedures using our devices. Although no uniform policy of coverage and reimbursement among payors exists and coverage and reimbursement for procedures can differ significantly from payor to payor, reimbursement decisions by particular third-party payors may depend upon a number of factors, including the payor's determination that use of a product is:

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

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

Medicare, which is administered by the Centers for Medicare and Medicaid Services (CMS), does not currently have a national coverage determination or local coverage determinations applicable to our device. As a result, coverage determinations are made on a case-by-case basis for Medicare beneficiaries. Medicaid programs are funded by both federal and state governments, and coverage and reimbursement policies vary from state to state and from year to year. Effective July 1, 2023, the New York State Medicaid fee-for-service program covers FDA-cleared vagus nerve stimulator, or VNS, devices used for stroke therapy in conjunction with rehabilitation to recover function in hands and arms after an ischemic stroke. Most commercial payors currently consider Vivistim Therapy as experimental or investigational and require prior authorization.

Obtaining and maintaining coverage and reimbursement can be a time-consuming and expensive process. For example, payors typically require us to provide supporting scientific, clinical and cost-effectiveness data for the use of our products before providing coverage. We may not be able to provide data sufficient to satisfy third-party payors that procedures using our products should be covered and reimbursed, and even if we are, such data may be time-consuming and costly to obtain and the incremental revenue from the positive coverage decisions it generates (if any) may not be sufficient to recoup the expense associated with data collection. Payors also continually review

new and existing technologies for possible coverage and can, without notice, deny or reverse coverage for new or existing products and procedures. While some payors currently cover and provide reimbursement for procedures using our currently cleared or approved products on a case-by-case basis, we can give no assurance that these third-party payors will continue to provide coverage and adequate reimbursement for the procedures using our products, or that additional third-party payors will provide coverage for our products in the future. If we are not successful in reversing any non-coverage policies, or if third-party payors that currently cover or reimburse procedures in which our products are used reverse or limit their coverage in the future, or if other third-party payors issue similar non-coverage policies, this could have a material adverse effect on our business.

Third-party payors are also increasingly examining the cost effectiveness of products, in addition to their safety and efficacy, when making coverage and payment decisions. Third-party payors have instituted initiatives to limit the growth of healthcare costs using, for example, price regulation or controls and competitive pricing programs. Some third-party payors also require demonstrated superiority, on the basis of randomized clinical trials, or pre-approval of coverage, for new or innovative devices or procedures before they will reimburse healthcare providers who use such devices or procedures. It is uncertain whether our current products or any future products will be viewed as sufficiently cost effective by payors to warrant coverage and adequate reimbursement levels for procedures using such products in any given jurisdiction. For example, there can be no assurance that payors will find Vivistim Therapy attractive from a cost/benefit perspective, or that they will deem our data on economic benefits of Vivistim Therapy sufficiently persuasive.

High rates of coverage denials or prolonged, burdensome prior authorization processes by commercial and government payors may discourage physicians from recommending Vivistim Therapy to their patients. Certain of our customers have, from time to time, experienced coverage denials and extended prior authorization requirements for Vivistim Therapy, and there can be no assurance that payor behavior will improve or that such denials will not persist or increase in the future. If medical centers and physicians perceive that reimbursement is uncertain or routinely denied, they may be less willing to invest the time required to pursue appeals or recommend Vivistim Therapy to their patients, which could reduce utilization of Vivistim Therapy. Persistent denial trends could also influence hospital committees and practice groups to deprioritize Vivistim Therapy in their care protocols, further limiting adoption and adversely affecting our revenue, reputation and growth prospects.

In addition, government payors, such as CMS, have increased their efforts to control the cost, utilization and delivery of healthcare services. CMS establishes Medicare payment levels for hospitals and physicians on an annual basis, which can increase or decrease payment to such entities. The Vivistim System is typically implanted in the hospital outpatient setting, and all items and services paid under the Medicare hospital outpatient prospective payment system, or OPPS, are assigned to payment groups called Ambulatory Payment Classifications, or APCs, which group together items and services that are similar clinically and in terms of resource use. Reimbursement for professional services performed by physicians are reported using CPT codes and based on a different payment methodology. Implantation of the Vivistim System falls under CPT Code 64568 (“Incision for implantation of a cranial nerve (e.g., vagus) neurostimulator electrode array and pulse generator”). From January 1, 2023 through December 31, 2025, CMS granted transitional pass-through payment status for the Vivistim System under HCPCS code C1827 (“Generator, neurostimulator (implantable), non-rechargeable, with implantable stimulation lead and external paired stimulation controller”) when used in combination with CPT code 64568. This status is granted by CMS to facilitate access to innovative devices that significantly improves clinical outcomes as compared to currently available treatment options. Effective January 1, 2026, CPT code 64568 is assigned to New Technology APC 1580. A service is not paid under a New Technology APC until sufficient claims data have been collected to allow CMS to assign the procedure to a clinical APC group that is appropriate in clinical and resource terms. CMS generally expects this to occur within two to three years. We cannot provide any assurances that CPT code 64568 will continue to be assigned to APC 1580 during this time, or that reimbursement amount associated with any subsequent assignment to a clinical APC group will be adequate to cover the costs associated with our device. Individual states may also enact legislation that impacts Medicaid payments to hospitals and physicians.

The marketability of our products may suffer if government and commercial third-party payors fail to provide adequate coverage and reimbursement. Even if favorable coverage and reimbursement status is attained, less favorable coverage policies and reimbursement rates may be implemented in the future.

We depend on a small number of third-party contract manufacturers and suppliers, some of which are single source, to produce and package all elements comprising our Vivistim System as well as certain implantation tools, and if these suppliers and manufacturers fail to supply our Vivistim System or its components or subcomponents in sufficient quantities or at all, it will have a material adverse effect on our business, financial condition, and results of operations.

We utilize a small number of qualified medical device contract manufacturers and suppliers, some of which are single source, to produce and package all elements comprising our Vivistim System as well as certain implantation tools. In certain cases, these third parties also perform design engineering activities for specific components. We generally do not have long-term contracts with our suppliers, and our supply arrangements generally do not include minimum manufacturing or purchase obligations. For these arrangements, we primarily order products through the use of purchase orders, do not have any obligation to purchase any given quantity of products, and our suppliers generally have no obligation to sell to us or to manufacture for us any given quantity of our products or components of our systems. Certain supplier arrangements include non-cancelable purchase commitments and binding forecast obligations. For these arrangements, we primarily order products through the use of purchase orders that are generally non-cancelable once accepted by the respective supplier. Although we continue to fortify our supply chain by seeking additional sourcing channels, all of the critical components of the Vivistim System, including the IPG and lead, are supplied to us from single sources that are qualified medical device contract manufacturers and suppliers. Our lead is manufactured by Cirtec Medical. Our IPG is manufactured by Integer Holdings Corporation (Integer).

We entered into supply agreements with Integer pursuant to which Integer agreed to manufacture our IPG component for us. Our first supply agreement with Integer provides that we may order from Integer on a non-exclusive, purchase order basis with no minimum purchase requirements. The agreement includes, among other provisions, customary representations and warranties by the parties, ordering and payment and shipping terms, customary provisions with respect to the ownership of any intellectual property and customary confidentiality provisions. The agreement continues until termination by the parties. Either party may terminate the agreement upon written notice in the event of a material breach that is not cured within 30 days of the other party's written notice of such breach; upon bankruptcy, insolvency or reorganization that has not been dismissed within 30 days after commencement; or in the event that the other party commits a crime, intentionally imparts material information or misappropriates intellectual property. In addition, we may terminate the agreement if Integer fails to meet our specifications or is unable to manufacture products, or for our convenience if we are current in our payment obligations to Integer. To further support our anticipated growth and IPG supply needs, we also entered into a second supply agreement (the IPG Supply Agreement), effective September 24, 2024, with Greatbatch Ltd., a subsidiary of Integer. The IPG Supply Agreement contains, among other provisions, customary representations and warranties by the parties, ordering and payment and shipping terms, customary provisions with respect to the ownership of any intellectual property created during the term of the IPG Supply Agreement, certain indemnification rights in favor of both parties, limitations of liability and customary confidentiality provisions, and minimum purchase requirements. The minimum purchase requirements are expected to commence in 2028. Under the minimum purchase requirements, we are obligated to purchase a high double-digit fixed percentage of our IPG supply requirements from Integer and must purchase a minimum number of IPGs from Integer per year. The aggregate minimum purchase obligation for the initial five-year period is approximately $5.8 million. The IPG Supply Agreement has an initial five-year term commencing upon the first commercial shipment of product, and will automatically renew for one-year periods unless either party delivers a notice of non-renewal prior to the renewal date. Either party may terminate the IPG Supply Agreement upon written notice in the event of a material breach of the IPG Supply Agreement that is not cured within 60 days of the other party's written notice of such breach, subject to certain conditions; or upon bankruptcy, insolvency or reorganization that has not been dismissed within 60 days after commencement. We may terminate the IPG Supply Agreement if Integer fails to adequately supply non-defective products, if the products are subject to repeating failures over time that fail to meet our specifications, or if Integer is unable to manufacture products for a specified period of time.

Where we rely on a single-source supplier, alternative second-source suppliers may not be readily available or qualifying them may take significant time and expense. The level of inventory we maintain for certain of our sole-sourced supplies may not be sufficient to support our customer demand for the length of time that may be required to

qualify an alternative supplier should this become necessary. We seek to strategically maintain sufficient levels of inventory to help mitigate supply disruption, to accommodate varying demand mix and to achieve more efficient volume-based pricing on our components; however, we may not be accurate in our estimates which could result in insufficient inventory to meet demand or excess inventory and the risk of inventory obsolescence and expiration. If our estimates result in carrying insufficient levels of inventory to meet customer demand, this may lead to customer backorders due to a lack of manufacturing capacity or supply chain challenges, which could result in delays or inability to reach sales potential, cause reputational harm or otherwise have a material adverse effect on our business, financial condition and results of operations.

Where these third parties perform design engineering work, we are additionally reliant on their design engineering capacities and proprietary know-how, and we may have reduced visibility and control over design decisions and related changes. This reliance can increase the time and cost to implement, validate and transfer design changes, complicate second-sourcing efforts, and heighten the risk of disputes over intellectual property ownership, licensing scope, and access to design files and documentation necessary to manufacture and support our device.

Our suppliers may encounter problems during manufacturing for a variety of reasons, including, for example, failure to follow specific protocols and procedures, failure to comply with applicable legal and regulatory requirements, equipment malfunction and environmental factors, failure to properly conduct their own business affairs, and infringement of third-party intellectual property rights, any of which could delay or impede their ability to meet our requirements. Our reliance on a third-party manufacturer and third-party suppliers also subjects us to other risks that could harm our business that we would not be subject to if we manufactured products ourselves, including:

- we may not be a major customer of many of our suppliers, and these suppliers may therefore give other customers' needs higher priority than ours;
- third parties may threaten or enforce their intellectual property rights against our suppliers, which may cause disruptions or delays in shipment, or may force our suppliers to cease conducting business with us;
- we may not be able to obtain an adequate supply of an acceptable quality in a timely manner or on commercially reasonable terms or at all;
- our suppliers, especially new suppliers, may make errors in manufacturing that could negatively affect the efficacy or safety of Vivistim Therapy or cause delays in shipment or product recalls;
- we may have difficulty locating and qualifying alternative suppliers;
- the capacity, technical capabilities and qualifications of our suppliers may not expand in line with our future volume requirements or support the manufacture of new products on our desired schedule, or at all;
- switching components or suppliers may require product redesign and possibly submission to FDA or other regulatory bodies, which could significantly impede or delay our commercial activities;
- one or more of our single-source suppliers may be unwilling or unable to supply components of our Vivistim System;
- other customers may use fair or unfair negotiation tactics or pressures to impede our use of the suppliers;
- the occurrence of a fire, natural or man-made disaster or other catastrophe impacting one or more of our suppliers may affect their ability to deliver products to us in a timely manner or at all;
- our suppliers may encounter financial or other business hardships unrelated to our demand, which could inhibit their ability to fulfill our orders and meet our requirements;
- our suppliers may not maintain the confidentiality of our confidential information; and
- higher manufacturing and product costs than more vertically integrated companies.

Any of these factors could cause delays or suspension of commercialization and marketing, clinical trials, regulatory submissions or required approvals, cause us to incur higher costs, inability to meet customer demand, and product quality issues or recalls. Furthermore, if our contract manufacturers fail to deliver the required commercial quantities of finished products of an acceptable quality on a timely basis and at commercially reasonable prices and we are unable to find one or more replacement manufacturers capable of production at a substantially equivalent cost, in substantially equivalent volumes and quality, and on a timely basis, we would likely be unable to meet demand for our products and we would lose potential revenue. Any difficulties in locating and hiring third-party manufacturers, or in the ability of third-party manufacturers to supply quantities of our products at the times and in the quantities we need, could have a material adverse effect on our business. It may take a significant amount of time and resources (including costs) to establish an alternative source of supply for our products and to have any such new source approved by the FDA. Given our reliance on certain single-source suppliers, we are especially susceptible to supply shortages because we do not have alternate suppliers currently available, which can result in increased costs and production delays and potentially adversely impact our ability to meet demand for our products in a timely manner or at all.

Moreover, some third parties or their facilities are or may in the future be located in markets subject to political, social and economic risk, corruption, infrastructure problems, tariffs and natural or man-made disasters, in addition to country-specific intellectual property protection, privacy and data security and tax risks and the risk of nationalization and expropriation, given current legal and regulatory environments. Failure of third parties to meet their contractual, regulatory, and other obligations may have a material adverse effect on our business, financial condition and results of operations. Because we rely on some suppliers in countries outside of the United States, we are exposed to the possibility of product supply disruption and increased costs in the event of changes in the policies of the United States or the governments in the countries these suppliers are located, including changes in tariff policies, political or social unrest, or unstable economic conditions. Any of these matters could materially and adversely affect our business, financial condition and results of operations.

The size of our market opportunity has not been established with precision and may be smaller than we estimate, possibly materially.

We estimate that there are more than 4 million chronic ischemic stroke survivors living with moderate to severe upper extremity impairment in the United States and that are within the current on-label indication for our Vivistim System. We believe that an initial market opportunity comprises approximately 1 million of those survivors, which equates to an initial market opportunity of over $30 billion based on the average selling price of the Vivistim System. This initial market represents the total overall revenue opportunity that we believe is available if we achieve 100% market share for Vivistim Therapy among these survivors, and is not a representation that we will achieve any such market share. The market share we achieve is subject to a number of assumptions, risks and uncertainties, including our ability to execute on our commercial strategy and the extent of adoption of Vivistim Therapy. Further, these estimates are based on a number of internal and third-party estimates which may prove to be inaccurate. The actual size of our addressable markets may be smaller than our estimates for a number of reasons. The Vivistim System is currently the first and only FDA-approved solution for chronic ischemic stroke survivors with moderate to severe upper extremity impairment. As such, we will have to expend significant resources to educate and promote awareness of this solution among patients, caregivers and healthcare providers. If we are not able to successfully drive adoption of our solution, we may not be able to access a significant part of this estimated market opportunity.

Our Vivistim System implantation procedure falls under Category 1 CPT code. Medicare fee-for-service patients can typically access Vivistim Therapy when medically necessary, without prior authorization. Commercial insurance, Medicaid and Medicare Advantage generally require prior authorization. As such, commercial insurance coverage represents the largest gap in coverage and continues to evolve, and may never become widely available. Medicare reimbursement rates may also be reduced. The foregoing may slow or prevent broad adoption of our solution or require us to reduce our average selling prices to accommodate reduced reimbursement rates. We have determined our serviceable addressable market using an assumed average selling price for our Vivistim System. A decrease or increase in our assumed average selling price would change our serviceable addressable market.

Additionally, the market for our solution may be slow to develop as a result of physician concerns associated with Vivistim Therapy due to the limited long term clinical data, limited or challenges regarding commercial

reimbursement, and limited network of referral sources that may take some time to develop, if they develop at all. In order to generate future growth, we are building out a dedicated group of field-based TMs and TDSs focused on developing our market, including driving awareness of Vivistim Therapy and its clinical benefits as well as supporting VNS-specific professional education, but our efforts to do so may not be successful. Moreover, our total market opportunity could decrease if preventive therapies, drugs or devices that broadly reduce stroke incidence (such as glucagon-like peptide agonists, or GLP-1 drugs, if proved to be effective for such purpose) are prescribed or utilized more widely or if stroke incidence generally decreases due to, among other reasons, the population in the United States becoming healthier or new drugs being developed.

Any of the foregoing could cause our total addressable market and serviceable addressable market to be lower than we currently estimate. If our market does not continue to develop at the rate we expect, our business, financial condition, and results of operations could be materially and adversely affected.

Adverse events, product recalls, or other complications or customer satisfaction issues associated with Vivistim Therapy, including regarding the finite IPG battery life, could limit its adoption.

Risks of using our products include risks that are common to any surgical procedure. Adverse events that have been experienced in connection with our device in clinical trials and clinical practice include infection, pain and discomfort, migration of the implanted device, irritation, bruising, swelling and non-healing wounds. Certain of these procedure or device related adverse events have, in some cases, required device explantations or revisions; in some of these cases, patients have not been re-implanted. Complications or adverse events could result from improper implantation and lack of adequate physician experience or training with our products as well as other user errors, pre-existing patient conditions or anatomical factors and manufacturing defects.

In addition, since the IPG battery is indicated for approximately five years of service life under continuous use conditions, long-term use past five years have in the past, and may in the future, require one or more replacement procedures when the IPG battery reaches its end-of-life. Replacement of the IPG necessarily involves surgical intervention (such as explant or replacement) and is subject to the risk of additional adverse reactions, including infection, pain and discomfort, irritation, bruising, swelling, non-healing wounds and adverse reactions to general anesthesia. The prospect of having to eventually explant or replace our Vivistim System, which would involve additional surgery and its associated risks (which may be heightened at the more advanced age of any such explant or replacement procedure), may dissuade patients from using Vivistim Therapy in the first instance.

In addition to the adverse events described above, users have in the past experienced, and may in the future experience, issues with the SAPS interface and accessories and their interactions with the IPG, and we have received, and may in the future receive, complaints regarding these issues. These issues have included SAPS screen anomalies and connection errors between the SAPS user interface and the wireless transmitter, which are typically resolved by rebooting SAPS or replacing the respective laptop, and connection issues between the wireless transmitter and the IPG, which are typically resolved by reconnecting or repositioning the wireless transmitter. Our device manual includes detailed instructions regarding how to resolve these issues, and a team of field-based clinical engineers are available to provide remote and in-person support to clinicians and therapists. While these issues have not been material or presented significant risks or issues for our business to date, if any such issues become systemic, persist, or we are unable to remediate them promptly, or if they otherwise inconvenience or frustrate users, they could impair device performance, disrupt therapy, necessitate replacement procedures, dissuade patients and physicians from using Vivistim Therapy and damage our reputation. Customers may attribute these or similar issues to our products even if caused by reasons not directly related to our products, such as pre-existing conditions, complications associated with the surgical procedure or related anesthesia itself, implantation of the device too deep in the tissue, making a larger-than-necessary incision that results in device migration, movement in the body or other types of user error or patient anatomical features. Even if these types of events are not directly attributable to the devices, they could decrease acceptance of our products by our customers, including hospitals, physicians, therapists, patients or caregivers, and result in a material adverse effect on our business, financial condition, and results of operations. Our reputation among our current or potential customers and referral sources, including but not limited to, stroke interventionalists, neurosurgeons, neurologists, physical medicine and rehabilitation physicians, occupational and physical therapists, stroke coordinators and nurses could also be materially and adversely affected by safety or customer satisfaction issues involving us or our products. For example, our customer service and

clinical representatives may be unable to, or be perceived to be unable to, provide technical and customer service support effectively and in a timely manner or at all. These or other customer satisfaction issues, in addition to any product recalls or other safety or efficacy issues, could materially and adversely affect our reputation and our ability to establish or maintain broad adoption of our products, which would harm our future prospects and have a material adverse effect on our business, financial condition, and results of operations. Additionally, any unfavorable publicity or news coverage regarding our Vivistim System, whether or not accurate, may dissuade patients from using our Vivistim System.

Screening procedures designed to identify patients who are contraindicated for use of Vivistim Therapy may be inconsistently or incorrectly applied by healthcare providers or may otherwise fail to identify individuals who should not have been eligible for Vivistim Therapy, resulting in customer dissatisfaction by such patients. Also, hospitals and physicians may not prescribe our products due to potential interference or complications with other medical procedures. For example, because our products include implantation of certain medical-grade metals, our labeling our Vivistim System is designated as MR Conditional and includes specific considerations for procedures using magnetic resonance imaging, or MRI. Any of these events could materially and adversely affect our ability to commercialize our products and to compete with other products in stroke recovery.

We operate in a competitive industry that is subject to technological change and significantly affected by new product introductions and market activities of other industry participants.

We operate in a competitive industry that is subject to technological change and significantly affected by new product introductions and market activities of other industry participants. For example, industry participants include medical device manufacturers and robotics companies, including a significant number of companies focused on stroke prevention and acute stroke care. To the extent these companies decide to focus on longer term stroke care, particularly in the chronic phase, we may face increased competition. Many of these companies have longer, more established operating histories, and significantly greater name recognition and financial, technical, marketing, sales, distribution and other resources. In addition, certain companies have several competitive advantages, including significant scale and established relationships with healthcare providers and third-party payors. Irrespective of their current focus, we also compete with these companies for personnel, including qualified personnel that are necessary to grow our business, including TMs and TDSs.

Competitors may be able to offer products similar or superior to ours, including products that may, or may be perceived to, have improved features, such as smaller form factors, improved ease of use, longer battery life or rechargeable battery, aesthetics, reliability, safety and effectiveness; have improved reimbursement; be better supported by clinical evidence; more widely recognized and adopted by healthcare providers and patients; or be more cost-efficient. For example, competitors may utilize existing or newly developed products to enter the VNS market in the future, which would increase our competition and could materially and adversely affect demand for Vivistim Therapy. Increased competition may result in price reductions, reduced gross margins and loss of market share. To the extent we expand internationally, we will face additional competition in geographies outside the United States. In addition, we face competition from pharmaceutical companies that produce drugs which aim to aid in stroke recovery, and other companies that produce other devices or therapies that aim to assist in stroke recovery. Further, if medical research were to lead to the discovery of alternative therapies or technologies that address chronic stroke impairments in a way that is or is perceived to be more accurate, reliable, cost-effective, or otherwise improved relative to Vivistim Therapy, for example through alternative monitoring or testing technologies, medication, or therapies, the demand for our products could decrease significantly. For example, some of our patients have experienced pain and discomfort associated with the surgical implantation of our product, and some prospective patients have been reluctant to undergo surgery; if competitors develop or commercialize minimally invasive or non-surgical alternatives that avoid implantation, patients and providers may prefer those options over Vivistim Therapy, which could further reduce demand for our products. There can be no assurance that we will be able to compete successfully against our current or future competitors, or that competitive pressures will not have a material adverse effect on our business, financial condition and results of operations.

In addition, many medical device companies are consolidating to create new companies with greater market power. As the medical device industry consolidates, competition to provide goods and services to industry participants will become more intense. These industry participants may try to use their market power to negotiate

price concessions or reductions for our products. If we reduce our prices because of consolidation in the healthcare industry, our revenue would decrease, which could have a material adverse effect on our business, financial condition, and results of operations.

If rising prices or limited availability of raw materials continues to persist, our business and results of operations may be adversely affected.

Volatility in raw material prices and availability can occur due to numerous factors beyond our control, including general, domestic, and international economic conditions, labor costs, production levels, competition, consumer demand, import duties, tariffs and taxes, inflation and currency exchange rates. This volatility can significantly affect the availability and cost of raw materials that our suppliers purchase and are ultimately used in our systems, and may therefore have a material adverse effect on our business, financial condition and results of operations.

In addition, the current U.S. administration has expressed strong concerns about imports from countries that it perceives as engaging in unfair trade practices, and has imposed tariffs or other restrictions on products, components or raw materials sourced from those countries. The legal basis for some of these tariffs have been challenged, and recent judicial decisions, including from the U.S. Supreme Court, have invalidated or called into question certain tariff measures. However, other tariffs remain in place, new or additional tariffs have been and may continue to be imposed, and the overall trade policy environment remains fluid and subject to rapid change. Moreover, changes in U.S. trade policy have triggered and may in the future trigger retaliatory actions, countermeasures, or trade restrictions by affected countries. For example, there have been and continue to be further indications that there may be an increase in tariff rates on various types of goods imported from Canada, Mexico, South America and Europe that could apply to the raw materials we require in our products, including certain types of metal powders used for coating our products as well as entire components of our Vivistim System. In the event that any such possible tariff increases remain in place or become enacted in the future, they could significantly increase the cost of materials and components that our suppliers import and use in our systems, which in turn could increase our supply costs. At this time, there can be no assurance that we will be able to pass any portion of such increases on to customers. We currently do not hedge against our exposure to changing raw material prices and are not aware as to whether our suppliers hedge. As a result, fluctuations in raw material prices could have a material adverse effect on our business, results of operations and financial condition. Supply shortages or changes in availability for any particular type of raw material can delay supplier volume and production capabilities or cause increases in the cost of manufacturing our products. We may be materially and adversely affected by changes in availability and pricing of raw materials, which could materially and adversely affect our results of operations.

In order to support our continued operations and the growth of our business, we may seek to raise additional capital, which may not be available to us on acceptable terms, or at all.

We expect our operating expenses to continue to increase for the foreseeable future as we continue to make significant investments in our commercial organization; seek to expand our marketing programs to help facilitate further awareness and adoption among healthcare providers and patients; seek payor reimbursement; continue to make investments in research and development, regulatory affairs, and clinical trials to develop future generations of products based on Vivistim Therapy, support regulatory submissions, and demonstrate the clinical efficacy of our products; and as we continue to scale the business infrastructure and manufacturing capacity. Moreover, we expect to incur additional expenses associated with operating as a public company, including legal, accounting, insurance, exchange listing and SEC compliance, investor relations, and other expenses. In addition, we may in the future seek to acquire or invest in, additional businesses, products, or technologies that we believe could complement or expand our portfolio, enhance our technical capabilities, or otherwise offer growth opportunities.

As of December 31, 2025, we had $33.6 million in cash and cash equivalents. Based on our current operating plan, we believe that the estimated net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to fund our planned operating expenses for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect. Changing circumstances, some of which may be beyond our control, could cause us to consume

capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned.

Because of these and other factors, we expect to continue to incur substantial net losses and negative cash flows from operations for at least the next several years. Our future liquidity and capital funding requirements will depend on numerous factors, including:

- our revenue growth;
- the market awareness and adoption of our Vivistim System, including by our customers and their patients, and the extent to which we are able to successfully educate patients and customers about our current and future indications, and the benefits of our Vivistim Therapy in treating such conditions;
- our ability to expand our sales, marketing, and distribution capabilities in a timely and cost efficient manner, or at all;
- the availability and amount of reimbursement for procedures using our products;
- the new adoption and continued acceptance of private payor coverage of Vivistim Therapy;
- the emergence of competing, complementary or alternative technologies or therapies, including from other VNS neurostimulation device manufacturers or other stroke rehabilitation alternatives;
- the timing and extent of our research and development efforts;
- our ability to sustain meaningful clinical benefits for our patients;
- our ability to retain our current employees and the need and ability to hire additional management, sales, scientific, and clinical personnel;
- our need to implement additional infrastructure and internal systems;
- our ability to raise additional funds to finance our operations;
- general economic, industry and market conditions or extraordinary external events, such as a recession;
- the timing and success or failure of clinical trials or post-approval studies for our products or competing products;
- litigation or other claims against us for intellectual property infringement or otherwise; and
- our ability to hire additional personnel and undertake initiatives to support our operations as a public company.

To the extent that we need additional capital to continue to fund our operations, we intend to obtain such capital through public or private equity offerings or debt financings, credit or loan facilities, or a combination of one or more of these funding sources. If we raise additional funds by issuing equity securities, our stockholders will experience dilution. Any future debt financing into which we enter may impose upon us additional covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments, and engage in certain merger, consolidation, or asset sale transactions. In the case of an insolvency, debt holders would be repaid before holders of our equity securities receive any distribution of our corporate assets. Any debt financing or additional equity that we raise may also contain terms that are not favorable to us or our stockholders. If we raise additional funds through licensing or collaboration arrangements with third parties, we may have to relinquish valuable rights to our current or future product candidates, or grant licenses on terms that are not favorable to us. We may also seek additional financing opportunistically. We may be unable to raise additional funds on favorable terms, or at all.

Volatility in the capital markets and general economic conditions may be a significant obstacle to raising the required funds. Our ability to raise additional funds may be adversely impacted by potential worsening global economic conditions and the disruptions to, and volatility in, the credit and financial markets in the United States and worldwide resulting from factors that include but are not limited to, tariffs, trade and socioeconomic tensions, inflation, the conflict between Russia and Ukraine and in the Middle East, diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, and uncertainty about economic stability. If the equity and credit markets deteriorate, it may make any necessary debt or equity financing more difficult, more costly and more dilutive. If we are unable to raise sufficient capital on acceptable terms, or at all, our ability to finance our planned operations and support business growth, our business, financial condition and results of operations will be materially and adversely affected.

We have limited clinical data, evidence and experience regarding the safety and efficacy of Vivistim Therapy.

Clinical testing is difficult to design and implement, can take many years, can be expensive, and carries uncertain outcomes. Because Vivistim Therapy is relatively new in the treatment of upper extremity impairment for chronic stroke survivors, we have performed clinical trials only with limited patient populations relevant to our FDA-approved indication. The trials conducted to date have involved relatively small sample sizes, which may limit the statistical power of the findings and the precision of estimated treatment effects. For example, the largest population we studied was 108 participants in our pivotal REHAB trial. As a result, there is uncertainty as to whether the observed safety, efficacy and other outcomes will be applicable across broader patient populations and other, different sub-groups, including for variations in age, sex, race and ethnicity. The effects of using Vivistim Therapy in a large number of patients have not been studied extensively or over a long-term period, and the results of short-term clinical use of such products do not necessarily predict long-term clinical benefits or reveal long-term adverse effects. While we have one year efficacy data from our pivotal REHAB trial and three year efficacy data from our pilot trial, these results were based on a small number of participants of 74 and 14, respectively. Moreover, clinical benefits may not persist in various circumstances, including if the patient discontinues or pauses occupational or physical therapy, does not otherwise adhere to the prescribed treatment regimen, or experiences an intervening medical or functional setback, and we have not studied the durability of effect in these scenarios.

After patients complete their initial in-clinic therapy protocol, they are expected to continue Vivistim Therapy at home with functional movements for at least 90 days. At-home Vivistim Therapy sessions last thirty minutes and follow the same principles as the in-clinic therapy. Patients who do not use the device as directed, such as not turning the device on during such sessions, or who fail to engage in the recommended task-specific therapy with the appropriate frequency or at all, may experience limited or no improvement from the completion of the in-clinic therapy, may be dissatisfied with their outcomes, and may attribute such poor results to Vivistim Therapy. We have no clinical data that indicates whether functional gains from the in-clinic therapy would be reversed if patients do not complete the home therapy sessions properly or sufficiently. As such, it is possible that patient noncompliance could lead to reversal of the functional gains during in-clinic therapy. Negative patient experiences – whether due to misuse, noncompliance, or unrealistic expectations – could reduce physician and patient acceptance, harm our reputation, and adversely affect demand.

In addition, the clinical outcomes supporting Vivistim Therapy have primarily been evaluated using the FMA-UE and the Wolf Motor Function Test (WMFT). Clinicians and therapists who rely on different outcome measures or standards may view our trial results as less relevant or may not accept these endpoints, and patients implanted with our device who are treated in settings that emphasize alternative scoring systems may not experience similar levels of observed benefits. Variability in accepted assessment methodologies among physicians and therapists could reduce the perceived effectiveness of, and limit adoption of Vivistim Therapy, which could have a material adverse effect on our business, financial condition and results of operations.

The results of preclinical trials and clinical trials of our product conducted to date and ongoing or future trials of our current or future products may not be predictive of the results of later clinical trials, and interim results of a clinical trial do not necessarily predict final results, because they may include assumptions, calculations and conclusions that may prove to be inaccurate and because we may not have received or had the opportunity to fully and carefully evaluate all data. Data and results from our clinical trials do not ensure that we will achieve similar results in future clinical trials in other patient populations, indications or in the commercial use of our products. In

addition, preclinical and clinical data are often susceptible to various interpretations and analyses, and many companies that have believed their products performed satisfactorily in preclinical trials and earlier clinical trials have nonetheless failed to replicate results in later clinical trials and subsequently failed to obtain marketing approval or commercial acceptance. Products in later stages of clinical trials may fail to show the desired safety and efficacy despite having progressed through non-clinical trials and earlier clinical trials. We incur substantial expenses for, and devote significant time to, clinical trials but cannot be certain that the trials will continue to support positive commercial payor reimbursement coverage or result in commercial revenue. Failure can occur at any stage of clinical testing. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and non-clinical testing in addition to those we have planned.

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

Our quarterly and annual results of operations, including our revenue, profitability, and cash flow, may vary significantly in the future, and period-to-period comparisons of our results of operations may not be meaningful. Accordingly, the results of any one quarter or other period should not be relied upon as an indication of future performance. Our quarterly and annual financial results may fluctuate as a result of a variety of factors, many of which are outside our control and, as a result, may not fully reflect the underlying performance of our business. Factors that may cause fluctuations in our quarterly and annual results include, without limitation:

- the level of demand for our products, which may vary significantly from period to period;
- the rate at which we grow our sales force and the speed at which newly hired TMs and TDSs become effective, and the cost and level of investment therein;
- expenditures that we may incur to acquire, develop, or commercialize additional products and technologies;
- the degree of competition in our industry and any change in the competitive landscape of our industry;
- the timing and cost of obtaining regulatory approvals or clearances for future products;
- coverage and reimbursement policies with respect to the procedures using our products and potential future products that compete with our products;
- the timing and success or failure of clinical trials for our current or future products or any future products we develop or competing products;
- the timing and cost of, and level of investment in, research, development, regulatory approval, and commercialization activities relating to our products, which may change from time to time;
- the timing of customer orders or medical procedures, the number of available selling days in a particular period, which can be impacted by a number of factors, such as holidays or days of severe inclement weather in a particular geography, the mix of products sold, and the geographic mix of where products are sold;
- the cost of manufacturing our products, which may vary depending on the quantity of production and the terms of our agreements with third-party suppliers and manufacturers;
- timing and adequacy of supply chain to meet demand;
- natural or man-made disasters, outbreaks of disease or public health crises;
- the timing and nature of any future acquisitions or strategic partnerships; and
- future accounting pronouncements or changes in our accounting policies.

Because our quarterly and annual results may fluctuate, period-to-period comparisons may not be the best indication of the underlying results of our business and should only be relied upon as one factor in determining how our business is performing.

In addition, this variability and unpredictability could result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or results of operations fall below the expectations of analysts or investors or below any forecasts we may provide to the market, it may result in a decrease in the price of our common stock.

If our clinical trials are unsuccessful or significantly delayed, or if we do not complete our clinical trials, our business may be materially and adversely affected.

We are currently engaged in ongoing clinical trials of Vivistim Therapy and we may pursue other clinical trials in the future. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory authorization to commence a trial, in reaching an agreement on acceptable clinical trial terms with prospective sites, in obtaining institutional review board approval at each site, in recruiting patients to participate in a trial, or in obtaining sufficient supplies of clinical trial materials. We cannot provide any assurance that we will successfully, or in a timely manner, enroll our clinical trials, that our clinical trials will meet their primary endpoints, or that such trials or their results will be accepted by the FDA or foreign regulatory authorities or lead to more positive reimbursement coverage decisions from commercial payors.

The initiation and completion of any clinical trials may be prevented, delayed, or halted, or the integrity of data collected may be compromised, for numerous reasons. We may experience delays in our ongoing clinical trials for a number of reasons, which could adversely affect the costs, timing, or successful completion of our clinical trials, including new indications for our existing product, including:

- we may be required to submit an Investigational Device Exemption (IDE) application to FDA, which must become effective prior to commencing certain human clinical trials of medical devices, and FDA may reject our IDE application and notify us that we may not begin clinical trials;
- regulators and other comparable foreign regulatory authorities may disagree as to the design or conduct of our clinical trials;
- regulators or institutional review boards (IRBs) or other reviewing bodies may not authorize us or our investigators to commence a clinical trial, or to conduct or continue a clinical trial at a prospective or specific trial site;
- we may not reach agreement on acceptable terms with prospective contract research organizations (CROs) and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- the number of subjects or patients required for clinical trials may be larger than we anticipate, enrollment in our clinical trials may be slower than we anticipate, or we may experience high screen failure rates in our clinical trials, and the number of clinical trials being conducted at any given time may be high and result in fewer available patients for any given clinical trial, or patients may drop out of these clinical trials at a higher rate than we anticipate, each resulting in significant delays;
- our third-party contractors, including those manufacturing products or conducting clinical trials on our behalf, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all, or may fail to comply with our clinical trial, consent or screening protocols;
- our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical or preclinical testing which may be expensive and time-consuming;
- trial results may not meet the level of statistical significance required by the FDA, other regulatory authorities, or payors;

- the FDA or similar foreign regulatory authorities may find the product is not sufficiently safe for investigational use in humans;
- the FDA or similar foreign regulatory authorities may interpret data from preclinical testing and clinical trials in different ways than we do;
- there may be delays or failure in obtaining approval of our clinical trial protocols from the FDA or other regulatory authorities;
- we may have to amend clinical trial protocols or conduct additional studies to reflect changes in regulatory requirements or guidance, which we may be required to submit to an IRB or regulatory authorities for re-examination;
- the FDA or similar foreign regulatory authorities may find our or our suppliers' manufacturing processes or facilities unsatisfactory;
- the FDA or similar foreign regulatory authorities may change their review policies or adopt new regulations that may negatively affect or delay our ability to bring a product to market or receive approvals or clearances to treat new indications;
- clinical sites may not adhere to our clinical protocol or may drop out of a clinical trial;
- we may have trouble finding patients to enroll in our trials;
- we may experience delays in agreeing on acceptable terms with third-party research organizations and trial sites that may help us conduct the clinical trials;
- we, or regulators, may suspend or terminate our clinical trials because the participating patients are being exposed to unacceptable health risks;
- regulators, IRBs, or other reviewing bodies may fail to approve or subsequently find fault with our manufacturing processes or facilities of third-party manufacturers with which we enter into agreement for clinical and commercial supplies, the supply of devices or other materials necessary to conduct clinical trials may be insufficient, inadequate, or not available at an acceptable cost, or we may experience interruptions in supply;
- approval policies or regulations of FDA or applicable foreign regulatory agencies may change in a manner rendering our clinical data insufficient for approval; and
- our current or future products may have undesirable side effects or other unexpected characteristics.

Failures or perceived failures in our clinical trials will delay and may prevent our product development and regulatory approval process, damage our business prospects, and negatively affect our reputation and competitive position.

Patient enrollment in clinical trials and completion of patient follow-up depend on many factors, including the size of the patient population, the nature of the trial protocol, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, patient compliance, competing clinical trials, and clinicians' and patients' perceptions as to the potential advantages of the product being studied in relation to other available therapies, including any new treatments that may be approved for the indications we are investigating. For example, patients may be discouraged from enrolling in our clinical trials if the trial protocol requires them to undergo extensive post treatment procedures, monitoring or follow-up to assess the safety and efficacy of a product, or they may be persuaded to participate in contemporaneous clinical trials of a competitor's product. In addition, patients participating in our clinical trials may drop out before completion of the trial or experience adverse medical events unrelated to our products. Delays in patient enrollment or failure of patients to continue to participate in a clinical trial may delay commencement or completion of the clinical trial, cause an increase in the costs of the clinical trial and delays, or result in the failure of the clinical trial.

From time to time, we engage outside parties to perform services related to certain of our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates or obtain positive commercial reimbursement coverage for our products.

Clinical trials must be conducted in accordance with the laws and regulations of the FDA and other applicable regulatory authorities' legal requirements, regulations, or guidelines, and are subject to oversight by these governmental agencies and IRBs at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of our devices produced under Quality Systems Regulations (the QSR) requirements and other regulations. From time to time, we engage consultants to help design, monitor and analyze the results of certain of our clinical trials, and we may have limited influence over their actual performance. The consultants we engage interact with clinical investigators to enroll patients in our clinical trials. We depend on these consultants and clinical investigators to conduct clinical trials and monitor and analyze data from these trials under the investigational plan and protocol for the study or trial and in compliance with applicable regulations and standards, such as GCP guidelines, the Common Rule, and FDA human subject protection regulations. We may face delays in our regulatory approval process if these parties do not perform their obligations in a timely, compliant, or competent manner. If these third parties do not successfully carry out their duties or meet expected deadlines, or if the quality, completeness, or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical trial protocols or for other reasons, our clinical trials or trials may be extended, delayed or terminated or may otherwise prove to be unsuccessful, and we may have to conduct additional trials, which would significantly increase our costs.

Our long-term growth depends in part on our ability to innovate and enhance our Vivistim System, expand our approved indications and develop and commercialize additional products in a timely manner. If we fail to identify, acquire, or develop other products, we may be unable to grow our business.

The market for Vivistim Therapy is highly competitive, dynamic, and marked by rapid and substantial technological development and product innovation. New entrants or existing competitors could attempt to develop products that compete directly with ours. Demand for Vivistim Therapy and future related products could be diminished by equivalent or superior products and technologies offered by competitors. If we are unable to innovate successfully, our products could become obsolete, and our revenue would decline as our customers purchase our competitors' products. Developing products is expensive and time-consuming and could divert management's attention away from our core business. The success of any new product offering or product enhancements to our solution will depend on several factors, including our ability to:

- develop an effective and dedicated commercial team;
- assemble sufficient resources to acquire or discover additional products;
- receive adequate coverage and reimbursement for procedures performed with our products;
- develop and introduce new products and product enhancements in a timely manner;
- properly identify and anticipate physician and patient needs;
- anticipate and respond to competitive developments;
- avoid infringing upon the intellectual property rights of third-parties and protect our own intellectual property rights;
- demonstrate, if required, the safety and efficacy of new products or new indications with data from preclinical trials and clinical trials;
- obtain and maintain the necessary regulatory clearances or approvals for expanded indications, new products, or product modifications;
- be fully FDA-compliant with marketing of new devices or modified products;

- provide timely and effective customer and technical support;
- produce new products of an acceptable quality, in commercial quantities at an acceptable cost; and
- provide adequate training to physicians implanting and patients using of our products.

If we are unable to develop or improve products, applications or features due to constraints, such as insufficient cash resources, high employee turnover, inability to hire personnel with sufficient technical skills, or a lack of other research and development resources, we may not be able to maintain our competitive position compared to other companies. Furthermore, many of our competitors devote a considerably greater amount of funds to their research and development programs than we do, and those that do not may be acquired by larger companies that would allocate greater resources to research and development programs. Our failure or inability to devote adequate research and development resources or compete effectively with the research and development programs of our competitors could harm our business.

In addition, we may choose to focus our efforts and resources on potential products or indications that ultimately prove to be unsuccessful, or to license or purchase a marketed product that does not meet our financial expectations. As a result, we may fail to capitalize on viable commercial products or profitable market opportunities, be required to forego or delay pursuit of opportunities with other potential products or other diseases that may later prove to have greater commercial potential, or relinquish valuable rights to such potential products through collaboration, licensing or other royalty arrangements in cases in which it would have been advantageous for us to retain sole development and commercialization rights, which could adversely impact our business, financial condition and results of operations.

Our success is highly dependent on our ability to attract and retain highly skilled executive officers and employees.

To succeed, we must continue to recruit, retain, manage, and motivate qualified executives as we build out the management team, and we face significant competition for experienced personnel. We are highly dependent on executive officers, other members of senior management, as well as on our sales personnel, which includes TMs and TDSs. If we do not succeed in attracting and retaining qualified personnel, particularly at the management level, it could adversely affect our ability to execute our business plan and harm our results of operations. In particular, the loss of one or more of our executive officers could be detrimental to us if we cannot recruit suitable replacements in a timely manner. The competition for qualified personnel in the medical device and neurostimulation field is intense and as a result, we may be unable to continue to attract and retain qualified personnel necessary for the future success of our business. We could in the future have difficulty attracting experienced personnel to our company and may be required to expend significant financial resources in our employee recruitment and retention efforts.

Many of the other medical device, life science, and technology companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They also may provide more diverse opportunities and better prospects for career advancement. Some of these characteristics may be more appealing to high-quality candidates than what we have to offer. If our business performance declines, we may be unable to offer competitive compensation packages, which could make it difficult to retain our current sales personnel. Additionally, if our competitors increase the compensation offered to their sales personnel, we may be required to increase our own compensation levels, which could increase our operating expenses and negatively impact our profitability. If we fail to increase our own compensation levels to match that of competitors, we may be unable to attract or retain our existing TMs and TDSs, or to attract new TMs or TDSs, which would prevent us from expanding our business and generating sales. If we are unable to continue to attract and retain high-quality sales personnel, the rate and success at which we can discover, develop, and commercialize our current and future products will be limited and the potential for successfully growing our business will be materially and adversely affected.

In addition, job candidates and existing employees often consider the value of the share awards they receive in connection with their employment. If the perceived value of our share awards declines, it may harm our ability to recruit and retain highly skilled employees. Many of our employees have become or will soon become vested in a substantial amount of our common stock or a number of common stock underlying options. Our employees may be

more likely to leave our company if the common stock they own has significantly depreciated in value relative to the original purchase prices of the common stock, or if the exercise prices of the options that they hold are significantly above the market price of our common stock.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit or halt the marketing and sale of our Vivistim System. The expense and potential unavailability of insurance coverage for liabilities resulting from our Vivistim System could harm us and our ability to sell our Vivistim System.

We face an inherent risk of product liability as a result of the marketing and sale of our products. For example, we may be sued if our products cause or are perceived to cause injury or are found to be otherwise unsuitable. Any such product liability claim may include allegations of defects in manufacturing, defects in design, a failure to warn of dangers inherent in the product, negligence, strict liability, or a breach of warranties. In addition, we may be subject to claims against us even if the apparent injury is due to the actions of others or the pre-existing health of the patient. For example, we rely on physicians to implant our Vivistim System in patients. If these physicians are not properly trained, do not appropriately screen out patients who are contraindicated or otherwise not well-suited for an implant procedure or general anesthesia, or are negligent, the capabilities of our products may be diminished, or the patient may suffer critical injury. We may also be subject to claims that are caused by the activities of our suppliers, such as those who provide us with components and sub-assemblies.

If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit or halt commercialization of our products. Even successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- decreased demand for our products;
- injury to our reputation;
- initiation of investigations by regulators;
- costs to defend the related litigation;
- a diversion of management's time and our resources;
- substantial monetary awards to trial participants or patients;
- product recalls, withdrawals, or labeling, marketing or promotional restrictions;
- loss of revenue;
- exhaustion of any available insurance and our capital resources; and
- the inability to market and sell our products.

Although we carry product liability insurance, it may not prove to be adequate to cover all liabilities that we may incur. Insurance coverage is increasingly expensive. We may not be able to maintain or obtain insurance at a reasonable cost or in an amount adequate to satisfy any liability that may arise. Our insurance policy contains various exclusions, and we may be subject to a product liability claim for which we have no coverage. The potential inability to obtain sufficient product liability insurance at an acceptable cost to protect against product liability claims could prevent or inhibit the marketing and sale of products we develop. We may have to pay any amounts awarded by a court or negotiated in a settlement that exceed our coverage limitations or that are not covered by our insurance, and we may not have, or be able to obtain, sufficient capital to pay such amounts, which would have a material adverse effect on our business, financial condition, and results of operations. In addition, any product liability claims brought against us, with or without merit, could increase our product liability insurance rates or prevent us from securing continuing coverage, harm our reputation in the industry, significantly increase our expenses and reduce product sales.

Some of our customers and prospective customers may also have difficulty in procuring or maintaining liability insurance to cover their operations and use of our products. Medical malpractice carriers are withdrawing coverage in certain states or substantially increasing premiums. If this trend continues or worsens, our customers may discontinue using our products and potential customers may opt against purchasing our products due to the cost or inability to procure insurance coverage.

The terms of our loan and security agreement places restrictions on our operations and financial covenants and place restrictions on our operating and financial flexibility. If we raise additional capital through debt financing, the terms of any new debt could further restrict our ability to operate our business.

On December 29, 2023, we entered into a loan and security agreement (the Loan and Security Agreement) with Horizon Technology Finance Corporation as lender and collateral agent. On June 1, 2024, Horizon Technology Finance Corporation assigned all of its right, title and interest in and to the loans outstanding under the Loan and Security Agreement and related warrants to Horizon Funding II, LLC, its wholly-owned subsidiary (together with Horizon Technology Finance Corporation, Horizon). The Loan and Security Agreement provides for term loans of up to an aggregate principal amount of $30.0 million, available in four equal tranches of $7.5 million available at various dates (the Commitments). The Company's ability to draw additional loans under the Loan and Security Agreement expired on December 31, 2025. The Loan and Security Agreement matures on January 1, 2029. As of December 31, 2025, there was $7.5 million outstanding under the Loan and Security Agreement, representing the full available aggregate principal amount under the Loan and Security Agreement, and no additional tranches are available to draw down under the Loan and Security Agreement in the future.

Borrowings under the Loan and Security Agreement bear interest at an annual rate equal to the greater of (i) The Wall Street Journal (or any successor thereto) prime rate (subject to a floor of 8.50%) plus 3.75%, and (ii) 12.25%. Amounts outstanding under the Loan and Security Agreement are secured by substantially all of our assets, excluding intellectual property. We must make interest payments under the Loan and Security Agreement, which have diverted and will continue to divert resources from other activities. The Loan and Security Agreement includes customary affirmative and negative covenants and events of default. The covenants related to the Loan and Security Agreement, as well as any future financing agreements into which we may enter, may restrict our ability to finance our operations and engage in, expand or otherwise pursue our business activities and strategies.

While we have not previously breached and are not currently in breach of these or any other covenants contained in the Loan and Security Agreement, there can be no guarantee that we will not breach these covenants or any covenants under any other debt arrangements in the future. Our ability to comply with these covenants may be affected by events beyond our control, and future breaches of any of these covenants could result in a default under the Loan and Security Agreement. If not waived, future defaults could cause all of the outstanding indebtedness under the Loan and Security Agreement to become immediately due and payable and terminate commitments to extend further credit and foreclose on the collateral granted to it to collateralize such indebtedness. If we do not have or are unable to generate sufficient cash available to repay our debt obligations when they become due and payable, either upon maturity or in the event of a default, our assets could be foreclosed upon and we may not be able to obtain additional debt or equity financing on favorable terms, if at all, which may negatively impact our ability to operate and continue our business as a going concern.

If we default under the Loan and Security Agreement, Horizon will be able to declare all obligations immediately due and payable and take control of our pledged assets, potentially requiring us to renegotiate our agreement on terms less favorable to us or to immediately cease operations. The lenders could declare a default under the Loan and Security Agreement upon the occurrence of specific events such as our failure to pay or our failure to comply with specified covenants, thereby requiring us to repay the loan immediately. Any declaration by the lenders of an event of default could significantly harm our business and prospects and could cause the price of our common shares to decline.

In order to service this indebtedness and any additional indebtedness we may incur in the future, we need to generate cash from our operating activities. Our ability to generate cash is subject, in part, to our ability to successfully execute our business strategy, as well as general economic, financial, competitive, regulatory and other factors beyond our control. We cannot assure you that our business will be able to generate sufficient cash flow from

operations or that future borrowings or other financings will be available to us in an amount sufficient to enable us to service our indebtedness and fund our other liquidity needs. To the extent we are required to use cash from operations or the proceeds of any future financing to service our indebtedness instead of funding working capital, capital expenditures or other general corporate purposes, we will be less able to plan for, or react to, changes in our business, industry and in the economy generally. This may place us at a competitive disadvantage compared to our competitors that have less indebtedness.

We may incur additional indebtedness in the future. The debt instruments governing such indebtedness may contain provisions that are as, or more, restrictive than the provisions governing our existing indebtedness. If we are unable to repay, refinance or restructure our indebtedness when payment is due, the lenders could proceed against the collateral or force us into bankruptcy or liquidation.

Cost-containment efforts of our customers, purchasing groups and governmental organizations could have a material adverse effect on our business, financial condition and results of operations.

In an effort to reduce costs, many hospitals and ambulatory surgery centers (ASCs) in the United States have become members of group purchasing organizations (GPOs) and integrated delivery networks (IDNs). GPOs and IDNs negotiate pricing arrangements with medical device companies and distributors and then offer these negotiated prices to affiliated hospitals, ASCs and other members. GPOs and IDNs typically award contracts on a category-by-category basis through a competitive bidding process. Bids are generally solicited from multiple providers with the intention of driving down pricing or reducing the number of vendors. Due to the highly competitive nature of the GPO and IDN contracting processes, we may not be able to obtain new, or maintain existing, contract positions with major GPOs and IDNs. Furthermore, the increasing leverage of organized buying groups may reduce market prices for our products, thereby reducing our revenue and margins.

While having a contract with a GPO or IDN for a given product category can facilitate sales to members of that GPO or IDN, such contract positions can offer no assurance that any level of sales will be achieved, as sales are typically made pursuant to individual purchase orders. Even when a provider is the sole contracted supplier of a GPO or IDN for a certain product category, members of the GPO or IDN are generally free to purchase from other suppliers. Accordingly, even if we secure a contract with a GPO or an IDN, we nonetheless need to negotiate contracts or purchase orders with individual GPO or IDN members, which can further increase the length of our sales cycle, increase sales costs and means that our sales success is uncertain even if we contract with a GPO or IDN. Furthermore, the members of such groups may choose to purchase alternative products due to the price or quality offered by other companies, which could result in a decline in our revenue.

If we or our third-party providers fail to protect confidential information and/or experience data security incidents, there may be damage to our brand and reputation, material financial penalties, and legal liability, which could materially and adversely affect our business, results of operations and financial condition.

We rely on computer systems, hardware, software, technology infrastructure and online sites and networks for both internal and external operations that are critical to our business (collectively, IT Systems). We own and manage some of these IT Systems but also rely on third parties for a range of IT Systems and related products and services, including but not limited to financial records, facilitate our research and development initiatives, manage our manufacturing operations, maintain quality control, fulfill customer orders, maintain corporate records, communicate with staff and external parties and operate other critical functions. We and certain of our third-party providers collect, maintain and process data about customers, employees, business partners and others, including information about individuals, as well as confidential or proprietary information belonging to our business such as trade secrets (collectively, Confidential Information).

We face numerous and evolving cybersecurity risks that threaten the confidentiality, integrity and availability of our IT Systems and Confidential Information, including from diverse threat actors, such as state-sponsored organizations, opportunistic hackers and hacktivists, as well as through diverse attack vectors, such as earthquakes and hurricanes, fires, floods and other natural or man-made disasters, social engineering/phishing, malware (including ransomware), malfeasance by insiders, human or technological error, and as a result of malicious code embedded in open-source software, or misconfigurations, bugs or other vulnerabilities in commercial software that

is integrated into our (or our suppliers' or service providers') IT Systems, products or services. Because we make extensive use of third party suppliers and service providers, such as cloud services that support our internal and customer-facing operations, successful cyberattacks that disrupt or result in unauthorized access to third party IT Systems can materially impact our operations and financial results. Remote and hybrid working arrangements at our company (and at many third-party providers) also increase cybersecurity risks due to the challenges associated with managing remote computing assets and security vulnerabilities that are present in many non-corporate and home networks. Additionally, because our products and services are integrated with third party systems and processes, any circumvention or failure of our cybersecurity defenses or measures could compromise the confidentiality, integrity, and availability of the third parties' IT Systems and/or Confidential Information as well.

Additionally, any integration of artificial intelligence (AI) in our or any service providers' operations, products or services is expected to pose new or unknown cybersecurity risks and challenges. The development, adoption, and use of AI is still in early stages, and ineffective or inadequate AI development or deployment practices by us or any service providers could result in unintended consequences that could materially harm our business.

Cyberattacks are expected to accelerate on a global basis in frequency and magnitude as threat actors are becoming increasingly sophisticated in using techniques and tools—including AI—that circumvent security controls, evade detection and remove forensic evidence. As a result, we may be unable to detect, investigate, remediate or recover from future attacks or incidents, or to avoid a material and adverse impact to our IT Systems, Confidential Information or business. There can also be no assurance that our cybersecurity risk management program and processes, including our policies, controls or procedures, will be fully implemented, complied with or effective in protecting our IT Systems and Confidential Information. Furthermore, given the nature of complex systems, software and services like ours, and the scanning tools that we deploy across our networks and products, we regularly identify and track security vulnerabilities. We are unable to comprehensively apply patches or confirm that measures are in place to mitigate all such vulnerabilities, or that patches will be applied before vulnerabilities are exploited by a threat actor. If attackers are able to exploit critical vulnerabilities before patches are installed or mitigating measures are implemented, significant compromises could impact our IT Systems and/or Confidential Information.

We and certain of our third-party providers regularly experience cyberattacks and other incidents, and we expect such attacks and incidents to continue in varying degrees. While to date no incidents have had a material impact on our operations or financial results, we cannot guarantee that material incidents will not occur in the future. Any adverse impact to the availability, integrity or confidentiality of our IT Systems or Confidential Information can result in legal claims or proceedings (such as class actions), regulatory investigations and enforcement actions, fines and penalties, negative reputational impacts that cause us to lose existing or future customers, and/or significant incident response, system restoration or remediation and future compliance costs. Any or all of the foregoing could materially and adversely affect our business, results of operations and financial condition. Finally, we cannot guarantee that any costs and liabilities incurred in relation to an attack or incident will be covered by our existing insurance policies or that applicable insurance will be available to us in the future on economically reasonable terms or at all.

Artificial intelligence presents risks and challenges that can impact our business, including by posing security risks to our confidential information, proprietary information and personal information.

Issues in the use of AI, combined with an uncertain regulatory environment, may result in reputational harm, liability, or other adverse consequences to our business operations. As with many technological innovations, AI presents risks and challenges that could impact our business. We may adopt and integrate generative AI tools throughout our business, including into our information systems. Our vendors may incorporate generative AI tools into their services and offerings without disclosing this use to us, and the providers of these generative AI tools may not meet existing or rapidly evolving regulatory or industry standards with respect to data privacy and data protection and may inhibit our or our vendors' ability to maintain an adequate level of service and experience. Any integration of AI in our or any third party's operations, products or services is expected to pose new or unknown cybersecurity risks and challenges. If we, our vendors, or our third-party partners experience an actual or perceived breach or data privacy or security incident because of the use of generative AI, we may lose valuable intellectual property and Confidential Information and our reputation and the public perception of the effectiveness of our

security measures could be harmed. Further, bad actors around the world use increasingly sophisticated methods, including the use of AI, to engage in illegal activities involving the theft and misuse of personal information, Confidential Information, and intellectual property. Any of these outcomes could damage our reputation, result in the loss of valuable property and information, and adversely impact our business.

Macroeconomic conditions could harm our business, financial condition and results of operations.

Macroeconomic conditions, such as high inflationary pressure, changes to monetary policy, high interest rates, volatile currency exchange rates, credit and debt concerns, decreasing consumer confidence and spending, including capital spending, concerns about the stability and liquidity of certain financial institutions, the introduction of or changes in tariffs or trade barriers, and global recessions can adversely impact demand for our products, which could negatively impact our business, financial condition and results of operations. Recent macroeconomic conditions have been adversely impacted by geopolitical instability and military hostilities in multiple geographies and monetary and financial uncertainties.

The impacts of these macroeconomic conditions, and the actions taken by governments, central banks, companies, and consumers in response, have resulted in, and may continue to result in, higher inflation in the United States and globally, which is likely, in turn, to lead to an increase in costs and may cause changes in fiscal and monetary policy, including additional increases in interest rates. Other adverse impacts of recent macroeconomic conditions have been, and may continue to be, imposition of tariffs and other trade measures, supply chain constraints, logistics challenges, liquidity concerns in the broader financial services industry and fluctuations in labor availability.

To the extent we expand sales of our products internationally in the future, we will be exposed to additional risks associated with international business.

While we do not currently market outside of the United States, sales of products internationally will be subject to foreign regulatory requirements governing clinical trials and marketing approval. To the extent we expand sales of our products internationally in the future, we will incur substantial expenses. Additional risks related to operating in foreign countries include:

- differing and evolving regulatory requirements and reimbursement regimes in foreign countries;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political or social instability in particular foreign economies and markets;
- weaker intellectual property protections in certain foreign markets;
- compliance with tax, employment, immigration, and labor laws for employees living, working, or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in the United States;
- potential liability under the U.S. Foreign Corrupt Practices Act (FCPA) or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as the United States;

- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad;
- there may be intellectual property held by third parties specific to one or more of those jurisdictions that would limit our ability to distribute the product without a license; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our international operations may materially and adversely affect our ability to attain or maintain profitable operations, which would have a material adverse effect on our business, financial condition and results of operations.

In addition, there can be no guarantee that we will receive marketing authorization to sell our products in every international market we target, nor can there be any guarantee that any sales would result even if such authorization is received. Regulatory requirements can vary widely from country to country and could delay the introduction of our products in those countries. Our inability to successfully enter all our desired international markets and manage business on a global scale could materially and adversely affect our business, financial results and results of operations.

We may acquire other companies' technologies or intellectual property, which could fail to result in a commercial product or net sales, divert our management's attention, result in additional dilution to our stockholders and otherwise disrupt our operations and materially and adversely affect our results of operations.

We may in the future seek to acquire or invest in businesses, applications, technologies or intellectual property that we believe could complement or expand our portfolio, enhance our technical capabilities, or otherwise offer growth opportunities. However, we cannot assure you that we would be able to successfully complete any acquisition we choose to pursue, or that we would be able to successfully integrate any acquired business, product, or technology in a cost-effective and non-disruptive manner. The pursuit of potential acquisitions may divert the attention of management and cause us to incur various costs and expenses in identifying, investigating, and pursuing suitable acquisitions, whether or not they are consummated. We may not be able to identify desirable acquisition targets or be successful in entering into an agreement with any particular target or obtain the expected benefits of any acquisition or investment. We may also be unable to identify all material liabilities associated with companies we acquire and any indemnities which we receive from the target in connection with an acquisition may be unavailable or insufficient to cover such liabilities.

To date, the growth of our operations has been organic, and we have limited experience in acquiring other businesses or technologies. We may not be able to successfully integrate any acquired personnel, operations, and technologies, or effectively manage the combined business following an acquisition. Acquisitions could also result in dilutive issuances of equity securities, the use of our available cash, or the incurrence of debt, which could materially and adversely affect our results of operations. In addition, if an acquired business fails to meet our expectations, our business, financial condition and results of operations may be materially and adversely affected.

Our ability to use our net operating loss carryforwards or certain other tax attributes to offset future taxable income or income taxes, as applicable, may be subject to certain limitations.

As of December 31, 2025, and 2024, the Company had U.S. federal net operating loss (NOL) carryforwards of approximately $127.4 million and $88.4 million, respectively. For U.S. federal income tax purposes, NOLs generated in tax years beginning before January 1, 2018, can be carried forward for up to 20 years, and NOLs generated in tax years beginning after December 31, 2017, can be carried forward indefinitely but can only offset up to 80% of taxable income in any given tax year beginning after December 31, 2020. Of the total U.S. federal NOL carryforward as of December 31, 2025, $22.1 million will begin to expire in 2027 and $105.3 million will not expire but will be subject to the 80% utilization limit.

Our U.S. federal NOL carryforwards could expire unused, to the extent subject to expiration, and be unavailable to offset future taxable income because of their limited duration or because of restrictions under U.S. federal law.

In addition, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the Code), if a corporation undergoes an "ownership change" (generally defined as a cumulative change in our ownership by "5-percent shareholders" that exceeds 50 percentage points (by value) over a rolling three-year period), the corporation's ability to use its pre-change NOL carryforwards or certain other pre-change tax attributes to offset its post-change taxable income or income taxes, as applicable, may be limited. Similar rules may apply under state tax laws. We believe (but have not undertaken any formal analysis or other assessment to determine) that no such ownership changes have occurred to date. Our ability to utilize our NOL carryforwards or other tax attributes to offset future taxable income or income taxes, as applicable, may be limited if such ownership changes have occurred. Furthermore, we may experience ownership changes as a result of this offering or in the future as a result of subsequent shifts in our stock ownership, some of which are outside our control, which could limit (or further limit) our ability to use our NOL carryforwards and other tax attributes. We have not conducted any studies to determine future annual limitations, if any, that could result from such changes in our stock ownership. Any such limitations on our ability to utilize our NOL carryforwards and certain other tax attributes could have a material adverse effect on our business, financial condition and results of operations.

Changes in tax laws could have a material adverse effect on our business, financial condition, and results of operations.

New income, sales, use or other tax laws, statutes, rules, regulations or ordinances could be enacted at any time, or interpreted, changed, modified or applied adversely to us. The likelihood of any such changes being enacted or implemented is uncertain. We are currently unable to predict whether such changes will occur and, if so, the ultimate impact on our business. To the extent that such changes have a negative impact on us, our customers or our suppliers, including as a result of related uncertainty, these changes could have a material adverse effect on our business, financial condition and results of operations.

Taxing authorities may successfully assert that we should have collected or in the future should collect sales and use, value added or similar taxes, and we could be subject to liability with respect to past or future sales, which could materially and adversely affect our results of operations.

We may not collect sales and use, value added, and similar taxes in all jurisdictions in which we have sales, based on our belief that such taxes are not applicable. Sales and use, value added, and similar tax laws and rates vary greatly by jurisdiction. Any jurisdictions in which we do not collect such taxes may assert that such taxes are applicable, which could result in tax assessments, penalties, and interest, and we may be required to collect such taxes in the future. Such tax assessments, penalties and interest or future requirements may materially and adversely affect the results of our operations.

Risks Related to Intellectual Property

If we are unable to maintain existing, and obtain additional, patent and other intellectual property protection for our technology and products, or if the scope of the patent protection we obtained is not sufficiently broad, we may not be able to compete effectively in our markets.

Our success depends in large part on our ability to maintain existing, and obtain additional, patent and other intellectual property protection in the United States and other countries with respect to our products and technology we develop.

We have protected and seek to protect our position by in-licensing intellectual property relating to our products and filing patent applications in the United States and abroad related to our technologies and products that are important to our business. Our ability to protect our products from unauthorized copying or recreation by third parties may be limited by the extent that such products are covered by valid and enforceable patents or include information that is effectively maintained as a trade secret. The actual protection afforded by a patent varies on a product-by-product basis, from country to country and depends upon many factors, including the type of patent and the scope of its coverage. For example, we rely on patents covering how the Vivistim System is used, commonly referred to as method patents.

We also rely on a combination of contractual provisions, confidentiality procedures and copyright, trademark, trade secret, and other intellectual property rights to protect the proprietary aspects of our brand, technologies, and data. These legal measures afford only limited protection, and competitors or others may gain access to or use our intellectual property and Confidential Information. Our success will depend, in part, on obtaining and maintaining patents, preserving our trade secrets, maintaining the security of our data and know-how, and obtaining other intellectual property rights.

We may not be able to obtain and maintain intellectual property or other proprietary rights necessary to our business or in a form that provides us with a competitive advantage. For example, our trade secrets, data, and know-how could be subject to unauthorized use, misappropriation, or disclosure to unauthorized parties, despite our efforts to enter into confidentiality or other restrictive covenant agreements with our employees, consultants, contractors, clients, and other vendors who have access to such information, and could otherwise become known or be independently discovered by third parties. In addition, the patent prosecution process is expensive, time-consuming, and complex, and we may not be able to file, prosecute, maintain, enforce, or license all necessary or desirable patent applications at a reasonable cost, in a timely manner, or in all jurisdictions where protection may be commercially advantageous, or we may not be able to protect our intellectual property at all. Despite our efforts to protect our intellectual property, unauthorized parties may be able to obtain and use information that we regard as proprietary. It is also possible that we will fail to identify patentable aspects of our research and development output in time to obtain patent protection. Although we enter into non-disclosure and confidentiality agreements with parties who have access to confidential or patentable aspects of our research and development output, such as our employees, consultants, contractors, collaborators, vendors, and other third parties, any of these parties may breach the agreements and disclose such output before a patent application is filed, thereby jeopardizing our ability to seek patent protection. In addition, publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all. Therefore, we cannot be certain that we were or will be the first to make the inventions claimed in our owned or any licensed patents or pending patent applications, or that we were or will be the first to file for patent protection of such inventions.

The patent position of medical device companies generally is highly uncertain, involves complex legal and factual questions, and has been the subject of much litigation in recent years. Changes in either the patent laws or their interpretation in the United States and other countries may diminish our ability to protect our inventions, obtain, maintain, and enforce our intellectual property rights and, more generally, could affect the value of our intellectual property or narrow the scope of our owned and licensed patents. With respect to both in-licensed and owned intellectual property, we cannot predict whether the patent applications we and our licensors are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient protection from competitors. As a result, the issuance, scope, validity, enforceability, and commercial value of our patent rights are highly uncertain.

Moreover, the coverage claimed in a patent application can be significantly reduced before a patent is issued, and its scope can be reinterpreted after issuance. Even if patent applications we license or own currently or in the future issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors or other third parties from competing with us, or otherwise provide us with any competitive advantage. Any patents that we hold or in-license may be challenged, narrowed, or invalidated by third parties. Additionally, our competitors or other third parties may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. Third parties may also have blocking patents that could prevent us from marketing our own products and practicing our own technology. Alternatively, third parties may seek approval to market their own products that are similar to or otherwise competitive with our products. In these circumstances, we may need to defend or assert our patents, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or agency with jurisdiction may find our patents invalid, unenforceable, or not infringed, in which case, our competitors and other third parties may then be able to market products and use manufacturing and analytical processes that are substantially similar to ours. Even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

Given that patent applications are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our products. Competitors may also contest our patents, if issued, by showing the patent examiner that the invention was not original, was not novel, or was obvious. In litigation, a competitor could claim that our patents, if issued, are not valid for a number of reasons. If a court agrees, we would lose our rights to those challenged patents.

In addition, given the amount of time required for the development, testing, and regulatory review of new products, patents protecting such products might expire before or shortly after such products are commercialized. As a result, our intellectual property may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours. Moreover, some of our owned and in-licensed patents and patent applications are, and may in the future, be co-owned with third parties. If we are unable to obtain an exclusive license to any such third-party co-owners' interests in such patents or patent applications, such co-owners may be able to license their rights to other third parties, including our competitors, and our competitors could market competing products and technology. In addition, we may need the cooperation of any such co-owners of our patents in order to enforce such patents against third parties, and such cooperation may not be provided to us.

Our other intellectual property, including our trademarks, could also be challenged, invalidated, infringed, and circumvented by third parties, and our trademarks could also be diluted, declared generic, or found to be infringing on other marks, in which case we could be forced to re-brand our products, resulting in loss of brand recognition and requiring us to devote significant resources to advertising and marketing new brands, and suffer other competitive harm. Third parties may also adopt trademarks similar to ours, which could harm our brand identity and lead to market confusion.

We may in the future also be subject to claims by our current or former employees, consultants, or contractors asserting an ownership right in our patents or patent applications, as a result of the work they performed on our behalf. Although we generally require all of our employees, consultants, contractors, and any other partners or collaborators who have access to our proprietary know-how, information or technology to assign or grant similar rights to their inventions to us, we cannot be certain that we have executed such agreements with all parties who may have contributed to our intellectual property, nor can we be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy.

Failure to obtain and maintain patents, trademarks, and other intellectual property rights necessary to our business and failure to protect, monitor, and control the use of our intellectual property rights could negatively impact our ability to compete and cause us to incur significant expenses. The intellectual property laws and other statutory and contractual arrangements in the United States and other jurisdictions we depend upon may not provide sufficient protection in the future to prevent the infringement, use, violation, or misappropriation of our patents, trademarks, data, technology, and other intellectual property, and may not provide an adequate remedy if our intellectual property rights are infringed, misappropriated, or otherwise violated. Any of the foregoing could have a material adverse effect on our business, financial condition, and results of operations.

Furthermore, our owned and in-licensed patents may be subject to a reservation of rights by one or more third parties. For example, this could arise if the research resulting in certain of our owned or in-licensed patent rights and technology was funded in part by the U.S. government. As a result, the government may have certain rights, or march-in rights, to such patent rights and technology. When new technologies are developed with government funding, the government generally obtains certain rights in any resulting patents, including a non-exclusive license authorizing the government to use the invention for non-commercial purposes. These rights may permit the government to disclose our Confidential Information to third parties and to exercise march-in rights to use or allow third parties to use our licensed technology. The government can exercise its march-in rights if it determines that action is necessary because we fail to achieve practical application of the government-funded technology, because action is necessary to alleviate health or safety needs, to meet requirements of federal regulations, or to give preference to U.S. industry. In addition, our rights in such inventions may be subject to certain requirements to manufacture products embodying such inventions in the United States. Any exercise by the government of such rights could materially and adversely affect our competitive position, business, financial condition, and results of operations.

Any intellectual property litigation or administrative proceedings can be costly and could interfere with our ability to sell and market our products.

The medical device industry has been characterized by extensive litigation regarding patents, trademarks, trade secrets, and other intellectual property rights, and companies in the industry have used intellectual property litigation to gain a competitive advantage. It is possible that United States and foreign patents and pending patent applications or trademarks controlled by third parties may be alleged to cover our products, or that we may be accused of misappropriating third parties' trade secrets. Additionally, our products include components that we purchase from vendors and may include design components that are outside of our direct control. Our competitors, many of which have substantially greater resources and have made substantial investments in patent portfolios, trade secrets, trademarks, and competing technologies, may have applied for or obtained, or may in the future apply for or obtain, patents or trademarks that will prevent, limit, or otherwise interfere with our ability to make, use, sell, or export our products or to use product names. Because patent applications can take years to issue and are often afforded confidentiality for some period of time, there may currently be pending applications, unknown to us, that later result in issued patents that could cover one or more of our products. Moreover, in recent years, individuals and groups that are non-practicing entities, commonly referred to as "patent trolls," have purchased patents and other intellectual property assets for the purpose of making claims of infringement in order to extract settlements. We may receive inquiries regarding our intellectual property, notices or "invitations to license," or may be the subject of claims that our products and business operations infringe or violate the intellectual property rights of others.

The defense of intellectual property litigation can be time consuming and costly, can divert management's attention and resources, damage our reputation and brand, and cause us to incur significant expenses or make substantial payments, whether or not we receive a determination favorable to us.

Even if we believe a third party's intellectual property claims are without merit, there is no assurance that a court would find in our favor, including on questions of infringement, validity, enforceability, or priority of patents. The strength of our defenses will depend on the patents asserted, the interpretation of these patents, and our ability to invalidate the asserted patents. In the United States, in order to successfully challenge the validity of a patent in federal court, we would need to overcome a presumption of validity. This standard of proof is a high one, requiring us to present clear and convincing evidence of the invalidity of each asserted claim of the patent. There is no assurance that the court would agree that we had met that standard. Conversely, the patent owner needs only to prove infringement by a preponderance of the evidence, which is a lower standard of proof. If a court of competent jurisdiction should hold that third-party patents are valid, enforceable, and infringed, this could materially and adversely affect our ability to commercialize any products or technology we may develop, and any other products or technologies covered by the asserted third-party patents.

Further, if patents, trademarks, or trade secrets are successfully asserted against us, this may harm our business and result in injunctions preventing us from developing, manufacturing, or selling our products or offering certain therapies with Vivistim Therapy, or result in obligations to pay license fees, damages, attorney fees, and court costs, which could be significant. In addition, if we are found to willfully infringe third-party patents or trademarks or to misappropriate trade secrets, we could be required to pay treble damages in addition to other penalties.

In addition, vendors from whom we purchase hardware or software may not indemnify us in the event that such hardware or software is accused of infringing a third party's patent or trademark or of misappropriating a third party's trade secret, or any indemnification granted by such vendors may not be sufficient to address any liability and costs we incur as a result of such claims. Additionally, we may be obligated to indemnify our customers or business partners in connection with litigation and to obtain licenses or refund subscription fees, which could further exhaust our resources.

Although patent, trademark, trade secret and other intellectual property disputes in the medical device area have often been settled through licensing or similar arrangements, costs associated with such arrangements may be substantial and could include ongoing royalties. We may be unable to obtain necessary licenses on satisfactory terms, if at all. In addition, if any license we obtain is non-exclusive, we may not be able to prevent our competitors and other third parties from using the intellectual property or technology covered by such license to compete with us. If we do not obtain necessary licenses, we may not be able to redesign our products to avoid infringement, and

we could be forced to cease some aspects of our business operations. Any of these events could materially and adversely affect our business, financial condition, and results of operations.

Similarly, interference proceedings provoked by third parties or brought by the U.S. Patent and Trademark Office (the USPTO), may be necessary to determine priority of, or ownership rights in, our patents, patent applications, trademarks, or trademark applications. We may also become involved in other proceedings, such as reexamination, *inter partes* review, derivation or opposition proceedings relating to our or a third party's patents or patent applications, or cancellation or opposition proceedings relating to our or a third party's registered trademarks, before the USPTO or the equivalent body in other jurisdictions. Adverse determinations in a judicial or administrative proceeding or failure to obtain necessary licenses could prevent us from manufacturing our products or using product names, which would have a material adverse effect on our business, financial condition, and results of operations.

Additionally, we may file lawsuits or initiate other proceedings to protect or enforce our patents or other intellectual property rights, which could be expensive, time consuming and unsuccessful. Competitors may infringe our issued patents or other intellectual property, which we may not always be able to detect. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. Any claims we assert against perceived infringers could provoke these parties to assert counterclaims against us alleging that we infringe on their intellectual property or alleging that our intellectual property is invalid or unenforceable. Grounds for a validity challenge could be an alleged failure to meet any of several statutory requirements, including lack of novelty, obviousness, or non-enablement. Grounds for an unenforceability assertion could be an allegation that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may raise challenges to the validity of certain of our owned or in-licensed patent claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post-grant review, *inter partes* review, interference proceedings, derivation proceedings and equivalent proceedings in foreign jurisdictions (e.g., opposition proceedings). In any such lawsuit or other proceedings, a court or other administrative body may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly, or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question.

The outcome following legal assertions of invalidity and unenforceability is unpredictable. If a third party were to prevail over a legal assertion of invalidity or unenforceability, we would lose at least part, and perhaps all, of the patent protection on our products or products that we may develop. If our patents are found to be valid and infringed, a court may refuse to grant injunctive relief against the infringer and instead grant us monetary damages or ongoing royalties. Such monetary compensation may be insufficient to adequately offset the damage to our business caused by the infringer's competition in the market. An adverse result in any litigation or other proceeding could put one or more of our patents at risk of being invalidated or interpreted narrowly. Any of these events could materially and adversely affect our business, financial condition, and results of operations.

Even if resolved in our favor, litigation or other proceedings relating to intellectual property claims may cause us to incur expenses and could distract our personnel from their normal responsibilities. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments, and if securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our common stock. Such litigation or proceedings could substantially increase our operating losses and reduce the resources available for development activities or any future sales, marketing, or distribution activities. We may not have sufficient financial or other resources to conduct such litigation or proceedings adequately. Some of our competitors may be able to sustain the costs of such litigation or proceedings more effectively than we can because of their greater financial resources and more mature and developed intellectual property portfolios. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential or sensitive information could be compromised by disclosure in the event of litigation. Uncertainties resulting from the initiation and continuation of patent and other intellectual property litigation or other proceedings could have a material adverse effect on our business, financial condition, and results of operations.

Obtaining and maintaining our patent protection depends on compliance with various procedural, document submission, fee payment, and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and other foreign patent agencies in several stages over the lifetime of the patent. The USPTO and various foreign national or international patent agencies require compliance with a number of procedural, documentary, fee payment, and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of patent rights include, but are not limited to, failure to timely file national and regional stage patent applications based on our international patent application, failure to respond to official actions within prescribed time limits, non-payment of fees, and failure to properly legalize and submit formal documents. If we or any of our current or future licensors fail to maintain the patents and patent applications that we in-license, our competitors may be able to enter the market, which would have a material adverse effect on our business.

The terms of our patents may not be sufficiently long to effectively protect our products and business.

Patents have a limited lifespan. In the United States, the natural expiration of a patent is generally 20 years after its first effective non-provisional filing date but can be shorter due to terminal disclaimers or similar term reductions in other jurisdictions. Although various extensions may be available, the term of a patent, and the protection it affords, are limited. Even if patents covering our technologies or products are obtained, once the patent term has expired, we may be open to competition. In addition, although upon issuance in the United States, a patent's term can be increased based on certain delays caused by the USPTO, this increase can be reduced or eliminated based on certain delays caused by the patent applicant during patent prosecution. Given the amount of time required for the development, testing, and regulatory review of products, patents protecting such product candidates might expire before or shortly after such products are commercialized. If we do not have sufficient patent life to protect our technologies and products, our business, financial condition, and results of operations will be materially and adversely affected.

We may not identify relevant third-party patents or may incorrectly interpret the relevance, scope, or expiration of a third-party patent, which might adversely affect our ability to develop and market our products.

We cannot guarantee that any of our patent searches or analyses, including the identification of relevant patents, the scope of patent claims, or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every third-party patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our current and future products in any jurisdiction.

The scope of a patent claim is a legal conclusion that rests upon consideration of the written disclosure in a patent, the patent's prosecution history, and usage by artisans in the relevant field. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products are not covered by a third-party patent or may incorrectly predict whether a third party's pending application will issue with claims of relevant scope. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, and our failure to identify and correctly interpret relevant patents may materially and adversely impact our ability to develop and market our products.

Reliance on third parties may require us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

If we rely on third parties to manufacture Vivistim Therapy, or any future products, or if we collaborate with third parties on future developments for Vivistim Therapy, or other future products, we may need to, at times, share trade secrets with them. We may also conduct research and development programs that may require us to share trade secrets under the terms of our research and development partnerships or similar agreements. We seek to protect our trade secrets and other proprietary technology in part by entering into confidentiality agreements with third parties

prior to disclosing Confidential Information. These agreements typically limit the rights of the third parties to use or disclose our Confidential Information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other Confidential Information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business, financial condition and results of operations.

In addition, these agreements typically restrict the ability of our advisors, employees, third-party contractors, and other service providers to publish data potentially relating to our trade secrets. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development, or publication of information by any of our third-party collaborators. Moreover, we cannot guarantee that we have entered into such agreements with each party that may have or have had access to our Confidential Information or proprietary technology and processes. Monitoring unauthorized uses and disclosures is difficult, and we do not know whether the steps we have taken to protect our proprietary technologies will be effective. If any of the third parties who are parties to these agreements breaches or violates the terms of any of these agreements, we may not have adequate remedies for any such breach or violation, and we could lose our trade secrets as a result. A competitor's discovery of our trade secrets would impair our competitive position and have a material adverse effect on our business.

We may be subject to claims that our employees, consultants, or independent contractors have wrongfully used or disclosed confidential information of third parties.

Many of our employees, consultants, and contractors were previously employed at or engaged by other medical device, biotechnology, or pharmaceutical companies, including our competitors or potential competitors. Some of these employees, consultants, and contractors may have executed proprietary rights, non-disclosure, non-competition or other restrictive covenant agreements in connection with such previous employment or engagement. Although we try to ensure that our employees and consultants do not use the intellectual property, confidential information, know-how, or trade secrets of others in their work for us, we may be subject to claims that we or these individuals have, inadvertently or otherwise, misappropriated the intellectual property or disclosed the alleged trade secrets or other confidential information of these former employers or competitors.

Additionally, we may be subject to claims from third parties challenging our ownership interest in intellectual property we regard as our own, based on claims that our employees, consultants, or contractors have breached an obligation to assign inventions to another employer, to a former employer, or to another person or entity. Litigation may be necessary to defend against any claims, and it may be necessary or we may desire to enter into a license to settle any such claim; however, there can be no assurance that we would be able to obtain a license on commercially reasonable terms, if at all. If our defense to those claims fails, in addition to paying monetary damages, a court could prohibit us from using technologies or features that are essential to our products, if such technologies or features are found to incorporate or be derived from the trade secrets or other confidential information of the former employers.

An inability to incorporate technologies or features that are important or essential to our products could have a material adverse effect on our business, financial condition, and results of operations, and may prevent us from selling our products. In addition, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against these claims, litigation could result in substantial costs and could be a distraction to management. Any litigation or the threat thereof may adversely affect our ability to hire employees or contract with independent TMs or TDSs. A loss of key personnel or their work product could hamper or prevent our ability to commercialize our products, which could have a material adverse effect on our business, financial condition, and results of operations.

We may be subject to claims challenging the inventorship or ownership of our future patents and other intellectual property.

We may be subject to claims that former employees, collaborators, or other third parties have an ownership interest in our patent applications, our future patents, or other intellectual property, including as an inventor or co-inventor. We may be subject to ownership or inventorship disputes in the future arising from, for example, conflicting obligations of consultants, contractors, or others who are involved in developing our products. Our success depends in part on our ability to obtain, maintain, protect, and enforce our intellectual property rights, including our patent rights, preserve the confidentiality of our trade secrets, and operate without infringing, misappropriating, or otherwise violating the intellectual property rights of others. We rely on a combination of patents, trademarks, trade secrets, and other intellectual property rights to protect the products and technology that we consider important to our business.

Although it is our policy to require our employees and contractors who may be involved in the conception or development of products, technology, know-how, and other proprietary materials (collectively, the Technology) to execute agreements assigning all intellectual property rights in and to such Technology to us, we may be unsuccessful in executing such an agreement with each party who, in fact, conceives or develops Technology that we regard as our own, and we cannot be certain that our agreements with such parties will be upheld in the face of a potential challenge, or that they will not be breached, for which we may not have an adequate remedy. The assignment of intellectual property rights may not be self-executing or the assignment agreements may be breached, and litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Our rights to develop and commercialize our products are subject, in part, to the terms and conditions of licenses granted to us by others.

We rely, in part, upon licenses to certain patent rights and proprietary technology from third parties that are important or necessary to the development of our products and technology. These and other licenses may not provide exclusive rights to use such intellectual property and technology in all relevant fields of use and in all territories in which we may wish to develop or commercialize our technology and products in the future. As a result, we may not be able to prevent competitors from developing and commercializing competitive products in territories included in all of our licenses.

In addition, we may not have the right to control the preparation, filing, prosecution, maintenance, enforcement, and defense of patents and patent applications covering the technology that we license from third parties. Therefore, we cannot be certain that these patents and patent applications will be prepared, filed, prosecuted, maintained, enforced, and defended in a manner consistent with the best interests of our business. If our licensors fail to prosecute, maintain, enforce, and defend such patents, or lose rights to those patents or patent applications, the rights we have licensed may be reduced or eliminated, and our right to develop and commercialize any of our products that are the subject of such licensed rights could be materially and adversely affected.

Our licensors may have relied on third-party consultants or collaborators or on funds from third parties such that our licensors are not the sole and exclusive owners of the patents we in-license. This could materially and adversely affect our business, financial condition, and results of operations.

The agreements under which we currently license intellectual property or technology from third parties are complex, and certain provisions in such agreements may be susceptible to multiple interpretations. The resolution of any contract interpretation disagreement that may arise could narrow what we believe to be the scope of our rights to the relevant intellectual property or technology, or increase what we believe to be our financial or other obligations under the relevant agreement. In spite of our best efforts, our licensors might also conclude that we have materially breached our license agreements and terminate the license agreements, thereby removing our ability to develop and commercialize products and technology covered by these license agreements. If these in-licenses are terminated, or

if the underlying patents fail to provide the intended exclusivity, competitors will have the freedom to seek regulatory approval of, and to market, products identical to ours. In addition, we may seek to obtain additional licenses from our licensors and, in connection with obtaining such licenses, we may agree to amend our existing licenses in a manner that may be more favorable to the licensors, including by agreeing to terms that could enable third parties (potentially including our competitors) to receive licenses to a portion of the intellectual property that is subject to our existing licenses. Any of these events could materially and adversely affect our business, financial condition and results of operations.

In the future, we may enter agreements involving licenses or collaborations that provide for access or sharing of intellectual property. If we fail to comply with our obligations under any license, collaboration, or other agreement, we may be required to pay damages and could lose intellectual property rights that are necessary for developing and protecting our current and future products.

We currently, and in the future may continue to, license from third parties certain intellectual property relating to our current and future products. In the event we do so, we may have certain obligations to such licensors. If we breach any material obligations, or use the intellectual property licensed to us in an unauthorized manner, we may be required to pay damages and the licensor may have the right to terminate the license, which could result in us being unable to develop, manufacture, and sell products that are covered by the licensed technology or enable a competitor to gain access to the licensed technology.

Disputes may arise between us and our future licensors regarding intellectual property subject to a license agreement, including:

- the scope of rights granted under the license agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement;
- our right to sublicense patents and other rights to third parties;
- our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our products, and what activities satisfy those diligence obligations;
- our right to transfer or assign the license; and
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by any of our future licensors and us and our partners.

If disputes over intellectual property that we license in the future prevent or impair our ability to maintain our licensing arrangements on acceptable terms, we may not be able to successfully develop and commercialize the affected products, which would have a material adverse effect on our business, financial condition and results of operations.

In addition, certain of our future agreements with third parties may limit or delay our ability to consummate certain transactions, may impact the value of those transactions, or may limit our ability to pursue certain activities. For example, we may in the future enter into license agreements that are not assignable or transferable, or that require the licensor's express consent in order for an assignment or transfer to take place.

Further, we or our future licensors, if any, may fail to identify patentable aspects of inventions made in the course of development and commercialization activities before it is too late to obtain patent protection on them. Therefore, we may miss potential opportunities to strengthen our patent position. It is possible that defects of form in the preparation or filing of our patents or patent applications may exist, or may arise in the future, for example with respect to proper priority claims, inventorship, claim scope, or requests for patent term adjustments. If we or our future licensors fail to establish, maintain, or protect such patents and other intellectual property rights, such rights may be reduced or eliminated. If our future licensors are not fully cooperative or disagree with us as to the prosecution, maintenance, or enforcement of any patent rights, such patent rights could be compromised. If there are material defects in the form, preparation, prosecution, or enforcement of our patents or patent applications, such

patents may be invalid or unenforceable, and such applications may never result in valid, enforceable patents. Any of these outcomes could impair our ability to prevent competition from third parties, which may have a material adverse effect on our business.

In addition, even where we have the right to control patent prosecution of patents and patent applications under future license from third parties, we may still be adversely affected or prejudiced by actions or inactions of our predecessors or licensors and their counsel that took place prior to us assuming control over patent prosecution.

Our technology acquired or licensed in the future from various third parties may be subject to retained rights. Our predecessors or licensors may retain certain rights under their agreements with us, including the right to use the underlying technology for noncommercial academic and research use, to publish general scientific findings from research related to the technology, and to make customary scientific and scholarly disclosures of information relating to the technology. It is difficult to monitor whether our predecessors or future licensors limit their use of the technology to these uses, and we could incur substantial expenses to enforce our rights to our licensed technology in the event of misuse.

In addition, the U.S. federal government retains certain rights in inventions produced with its financial assistance under the Patent and Trademark Law Amendments Act (Bayh-Dole Act). The federal government retains a "nonexclusive, nontransferable, irrevocable, paid-up license" for its own benefit. The Bayh-Dole Act also provides federal agencies with "march-in rights." March-in rights allow the government, in specified circumstances, to require the contractor or successors in title to the patent to grant a "nonexclusive, partially exclusive, or exclusive license" to a "responsible applicant or applicants." If the patent owner refuses to do so, the government may grant the license itself. If we choose to collaborate with academic institutions to accelerate our preclinical research or development, we cannot be sure that any co-developed intellectual property will be free from government rights pursuant to the Bayh-Dole Act. If, in the future, we co-own or license technology which is critical to our business that is developed in whole or in part with federal funds subject to the Bayh-Dole Act, our ability to enforce or otherwise exploit patents covering such technology may be materially and adversely affected.

If we are limited in our ability to utilize acquired or future licensed technologies, or if we lose our rights to critical future in-licensed technology, we may be unable to successfully develop, out-license, market, and sell our products, which could prevent or delay new product introductions. Our business strategy depends on the successful development of acquired technologies, and possibly in the future licensed technology, into commercial products. Therefore, any limitations on our ability to utilize these technologies may impair our ability to develop, out-license, or market and sell our products.

We may not be successful in obtaining necessary rights to any products we may develop through acquisitions and in-licenses.

We may need to obtain additional licenses from our existing licensors or otherwise acquire or in-license any intellectual property rights from third parties that we identify as necessary for our products. It is possible that we may be unable to obtain any additional licenses or acquire such intellectual property rights at a reasonable cost or on reasonable terms, if at all. The licensing or acquisition of third-party intellectual property rights is a competitive area, and several more established companies may pursue strategies to license or acquire third-party intellectual property rights that we may consider attractive or necessary. These established companies may have a competitive advantage over us due to their size, capital resources, and greater clinical development and commercialization capabilities. In addition, companies that perceive us to be a competitor may be unwilling to assign or license rights to us. We also may be unable to license or acquire third-party intellectual property rights on terms that would allow us to make an appropriate return on our investment or at all. In that event, we may be required to expend significant time and resources to redesign our technology, products, or the methods for manufacturing them or to develop or license replacement technology, all of which may not be feasible on a technical or commercial basis. If we are unable to do so, we may be unable to develop or commercialize the affected products, which could have a material adverse effect on our business, financial condition, and results of operations.

Any collaboration or partnership arrangements that we may enter into in the future may not be successful, which could materially and adversely affect our ability to develop and commercialize our products.

Any future collaborations that we enter into may not be successful. The success of our collaboration arrangements will depend heavily on the efforts and activities of our collaborators. Collaborations are subject to numerous risks, which may include that:

- collaborators have significant discretion in determining the efforts and resources that they will apply to collaborations;
- collaborators may not pursue development and commercialization of our products or may elect not to continue or renew development or commercialization programs based on trial or test results, changes in their strategic focus due to the acquisition of competitive products, availability of funding, or other external factors, such as a business combination that diverts resources or creates competing priorities;
- collaborators could independently develop, or develop with third parties, products that compete directly or indirectly with our current and future products;
- a collaborator with marketing, manufacturing, and distribution rights to one or more products may not commit sufficient resources to or otherwise not perform satisfactorily in carrying out these activities;
- we could grant exclusive rights to our collaborators that would prevent us from collaborating with others;
- collaborators may not properly maintain or defend our intellectual property rights or may use our intellectual property or Confidential Information in a way that gives rise to actual or threatened litigation that could jeopardize or invalidate our intellectual property or Confidential Information or expose us to potential liability;
- disputes may arise between us and a collaborator that cause the delay or termination of the research, development, or commercialization of our current or future products, or that result in costly litigation or arbitration that diverts management attention and resources;
- collaborations may be terminated, and, if terminated, may result in a need for additional capital to pursue further development or commercialization of the applicable current or future products;
- collaborators may own or co-own intellectual property covering our products that result from our collaborating with them, and in such cases, we would not have the exclusive right to develop or commercialize such intellectual property; and
- a collaborator's sales and marketing activities or other operations may not be in compliance with applicable laws, resulting in civil or criminal proceedings.

If we are unable to protect the confidentiality of our other Confidential Information, our business and competitive position may be materially and adversely affected.

In addition to patent protection, we also rely on other proprietary rights, including protection of trade secrets, and other Confidential Information that is not patentable or that we elect not to patent. However, trade secrets can be difficult to protect, and some courts are less willing or unwilling to protect trade secrets. To maintain the confidentiality of our trade secrets and Confidential Information, we rely heavily on confidentiality provisions and other restrictive covenants that we have in contracts with our employees, consultants, collaborators, and others upon the commencement of their relationship with us. We cannot guarantee that we have entered into such agreements with each party that may have or have had access to our trade secrets or proprietary technology and processes. We may not be able to prevent the unauthorized disclosure or use of our technical knowledge or other trade secrets by such third parties, despite the existence generally of these confidentiality restrictions. These contracts may not provide meaningful protection for our trade secrets, know-how, or other Confidential Information in the event of any unauthorized use, misappropriation, or disclosure of such trade secrets, know-how, or other Confidential Information. There can be no assurance that such third parties will not breach their agreements with us, that we will

have adequate remedies for any breach, or that our trade secrets will not otherwise become known or independently developed by competitors. Despite the protections we place on our intellectual property or other proprietary rights, monitoring unauthorized use and disclosure of our intellectual property is difficult, and we do not know whether the steps we have taken to protect our intellectual property or other proprietary rights will be adequate. In addition, the laws of many foreign countries will not protect our intellectual property or other proprietary rights to the same extent as the laws of the United States. Consequently, we may be unable to prevent our proprietary technology from being exploited abroad, which could materially and adversely affect our ability to expand to international markets or require costly efforts to protect our technology.

To the extent our intellectual property or other Confidential Information protection is incomplete, we are exposed to a greater risk of direct competition. A third party could, without authorization, copy or otherwise obtain and use our products or technology, or develop similar technology. Our competitors could purchase our products and attempt to replicate some or all of the competitive advantages we derive from our development efforts or design around our protected technology. Our failure to secure, protect, and enforce our intellectual property rights could materially and adversely harm the value of our products, brand, and business. The theft or unauthorized use or publication of our trade secrets and other Confidential Information could reduce the differentiation of our products and harm our business, the value of our investment in development or business acquisitions could be reduced, and third parties might make claims against us related to losses of their confidential information. Any of the foregoing could have a material adverse effect on our business, financial condition, and results of operations.

Further, it is possible that others will independently develop the same or similar technology or otherwise obtain access to our unpatented technology, and in such cases, we could not assert any trade secret rights against such parties. Costly and time-consuming litigation could be necessary to enforce and determine the scope of our trade secret rights and related confidentiality and nondisclosure provisions. If we fail to obtain or maintain trade secret protection, or if our competitors obtain our trade secrets or independently develop technology similar to ours or competing technologies, our competitive market position could be materially and adversely affected. In addition, some courts are less willing or unwilling to protect trade secrets, and agreement terms that address non-competition are difficult to enforce in many jurisdictions and might not be enforceable in certain cases.

We also seek to preserve the integrity and confidentiality of our data and other Confidential Information by maintaining physical security of our premises and physical and electronic security of our information technology systems. While we have confidence in these individuals, organizations, and systems, agreements or security measures may be breached and detecting the disclosure or misappropriation of Confidential Information and enforcing a claim that a party illegally disclosed or misappropriated Confidential Information is difficult, expensive, and time-consuming, and the outcome is unpredictable. Further, we may not be able to obtain adequate remedies for any breach.

Changes in U.S. patent law or the patent law of other countries or jurisdictions could diminish the value of our patents in general, thereby impairing our ability to protect our products and could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our current or future patents.

Our ability to obtain patents and the breadth of any patents obtained is uncertain in part because, to date, some legal principles remain unresolved, and there has not been a consistent policy regarding the breadth or interpretation of claims allowed in patents in the United States and other countries. Changes in either patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property rights or narrow the scope of our patent protection, which in turn could diminish the commercial value of our products, services, and technologies.

The United States has enacted and implemented wide-ranging patent reform legislation, and further patent reform legislation may pass in the future that could lead to additional uncertainties and increased costs surrounding the prosecution, enforcement, and defense of our patents and applications. The U.S. Supreme Court has ruled on several patent cases in recent years, either narrowing the scope of patent protection available in certain circumstances or weakening the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with

respect to the value of patents, once obtained. Depending on actions by Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce patents that we have licensed or that we might obtain in the future. Similarly, changes in patent law and regulations in other countries or jurisdictions, or changes in the governmental bodies that enforce them, or changes in how the relevant governmental authority enforces patent laws or regulations may weaken our ability to obtain new patents or to enforce patents that we have licensed or that we may obtain in the future. For example, in June 2023, the European Unitary Patent system and the European Unified Patent Court (UPC) were launched. European patent applications now have the option, upon grant of a patent, of becoming a Unitary Patent which is subject to the jurisdiction of the UPC. In addition, conventional European patents, both already granted at the time the new system began and granted thereafter, are subject to the jurisdiction of the UPC, unless actively opted out. This was a significant change in European patent practice, and deciding whether to opt-in or opt-out of Unitary Patent practice entails strategic and cost considerations. The UPC provides third parties with a new forum to centrally revoke our European patents and makes it possible for a third party to obtain pan-European injunctions against us. It will be several years before we will understand the scope of patent rights that will be recognized and the strength of patent remedies that will be provided by the UPC. While we have the right to opt our patents out of the UPC over the first seven years of the court's existence, doing so may preclude us from realizing the benefits of the UPC. Moreover, the decision whether to opt-in or opt-out of Unitary Patent status will require coordinating with co-applicants, if any, adding complexity to any such decision.

We cannot predict future changes in the interpretation of patent laws in the United States and other countries or changes to patent laws that might be enacted into law by U.S. and foreign legislative bodies. Those changes may materially and adversely affect our patents or patent applications and our ability to obtain additional patent protection in the future. Any of the foregoing could have a material adverse effect on our competitive position, business, financial condition, and results of operations.

We may not be able to protect our intellectual property rights throughout the world, which could impair our business.

Filing, prosecuting, and defending patents covering Vivistim Therapy, and any of our future products throughout the world would be prohibitively expensive, and the laws of foreign countries may not protect our rights to the same extent as the laws of the United States. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we may have or obtain patent protection, but where patent enforcement is not as strong as that in the United States. These unauthorized products may compete with our products in such jurisdictions and take away our market share where we do not have any issued or licensed patents, and any future patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Intellectual property rights do not necessarily address all potential threats to our competitive advantage.

The degree of future protection afforded by our intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect our business or permit us to maintain our competitive advantage. The following examples are illustrative:

- others may be able to make products that are similar to our current or future products we intend to commercialize that are not covered by the patents that we exclusively licensed and have the right to enforce;
- an in-license necessary for the manufacture, use, sale, offer for sale, or importation of one or more of our current or future products may be terminated by the licensor;
- we or any of our current or future licensors or collaborators might not have been the first to make the inventions covered by the issued patents or pending patent applications that we own;
- we or any of our current or future licensors might not have been the first to file patent applications covering certain of our inventions;

- others may independently develop similar or alternative technologies or duplicate any of our technologies without infringing our intellectual property rights;
- it is possible that our pending patent applications will not lead to issued patents;
- issued patents that we own may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges;
- our competitors might conduct research and development activities in the United States and other countries that provide a safe harbor from patent infringement claims for certain research and development activities, as well as in countries where we do not have patent rights, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets;
- the patents of others may have an adverse effect on our business; and
- we may not develop additional proprietary technologies that are patentable.

Our use of "open source" software could subject the proprietary software we use to general release, materially and adversely affect our ability to sell our products and subject us to possible litigation.

We use "open source software" in a portion of the products or technologies licensed, developed, or distributed by us, including as incorporated into software we receive from third-party commercial software vendors, and we may incorporate open source software into other products in the future. Such open source software is generally licensed by its authors or other third parties under open source licenses. Some open source licenses contain requirements that we disclose source code for modifications we make to the open source software and that we license such modifications to third parties at no cost. In some circumstances, distribution of the software we utilize in connection with open source software could require that we disclose and license some or all of our proprietary code in that software, as well as distribute our products that use particular open source software at no cost to the user. We monitor our use of open source software in an effort to avoid uses in a manner that would require us to disclose or grant licenses under our proprietary source code; however, there can be no assurance that such efforts will be successful. Open source license terms are often ambiguous and such use could inadvertently occur. There is little legal precedent governing the interpretation of many of the terms of these licenses, and the potential impact of these terms on our business may result in unanticipated obligations regarding our products and technologies. Companies that incorporate open source software into their products have, in the past, faced claims seeking enforcement of open source license provisions and claims asserting ownership of open source software incorporated into their products. If an author or other third party that distributes such open source software were to allege that we had not complied with the conditions of an open source license, we could incur significant legal costs defending ourselves against such allegations. In the event such claims were successful, we could be subject to significant damages or be enjoined from the distribution of our products. In addition, if we combine our proprietary software with open source software in certain ways, under some open source licenses, we could be required to release the source code of our proprietary software, which could substantially help our competitors develop products that are similar to or better than ours and otherwise adversely affect our business. These risks could be difficult to eliminate or manage, and, if not addressed, could materially and adversely affect our business, financial condition, and results of operations.

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

We rely on trademarks, service marks, tradenames, and brand names to distinguish our products from the products of our competitors and have registered or applied to register these trademarks. We cannot assure you that our trademark applications will be approved. During trademark registration proceedings, we may receive rejections. Although we are given an opportunity to respond to those rejections, we may be unable to overcome such rejections. In addition, in proceedings before the USPTO and comparable agencies in many foreign jurisdictions, third parties are given an opportunity to oppose pending trademark applications and to seek to cancel registered trademarks. Opposition or cancellation proceedings may be filed against our trademarks, and our trademarks may not survive such proceedings. In the event that our trademarks are successfully challenged, we could be forced to rebrand our

products, which could result in loss of brand recognition and could require us to devote resources towards advertising and marketing new brands.

For example, we have not registered the name "MicroTransponder," "Mobia" or "Mobia Medical" as a word trademark in the United States on the principal register, although we have obtained registration of the name "MicroTransponder" on the supplemental register. Registration on the principal register offers certain protections not provided to registrations on the supplemental register, including the right to obtain statutory damages and attorneys' fees in connection with third party infringement of the trademark, the right to register a mark with U.S. Customs to prevent the importation of goods that contain infringing marks and the ability to seek incontestability status after five years of registration on the primary register. Without a registered trademark on the principal register, we may encounter difficulty in enforcing, or be unable to enforce, the name "MicroTransponder," "Mobia" or "Mobia Medical" against third parties in the United States, which could adversely affect our business and our ability to effectively compete in the marketplace.

At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. Certain of our current or future trademarks may become so well known by the public that their use becomes generic and they lose trademark protection. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business, financial condition and results of operations may be materially and adversely affected.

Risks Related to Government Regulation

Our products and operations are subject to extensive government regulation and oversight in the United States, and our failure to comply with applicable requirements could materially and adversely affect our business.

Our products are regulated as medical devices in the United States. Medical devices and their manufacturers and product developers are subject to extensive regulation in the United States, including by the FDA. The FDA regulates, among other things, with respect to medical devices: design, development, and manufacturing; testing, labeling, content, and language of instructions for use and storage; clinical trials; product safety; establishment registration and device listing; marketing, sales, and distribution; premarket clearance, classification, and approval or certification; recordkeeping procedures; complaint procedures and protocols, including documentation thereof; advertising and promotion; recalls and field safety corrective actions; post-market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; post-market studies; and product import and export.

The regulations to which we are subject are complex, burdensome to understand and apply, and have tended to become more stringent over time. Regulatory changes could result in restrictions on our ability to carry on or expand our operations, higher than anticipated costs or lower than anticipated sales. The FDA enforces its regulatory requirements through, among other means, periodic unannounced inspections. We do not know whether we or any of our contract manufacturers will be found compliant in connection with any future FDA or foreign inspections. Failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as: FDA inspectional observations; warning letters; fines; injunctions; civil penalties; termination of distribution; import alerts; recalls or seizures of products; delays in the introduction of products into the market; total or partial suspension of production; refusal to grant future clearances or approvals; withdrawals or suspensions of clearances or approvals, resulting in prohibitions on sales of our products; and in the most serious cases, criminal penalties. For example, following a routine FDA inspection in March 2026, we received a notice of inspectional observations, or Form 483, with one observation involving two events for which a medical device report was not submitted within 30 days of receiving or otherwise becoming aware of information regarding such events. These events have since been reported and we believe we have since addressed this observation with a corrective and preventative action plan, which included streamlined procedures for evaluating potential adverse events and training for relevant personnel at the Company regarding these procedures and reporting. We submitted a formal written response to FDA in April 2026. To date, the FDA has not taken any further action with respect to the inspection or its findings.

Failure to maintain marketing authorizations for our products, or to timely obtain necessary marketing authorizations for our future products, may have a material and adverse effect on our business, financial condition and results of operations.

Our products are subject to extensive regulation by the FDA and the Federal Communications Commission (the FCC) in the United States and by regulatory agencies in other countries where we do business. For medical devices involving radio frequency (RF) wireless technologies, the FDA's policies on wireless medical devices coordinate with the FCC. In the United States, before we can market a new medical device, or a new use of, or other significant modification to an existing, marketed medical device, we must first receive either clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act (the FDCA), approval of a premarket approval (PMA) application, or grant of a *de novo* classification request from the FDA, unless an exemption applies. In the 510(k) clearance process, before a device may be marketed, the FDA must determine that a proposed device is "substantially equivalent" to a legally-marketed "predicate" device, which includes a device that has been previously cleared through the 510(k) process, a device that was legally marketed prior to May 28, 1976 (pre-amendments device), a device that was originally on the U.S. market pursuant to an approved PMA and later down-classified, or a 510(k)-exempt device. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data are sometimes required to support substantial equivalence. In the process of obtaining PMA approval, the FDA must determine that a proposed device is safe and effective for its intended use based, in part, on extensive data, including, but not limited to, technical, pre-clinical, clinical trial, manufacturing, and labeling data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting, or implantable devices.

In the *de novo* classification process, a manufacturer whose novel device under the FDCA would otherwise be automatically classified as Class III and require the submission and approval of a PMA prior to marketing is able to request down-classification of the device to Class I or Class II on the basis that the device presents a low or moderate risk. If the FDA grants the *de novo* classification request, the applicant will receive authorization to market the device. This device type may be used subsequently as a predicate device for future 510(k) submissions.

The PMA approval, 510(k) clearance and *de novo* classification processes can be expensive, lengthy, and uncertain. The FDA's 510(k) clearance process usually takes from three to 12 months, but can take longer. The process of obtaining a PMA is much more costly and uncertain than the 510(k) clearance process and generally takes from one to three years, or even longer, from the time the application is submitted to the FDA. In addition, a PMA generally requires the performance of one or more clinical trials. Clinical data may also be required in connection with an application for 510(k) clearance or a *de novo* classification request. Despite the time, effort and cost, a device may not obtain marketing authorization by the FDA. We have obtained PMA approval for Vivistim Therapy, and we must obtain marketing authorization for any future devices we develop or future additional indications for Vivistim Therapy, unless they are exempt. Marketing authorizations for any of our future products, if granted, may include significant limitations on the indicated uses for the device, which may limit the potential commercial market for the device.

In the United States, any modification to a medical device for which we have obtained a PMA may require us to submit a new PMA or PMA supplement and obtain FDA approval. For example, certain changes to an approved device, such as changes in manufacturing facilities, methods, or quality control procedures, or changes in the design performance specifications, which affect the safety or effectiveness of the device, require submission of a PMA supplement. Certain other changes to an approved device require the submission of a new PMA, such as when the design change causes a different intended use, mode of operation, and technical basis of operation, or when the design change is so significant that a new generation of the device will be developed, and the data that were submitted with the original PMA are not applicable for the change in demonstrating a reasonable assurance of safety and effectiveness. We have made modifications to our approved Vivistim Therapy and submitted and received approval of PMA supplements in the past. We may make modifications or add additional features in the future to Vivistim Therapy that we believe do not require a new approval of a PMA or PMA supplement. If the FDA disagrees with our determination and requires us to seek new marketing authorizations for the modifications for which we have concluded that new marketing authorizations are unnecessary, we may be required to cease

marketing or to recall the modified product until we obtain such marketing authorization, and we may be subject to significant regulatory fines or penalties. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected, product introductions or modifications could be delayed or canceled, which could adversely affect our business.

The FDA can delay, limit or deny marketing authorization of a device for many reasons, including:

- our inability to demonstrate to the satisfaction of the FDA that our products are substantially equivalent to a predicate device or are safe and effective for their intended uses;
- the disagreement of the FDA with the design or implementation of clinical trials or the interpretation of data from preclinical trials or clinical trials;
- serious and unexpected adverse device effects experienced by participants in clinical trials;
- the data from preclinical trials and clinical trials may be insufficient to support clearance, *de novo* classification, or approval, where required;
- our inability to demonstrate that the clinical and other benefits of the device outweigh the risks;
- the manufacturing process or facilities we use may not meet applicable requirements; and
- the potential for marketing authorization regulations of the FDA to change significantly in a manner rendering our clinical data or regulatory filings insufficient for marketing authorization.

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

We are subject to ongoing and extensive regulatory requirements governing, among other things, the manufacture, marketing, advertising, medical device reporting, sale, promotion, import, export, registration, and listing of devices. For example, medical device manufacturers must submit certain reports to the FDA and keep required records as a condition of obtaining and maintaining marketing authorization. These reports include information about failures and certain adverse events potentially associated with the device after its marketing authorization. Failure to submit such reports, or failure to submit the reports in a timely manner, could result in enforcement action by the FDA. Following its review of the periodic reports, the FDA might ask for additional information or initiate further investigation.

Regulatory changes could result in restrictions on our ability to continue or expand our operations, higher than anticipated costs, or lower than anticipated sales. We have ongoing responsibilities under FDA regulations, and the FDA and state regulatory authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state regulatory authorities, which may include any of the following or other sanctions:

- untitled letters or warning letters;
- fines, injunctions, consent decrees, and civil penalties;
- recalls, termination of distribution, administrative detention, or seizure of our products;
- customer notifications or repair, replacement, or refunds;
- operating restrictions or partial suspension or total shutdown of production;
- delays in or refusal to grant our requests for future clearances, de novo classifications or approvals, or comparable foreign marketing authorizations of new products, new intended uses, or modifications to existing products;

- withdrawals or suspensions of any granted marketing authorizations, resulting in prohibitions on sales of our products;
- FDA refusal to issue certificates to foreign governments needed to export products for sale in other countries; and
- criminal prosecution.

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

In addition, the FDA may change its marketing authorization policies which may affect future products. The FDA may adopt additional regulations or revise existing regulations, or take other actions, which may prevent or delay marketing authorization of any products under development or impact our ability to modify any products authorized for market on a timely basis. Such changes may also occur in foreign jurisdictions where we may market our products in the future. Such changes could impose additional requirements upon us that could delay our ability to obtain future marketing authorizations, increase the costs of compliance, or restrict our ability to maintain any marketing authorizations we have obtained. See the risk factor titled, *"Legislative or regulatory reforms in the United States may make it more difficult and costly for us to manufacture, market, or distribute our products, or to obtain marketing authorizations for any future products."*

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

Vivistim Therapy, and any marketing authorization we may receive for future products, is, and will be, limited to specified indications for use. We train our commercial team, including our direct sales force, to not promote our device for use outside of the FDA-authorized indications for use, known as "off-label uses." However, this training may not be effective in preventing all instances of off-label promotion. We cannot, in addition, prevent a healthcare professional from using our devices off-label, when in the healthcare professional's independent professional judgment he or she deems it appropriate. There may be increased risk of injury to patients if healthcare professionals attempt to use our devices off-label, which could harm our reputation in the marketplace among healthcare professionals and patients.

If the FDA determines that our promotional materials or training constitute promotion of an off-label use, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance or imposition of an untitled letter, which is used for violators that do not necessitate a warning letter, injunction, seizure, civil fine, or criminal penalties. It is also possible that other federal or state enforcement authorities might take action under other regulatory authority, such as false advertising and consumer protection laws, or false claims laws, if they consider our business activities to constitute promotion of an off-label use, which could result in significant penalties, including, but not limited to, criminal, civil, and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs, and the curtailment of our operations.

In addition, healthcare professionals may misuse our products or use improper techniques if they are not adequately trained, potentially leading to injury and an increased risk of product liability. If our devices are misused or used with improper technique, we may become subject to costly litigation by our customers or their patients. As described above, even if we are ultimately successful in our defense, product liability claims could divert management's attention from our core business, be expensive to defend, and result in sizeable damage awards against us that may not be covered by insurance, all of which would have a material adverse effect on our business, financial condition and results of operations.

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

In the United States, the methods used in, and the facilities used for, the manufacture of medical devices must comply with the FDA's Current Good Manufacturing Practices for medical devices, known as the Quality System Regulation (QSR), which is a complex regulatory scheme that covers the procedures and documentation of the design, testing, production, process controls, quality assurance, labeling, packaging, handling, storage, distribution, installation, servicing, and shipping of medical devices. On February 23, 2024, the FDA issued a final rule to amend the QSR to align more closely with the International Organization for Standardization (ISO) standards. Specifically, this final rule, which the FDA expects to go into effect on February 2, 2026, replaces the QSR with the Quality Management System Regulation (QMSR), and among other things, incorporates by reference the quality management system requirements of ISO 13485:2016. Although the FDA has stated that the standards contained in ISO 13485:2016 are substantially similar to those set forth in the QSR, it is unclear the extent to which this final rule, once effective, could impose additional or different regulatory requirements on us that could increase the costs of compliance or otherwise create market pressure that may negatively affect our business. Furthermore, we are required to verify that our suppliers maintain facilities, procedures, and operations that comply with our quality standards and applicable regulatory requirements. The FDA enforces the QSR, and is expected to enforce the QMSR, through periodic announced or unannounced inspections of medical device manufacturing facilities, which may include the facilities of subcontractors. Our products are also subject to similar state regulations governing manufacturing.

Despite our efforts to ensure compliance, we or our third-party manufacturers may not take the necessary steps to comply with applicable regulations, which could cause delays in the delivery of our medical devices. In addition, failure to comply with applicable FDA requirements or later discovery of previously unknown problems with our products or manufacturing processes could result in, among other things: warning letters or untitled letters; fines, injunctions, or civil penalties; suspension or withdrawal of marketing authorizations; seizures or recalls of our products; total or partial suspension of production or distribution; administrative or judicially imposed sanctions; the FDA's refusal to grant pending or future clearances or approvals for our products or similar decisions by foreign regulatory authorities or notified bodies; clinical holds; refusal to permit the import or export of our products; and criminal prosecution of us, our suppliers, or our employees. Any of these actions could significantly and negatively affect supply of our products. If any of these events occurs, our reputation could be harmed, we could be exposed to product liability claims and we could lose customers and experience reduced sales and increased costs. We are also subject to similar state requirements and licenses.

Our products have in the past, and may in the future cause or contribute to adverse medical events or be subject to failures or malfunctions which we may be required to report to the FDA, and if we fail to do so, we would be subject to sanctions that could materially and adversely affect our reputation, business, financial condition and results of operations. In addition, the discovery of serious safety issues with our products, or a recall of our products either voluntarily or at the direction of the FDA, could have a material adverse effect on us.

There have been, and there may continue to be side effects and adverse events associated with the use of our medical devices or any future devices we develop. The FDA's medical device reporting regulations require us to assess reportability of adverse events that come to our attention and report to the FDA when we receive or become aware of information that reasonably suggests that one or more of our products may have caused or contributed to a death or serious injury or malfunctioned in a way that, if the malfunction were to recur, it could cause or contribute to a death or serious injury. The timing of our obligation to report is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event or if it is an adverse event that is unexpected or removed in time from the use of the product. The FDA may also disagree with our determinations that an event was not reportable. If we fail to comply with our reporting obligations, the FDA could take action, including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our marketing authorizations, seizure of our products, or delay in obtaining marketing authorizations for our future products.

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

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

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

Healthcare reform initiatives and other administrative and legislative proposals in the United States may materially and adversely affect our business, financial condition and results of operations.

There have been and continue to be proposals by the federal government, state governments, regulators, and third-party payors to control or manage the increased costs of healthcare and, more generally, to reform the United States healthcare system. Outside of the United States, foreign governments and regulatory authorities may implement new requirements that could impact our business and market acceptance. Certain of these proposals could limit the prices we are able to charge for our products or the coverage and reimbursement available for our products and could limit the acceptance and availability of our products. The adoption of proposals to control costs could have a material adverse effect on our business, financial condition and results of operations.

For example, in the United States, in March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, together, the Affordable Care Act (the ACA) was enacted. The ACA made a number of substantial changes to the way healthcare is financed by both governmental and private insurers, including the imposition of health insurance mandates on employers and individuals, the provision of subsidies to eligible individuals enrolled in plans offered on the health insurance exchanges and the expansion of the Medicaid program.

Since its enactment, there have been judicial, executive and Congressional challenges to certain aspects of the ACA. On June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. More recently, the One Big Beautiful Bill Act (the OBBBA) was signed into law on July 4, 2025, and contains provisions that, among other changes, are expected to reduce the number of individuals enrolled in state Medicaid programs and ACA marketplace plans, which could adversely affect commercialization of Vivistim Therapy. We cannot predict how other litigation or legislative efforts, or the healthcare reform measures of the Trump administration will impact our business. The Trump administration is currently pursuing policies to reduce regulations and expenditures across government including at the U.S. Department of Health and Human Services, the FDA, the CMS, and related agencies. It is possible that certain of these changes could impose additional limitations on the rates we will be able to charge for our current and future products or the amounts of reimbursement available for our customers for

procedures in which our products are utilized from governmental agencies or third-party payors. We cannot assure you that the ACA or the OBBBA, as currently enacted or as amended in the future, will not harm our business and financial results, and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. On August 2, 2011, the Budget Control Act of 2011 was signed into law, which, among other things, includes reductions to Medicare payments to providers, which went into effect on April 1, 2013, which, due to subsequent legislative amendments, will stay in effect through 2032, unless additional congressional action is taken.

Additionally, the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. The Medicare Access and CHIP Reauthorization Act of 2015 (the MACRA) enacted on April 16, 2015, repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments that are based on various performance measures and physicians' participation in alternative payment models such as accountable care organizations. It is unclear what effect new quality and payment programs may have on our business, financial condition, results of operations, or cash flows. These new laws may result in additional reductions in Medicare and other healthcare funding, which could have a material adverse effect on customers for our products, if approved, and accordingly, our financial operations.

There likely will continue to be legislative and regulatory proposals at the federal and state levels directed at containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future or their full impact. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may harm:

- our ability to set a price that we believe is fair for our products;
- our ability to generate revenue and achieve or maintain profitability; and
- the availability of capital.

Further, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several U.S. Congressional inquiries and proposed and enacted federal legislation designed to bring transparency to product pricing and reduce the cost of products and services under government healthcare programs. While some of these measures may require additional authorization to become effective, Congress and the Federal administration have each indicated that it will continue to seek new legislative or administrative measures to control product costs. Additionally, individual states in the United States have also increasingly passed legislation and implemented regulations designed to control product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. Moreover, regional healthcare authorities and individual hospitals are increasingly using bidding procedures to determine what products to purchase and which suppliers will be included in their programs. Adoption of price controls and other cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures may prevent or limit our ability to generate revenue and attain profitability. Various new healthcare reform proposals are emerging at the federal and state level. Any new federal and state healthcare initiatives that may be adopted could limit the amounts that federal and state governments will pay for healthcare products and services and could have a material adverse effect on our business, financial condition and results of operations.

If we fail to comply with U.S. federal and state fraud and abuse and other healthcare laws and regulations, we could face substantial penalties and our business operations and financial condition could be materially and adversely affected. In addition, any challenge to or investigation into our practices under these laws could cause adverse publicity and be costly to respond to, and thus could materially and adversely affect our business.

The U.S. healthcare industry is heavily regulated and closely scrutinized by foreign, federal, state and local authorities. We are subject to various state and federal fraud and abuse, anti-kickback, false claims, transparency

requirements, consumer protection and other healthcare laws and regulations. These laws constrain the business and financial arrangements and relationships through which we research, sell, market, and distribute our products, such as our arrangements with hospitals, physicians, therapists, customers and third-party payors. Healthcare fraud and abuse laws and related regulations are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. The laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute (AKS), which prohibits the knowing and willful offer, payment, solicitation or receipt of any bribe, kickback, rebate or other remuneration for referring an individual, in return for ordering, leasing, purchasing or recommending or arranging for or to induce the referral of an individual or the ordering, purchasing or leasing of items or services covered, in whole or in part, by any federal healthcare program, such as Medicare and Medicaid. "Remuneration" includes the transfer of anything of value, in cash or in kind and directly or indirectly. A person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- the federal False Claims Act (FCA), which imposes civil and criminal liability on individuals or entities that knowingly submit false or fraudulent claims for payment to the government or knowingly making, or causing to be made, a false statement in order to have a false claim paid, including qui tam or whistleblower suits. Private individuals can bring False Claims Act "qui tam" actions, on behalf of the government and such individuals, commonly known as "whistleblowers," may share in amounts paid by the entity to the government in fines or settlement. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act;
- the federal Civil Monetary Penalties Law, which prohibits, among other things, offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier;
- the criminal healthcare fraud provisions of HIPAA and related rules, which prohibit knowingly and willfully executing a scheme or artifice to defraud any healthcare benefit program or falsifying, concealing or covering up a material fact or making any material false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the AKS, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it to have committed a violation;
- the federal transparency requirements under the Physician Payments Sunshine Act, which requires, among other things, certain manufacturers of drugs, devices, biologics and medical supplies reimbursed under Medicare, Medicaid, or the Children's Health Insurance Program to report to CMS information related to payments and other transfers of value provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician providers (physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiology assistants and certified nurse midwives), and teaching hospitals and physician ownership and investment interests, including such ownership and investment interests held by a physician's immediate family members;
- federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- federal and state anti-inducement laws, which prohibit the offer or transfer of remuneration that would influence the patient to order or receive a healthcare item or service; and
- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers or patients, state laws that require device companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, and state and local laws that require medical

device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and require the registration of their TMs or other sales personnel.

Due to the breadth of these laws and the narrowness of statutory exceptions and regulatory safe harbors available, it is possible that some of our current or future practices, such as our commercial activities, interactions with physicians and patients, and reimbursement support activities might be challenged, by regulatory authorities, our competitors or others, under one or more of these laws.

To enforce compliance with the healthcare regulatory laws, certain enforcement bodies have recently increased their scrutiny of interactions between medical device and pharmaceutical manufacturers and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations and qui tam actions can be time-and resource-consuming and can divert management's attention from the business. Additionally, as a result of these investigations, manufacturers may have to agree to additional compliance and reporting requirements as part of a consent decree or corporate integrity agreement. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business, financial condition and results of operations. Even an unsuccessful challenge or investigation into our practices could cause adverse publicity and be costly.

Achieving and sustaining compliance with applicable federal and state anti-fraud and abuse laws may prove costly. If our operations are found to be in violation of any of the federal, state and foreign laws described above or any other current or future fraud and abuse or other healthcare laws and regulations that apply to us, we may be subject to significant penalties, including significant criminal, civil, and administrative penalties, damages, fines, exclusion from participation in government programs, such as Medicare and Medicaid, imprisonment, contractual damages, reputational harm and disgorgement and we could be required to curtail, restructure or cease our operations. Any of the foregoing consequences will materially and adversely affect our business, financial condition and results of operations.

Legislative or regulatory reforms in the United States may make it more difficult and costly for us to manufacture, market, or distribute our products, or to obtain marketing authorizations for any future products.

From time to time, legislation is drafted and introduced in Congress that could significantly change the statutory provisions governing the regulation of medical devices. In addition, the FDA may change its clearance and approval policies, adopt additional regulations, or revise existing regulations, or take other actions, which may prevent or delay marketing authorization of any future products under development or impact our ability to modify any products for which we have already obtained marketing authorizations on a timely basis. For example, on January 31, 2024, the FDA issued a final rule to amend the QSR, which establishes current good manufacturing practice requirements for medical device manufacturers, to align more closely with the ISO standards. Specifically, this final rule, which the FDA expects to go into effect on February 2, 2026, replaces the QSR with the QMSR, and among other things, incorporates by reference the quality management system requirements of ISO 13485:2016. Although the FDA has stated that the standards contained in ISO 13485:2016 are substantially similar to those set forth in the existing QSR, it is unclear the extent to which this final rule, once effective, could impose additional or different regulatory requirements on us that could increase the costs of compliance or otherwise create market pressure that may materially and adversely affect our business. It is unclear to what extent any other legislative or regulatory proposal, if adopted, could impose additional or different regulatory requirements on us that could increase the costs of compliance or otherwise create competition that may materially and adversely affect our business.

In addition, FDA regulations and guidance are often revised or reinterpreted by the FDA in ways that may significantly affect our business and our products. Any new statutes, regulations or revisions or reinterpretations of existing regulations may make it more difficult and costly to manufacture, market, or distribute our commercialized products, or may impose additional costs, lengthen marketing authorization review times, or make it more difficult to obtain marketing authorizations for any future products we develop. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may be subject to enforcement action and we may not achieve or sustain profitability.

We are subject to numerous laws and regulations related to anti-bribery and anti-corruption laws, such as the FCPA, anti-money laundering laws, and economic and trade sanctions, in which violations of these laws could result in substantial penalties and prosecution.

We are similarly subject to various heavily enforced anti-bribery and anti-corruption laws, such as the FCPA, anti-money laundering laws, and similar laws around the world. The FCPA or other anti-corruption and anti-bribery laws generally prohibit U.S. companies and their employees and intermediaries from offering, promising, authorizing, or making improper payments to foreign government officials for the purpose of obtaining or retaining business or gaining any advantage. We face significant risks if we, which includes our third-party business partners and intermediaries, fail to comply with the FCPA or other anti-corruption and anti-bribery laws. Certain suppliers of components of our devices are located in countries known to experience corruption. Business activities in these countries create the risk of unauthorized payments or offers of payments by one of our employees, consultants, contractors, or agents that could be in violation of various laws, including the FCPA and anti-bribery laws in these countries, even though these parties are not always subject to our control. While we have implemented policies and procedures designed to discourage these practices by our employees, consultants, contractors and agents and to identify and address potentially impermissible transactions under such laws and regulations, we cannot assure you that none of our employees, consultants, contractors and agents will take actions in violation of our policies, for which we may be ultimately responsible.

We are also subject to certain economic and trade sanctions programs, including those administered by the U.S. Department of the Treasury's Office of Foreign Assets Control, which prohibit or restrict transactions or dealings with or involving specified countries, their governments, and in certain circumstances, their nationals, or with individuals and entities that are specially-designated nationals, narcotics traffickers, terrorists or terrorist organizations, or otherwise blocked or sanctioned pursuant to applicable regulations. In addition, we are subject to export controls and similar trade restrictions, which restrict or prohibit the export, re-export, and transfer of certain goods, software, technology, and services to specified countries, governments, entities, and individuals. For example, in December 2021, the U.S. Congress enacted the Uyghur Forced Labor Prevention Act in an effort to prevent what it views as forced labor and human rights abuses in the Xinjiang Uyghur Autonomous Region, or XUAR, of China. If it is determined that our third-party suppliers and manufacturers produce or manufacture our components or products wholly or in part from the XUAR, or certain designated entities, then we could be prohibited from importing such components or products into the United States. Similarly, the U.S. government has increasingly issued new restrictions limiting access to federal contracts or funds for companies that source certain types of equipment or services from designated companies in China or other so-called countries of concern.

Responding to any enforcement action or related investigation may result in a materially significant diversion of management's attention and resources and significant defense costs and other professional fees. Any violation of the FCPA or other applicable anti-bribery or anti-corruption laws, anti-money laundering laws, or sanctions could result in whistleblower complaints, adverse media coverage, investigations, loss of export privileges, severe criminal or civil sanctions and suspension or debarment from U.S. government contracts, which could have a material adverse effect on our business, financial condition and results of operations.

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

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

We provide a limited warranty that our products are free of material defects in workmanship and materials and conform to specifications, and offer to repair or replace defective products. Although we have had very few warranty claims to date, we bear the risk of potential warranty claims on our products. If we receive a significant number of warranty claims or our products require significant amounts of service after sale, our operating expenses may substantially increase and our business and financial results will be adversely affected. We have a limited history of commercial placements from which to judge our rate of warranty claims, and we expect that the number of warranty claims we receive may increase as we scale our operations and as our existing commercial placements age. If product returns or warranty claims are significant or exceed our expectations, we could incur unanticipated reductions in sales or additional operating expenditures for parts and service. In addition, our reputation could be damaged and our products may not achieve the level of market acceptance that we are targeting in order to achieve and maintain profitability. In the event that we attempt to recover some or all of the expenses associated with a warranty claim against us from our suppliers or vendors, we may not be successful in claiming recovery under any warranty or indemnity provided to us by such suppliers or vendors or that any recovery from such vendor or supplier would be adequate.

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

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

We are required to file adverse event reports under Medical Device Reporting (MDR) regulations with the FDA that are publicly available on the FDA’s website. We are required to file MDRs if our products may have caused or contributed to a serious injury or death or malfunctioned in a way that could likely cause or contribute to a serious injury or death if it were to recur. Any such MDR that reports a significant adverse event could result in negative publicity, which could harm our reputation and future sales. If we fail to report events required to be reported to the FDA within the required timeframes, or at all, the FDA could take enforcement action and impose sanctions against us. Any such adverse event involving our products also could result in future voluntary corrective actions, such as recalls or customer notifications, or agency action, such as inspection or enforcement action. Any corrective action, whether voluntary or involuntary, as well as defending ourselves in a lawsuit, would require our time and capital, distract management from operating our business and may harm our reputation and have a material adverse effect on our business, financial condition and results of operations.

Our employees, independent contractors, consultants, commercial partners, distributors, and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk that our employees, independent contractors, commercial team, consultants, commercial partners, distributors, and vendors may engage in fraudulent or illegal activity. Misconduct by these parties could include intentional, reckless or negligent conduct, or disclosure of unauthorized activities to us that violates: (i) FDA laws and laws of other similar foreign regulatory bodies, including those laws requiring the reporting of true, complete and accurate information to such regulators; (ii) manufacturing standards; (iii) healthcare fraud and abuse laws, including anti-kickback law and patient inducement laws, in the United States and similar foreign fraudulent misconduct laws; or (iv) laws that require the true, complete and accurate reporting of financial information or data. These laws may impact, among other things, future sales, marketing, and education programs. In particular, the promotion, sales, and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commissions, certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials.

It is not always possible to identify and deter misconduct by our employees and other third parties, and the precautions we take to detect and prevent these activities may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, imposition of a corporate integrity agreement, additional integrity reporting, compliance and oversight obligations, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment of operations, any of which could materially and adversely affect our ability to operate our business and our results of operations. Whether or not we are successful in defending against any such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these claims or investigations, which could have a material adverse effect on our business, financial condition and results of operations.

Environmental and health safety laws may result in liabilities, expenses, and restrictions on our operations. Failure to comply with environmental laws and regulations could subject us to significant liability.

Our research and development and supply chain operations involve the use of hazardous substances and are subject to a variety of federal, state, local and foreign environmental laws and regulations relating to the storage, use, discharge, disposal, remediation of, and human exposure to, hazardous substances and the sale, labeling, collection, recycling, treatment, and disposal of products containing hazardous substances. Liability under environmental laws and regulations can be joint and several and without regard to fault or negligence. Compliance with environmental laws and regulations may be expensive and noncompliance could result in substantial liabilities, fines and penalties, personal injury and third-party property damage claims and substantial investigation and remediation costs. Environmental laws and regulations could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. We cannot assure you that violations of these laws and regulations will not occur in the future or have not occurred in the past as a result of human error, accidents, equipment failure or other causes. The expense associated with environmental regulation and remediation could materially and adversely our business, financial condition and results of operations.

Federal, state, local, and foreign laws regarding environmental protection, hazardous substances and human health and safety may adversely affect our business. These operations are permitted by regulatory authorities, and the resultant waste materials are disposed of in material compliance with environmental laws and regulations. Using hazardous substances in our operations exposes us to the risk of accidental injury, contamination or other liability from the use, storage, importation, handling, or disposal of hazardous materials. If our or our suppliers' operations result in the contamination of the environment or expose individuals to hazardous substances, we could be liable for

damages and fines, and any liability could significantly exceed our insurance coverage and have a material adverse effect on our business, financial condition, and results of operations. Liability under environmental laws and regulations can be joint and several and without regard to fault or negligence. Compliance with environmental laws and regulations may be expensive, and non-compliance could result in substantial liabilities, fines and penalties, personal injury and third-party property damage claims and substantial investigation and remediation costs. Environmental laws and regulations could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations. We cannot assure you that violations of these laws and regulations will not occur in the future or have not occurred in the past as a result of human error, accidents, equipment failure, or other causes. The expense associated with environmental regulation and remediation could materially and adversely affect our business, financial condition and results of operation.

We are subject to, or may in the future become subject to, ever-evolving federal, state, and foreign laws and regulations imposing obligations on how we collect, store, use and process information collected from or about individuals or their procedures using our products. Our or our vendors' actual or perceived failure to comply with such obligations could materially and adversely our business. Ensuring compliance with such legal requirements could also impair our efforts to maintain and expand our customer base, and thereby decrease our revenue.

In the conduct of our business, we may at times process personal information, including health-related personal information including from and about patients, as well as our employees and business contacts. When conducting clinical trials, we face risks associated with collecting trial participants' data, especially health data, in a manner consistent with applicable laws and regulations, such as the Common Rule, GCP guidelines, or FDA human subject protection regulations. We also face risks inherent in handling large volumes of data and in protecting the security of such data. In addition to specific healthcare laws and regulations, the U.S. federal government and various states have adopted or proposed laws, regulations, guidelines, and rules with respect to the collection, distribution, use, and storage of personal information of patients. We also depend on a number of third party vendors in relation to the operation of our business, a number of which process personal information on our behalf.

As our operations and business grow, we may become subject to or affected by new or additional data protection laws and regulations and face increased scrutiny or attention from regulatory authorities. In the United States, HIPAA imposes data privacy, security and breach notification obligations, on certain healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their business associates that perform certain services that involve creating, receiving, maintaining or transmitting individually identifiable health information for or on behalf of such covered entities, and their covered subcontractors. HIPAA requires covered entities and business associates to, among other things, develop and maintain policies with respect to the protection of, use and disclosure of protected health information (PHI). To the extent we create, receive, maintain or transmit PHI on behalf of covered entity customers or other third parties as a business associate under HIPAA, we are required to comply with applicable provisions of the HIPAA privacy, security and breach notification rules. HIPAA imposes, among other things, certain standards relating to the privacy, security, and breach reporting of individually identifiable health information. To the extent we are found to be out of compliance with HIPAA, we could face significant civil, criminal and administrative fines and penalties and/or additional reporting and oversight obligations if required to enter into a resolution agreement and corrective action plan with HHS to settle allegations of HIPAA non-compliance. HIPAA also authorizes state Attorneys General to file suit on behalf of their residents. Courts may award damages, costs and attorneys' fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to sue us in civil court for violations of HIPAA, its standards have been used as the basis for duty of care in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI.

Furthermore, violation of consumers' privacy rights or failure to take appropriate steps to keep consumers' personal information secure may constitute unfair and/or deceptive acts or practices in or affecting commerce in violation of Section 5(a) of the Federal Trade Commission Act, including entities subject to HIPAA. The Federal Trade Commission (FTC) expects a company's data security measures to be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities. Individually identifiable health information is considered sensitive data that merits particularly strong safeguards.

In addition, in recent years, certain states have adopted or modified data privacy and security laws and regulations that may apply to our business. For example, the California Consumer Privacy Act (CCPA) requires businesses that process personal information of California residents to, among other things: provide certain disclosures to California residents regarding the business's collection, use, and disclosure of their personal information; receive and respond to requests from California residents to access, delete, and correct their personal information, or to opt-out of certain disclosures of their personal information; and enter into specific contractual provisions with service providers that process California resident personal information on the business's behalf. The enactment of the CCPA is prompting a wave of similar legislative developments in other states in the United States, which creates a patchwork of overlapping but different state laws. For example, since the CCPA went into effect, comprehensive privacy statutes that share similarities with the CCPA are now in effect and enforceable in numerous states, and will soon be enforceable in several other states as well. Similar laws have been proposed in many other states and at the federal level as well. Certain states have also enacted new laws regulating specific types of personal information, such as health data, including the Washington My Health My Data Act and Nevada's Senate Bill 370. In the event we are subject to such laws, they impose, among other things, onerous notice and consent obligations, and prohibit certain personal information processing. To the extent we are found to be out of compliance with such laws, we could face negative publicity, government investigations and enforcement actions, claims by third parties (including class action lawsuits and private litigation) and damage to our reputation, any of which could have a material adverse effect on our business, financial condition and results of operations. As a result, our processing of health data in such states may subject us to additional compliance obligations and expose us to increased risk of liability.

Additionally, laws, regulations, and standards covering marketing, advertising, and other activities conducted by telephone, email, mobile devices, and the internet may be or become applicable to our business. If we fail to comply with these laws, regulations, and standards, we could face liability, reputational harm, and experience other impacts that could have a material adverse effect on our business.

Further, laws in all 50 U.S. states require businesses to provide notice to consumers whose personal information has been disclosed as a result of a data breach. These laws are not consistent, and compliance in the event of a widespread data breach may be difficult and costly. We also may be contractually required to notify consumers or other counterparties of a security breach. Regardless of our contractual protections, any actual or perceived security breach or breach of our contractual obligations could harm our reputation and brand, expose us to potential liability or require us to expend significant resources on data security and in responding to any such actual or perceived breach.

We also expect that there will continue to be new laws, regulations, and industry standards concerning privacy, data protection, and information security proposed and enacted in various jurisdictions in which we do business. These laws are in some cases relatively new and the interpretation and application of these laws are uncertain, may be inconsistent with or restrict our collection, storage, transfer, use and disclosure of personal information, and may require changes to our data processing practices and policies, including the acceptance of more onerous obligations in our contracts or additional costs, and we may be unable to make such changes and modifications in a commercially reasonable manner, or at all.

This risk is enhanced in certain jurisdictions and, as we expand our operations domestically and internationally, we may be subject to additional laws in other jurisdictions. Any actual or perceived failure by us or the third parties with whom we work to comply with privacy or security laws, policies, legal obligations, or industry standards, or any security incident that results in the unauthorized release or transfer of personally identifiable information, may result in governmental enforcement actions and investigations by U.S. federal and state regulatory authorities, fines and penalties, claims, proceedings or actions against us by individuals, consumer rights groups, government agencies, or others and we could incur significant costs in investigating and defending such claims, orders to make changes to our business, and/or adverse publicity, including by consumer advocacy groups and other private parties, and could cause our customers, their patients, and other healthcare professionals to lose trust in us, which could materially and adversely affect our reputation and have a material adverse effect on our business, financial condition and results of operations.

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

The ability of the FDA and foreign regulatory authorities to review and approve new products can be affected by a variety of factors, including government budget and funding levels, statutory, regulatory, and policy changes, the FDA's or foreign regulatory authorities' ability to hire and retain key personnel and accept the payment of user fees, and other events that may otherwise affect the FDA's or foreign regulatory authorities' ability to perform routine functions. Average review times at the FDA and foreign regulatory authorities have fluctuated in recent years as a result. In addition, government funding of other government agencies that fund research and development activities is subject to the political process, which is inherently fluid and unpredictable. Disruptions at the FDA and other agencies may also slow the time necessary for new medical devices or modifications to be approved or cleared by necessary government agencies, which would materially and adversely affect our business. For example, in recent years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA, have had to furlough critical employees and stop critical activities. In addition, the current U.S. Presidential administration has issued certain policies and Executive Orders directed towards reducing the employee headcount and costs associated with U.S. administrative agencies, including the FDA, and it remains unclear the degree to which these efforts may limit or otherwise adversely affect the FDA's ability to conduct routine activities.

If a prolonged government shutdown occurs, or if funding shortages or staffing limitations hinder or prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA or other such regulatory authorities to timely review and process our regulatory submissions, which could have a material adverse effect on our business.

Risks Related to our Common Stock and to this Offering

The price of our stock may be volatile, and you could lose all or part of your investment.

The trading price of our common stock following this offering is likely to be highly volatile and subject to wide fluctuations in response to various factors, some of which we cannot control. The stock market in general has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our common stock, regardless of our actual operating performance. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this prospectus, these factors include:

- the timing and results of preclinical trials and clinical trials of our current and future products or those of our competitors;
- the success of competitive products or announcements by potential competitors of their product development efforts;
- regulatory actions with respect to our products or our competitors' products;
- actual or anticipated changes in our growth rate relative to our competitors;
- regulatory or legal developments in the United States and other countries;
- the recruitment or departure of key personnel;
- announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures, collaborations, or capital commitments;
- actual or anticipated changes in estimates as to financial results, development timelines or recommendations by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;

- market conditions in the medical device sector;
- changes in the structure of healthcare payment systems;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us, our insiders, or our other stockholders;
- the concentration in ownership of our common stock;
- expiration of lock-up agreements;
- lawsuits threatened or filed against us, including litigation by current or former employees, alleging wrongful termination, sexual harassment, whistleblower, or other claims; and
- general economic, industry and market conditions.

The realization of any of the above risks or any of a broad range of other risks, including those described in this "Risk Factors" section, could have a dramatic and adverse impact on the market price of our common stock, which could also cause you to lose all or part of your investment.

In addition, companies that have experienced volatility in the market price of their stock have been subject to securities class action litigation. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management's attention from other business concerns, which could materially and adversely affect our business.

If securities or industry analysts do not publish research or reports, or if they publish adverse or misleading research or reports, regarding us, our business or our market, our stock price, and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that securities or industry analysts publish about us, our business, or our market. We do not currently have and may never obtain research coverage by securities or industry analysts. If no or few securities or industry analysts commence coverage of us, the stock price would be negatively impacted. In the event we obtain securities or industry analyst coverage, if any of the analysts who cover us issue adverse or misleading research or reports regarding us, our business model, our intellectual property, our stock performance, or our market, or if our results of operations fail to meet the expectations of analysts, our stock price would likely decline. If one or more of these analysts cease coverage of us or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline.

We do not know whether an active, liquid, and orderly trading market will develop for our common stock or what the market price of our common stock will be and as a result it may be difficult for you to sell your shares of our common stock.

Prior to this offering, no market for shares of our common stock existed and an active trading market for our shares may never develop or be sustained following this offering. We will determine the initial public offering price for our common stock through negotiations with certain of the underwriters, and the negotiated price may not be indicative of the market price of our common stock after this offering. The market value of our common stock may decrease from the initial public offering price. As a result of these and other factors, you may be unable to resell your shares of our common stock at or above the initial public offering price. The lack of an active market may impair your ability to sell your shares at the time you wish to sell them or at a price that you consider reasonable. The lack of an active market may also reduce the fair market value of your shares. Furthermore, an inactive market may also impair our ability to raise capital by selling shares of our common stock and may impair our ability to enter into strategic collaborations or acquire companies, technologies, or other assets by using our shares of common stock as consideration.

Sales of a substantial number of shares of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock. After this offering, we will have 33,085,391 outstanding shares of common stock based on the number of shares outstanding as of December 31, 2025, assuming (i) no exercise of the underwriters' option to purchase additional shares, (ii) no exercise of outstanding options, (iii) the occurrence of the Preferred Stock Conversion, (iv) the Warrant Exercises and (v) the Note Conversion immediately prior to the completion of this offering. This includes the shares that we sell in this offering, which may be resold in the public market immediately without restriction, unless purchased by our affiliates.

We and our executive officers, directors and the holders of an aggregate of over 98% of shares of our common stock have entered into lock-up agreements with the underwriters under which they have agreed, subject to specific exceptions described in the section titled "Underwriting," not to sell, directly or indirectly, any shares of common stock without the permission of BofA Securities, Inc., J.P. Morgan Securities LLC and Goldman Sachs & Co. LLC for a period of 180 days following the date of this prospectus. We refer to such period as the lock-up period. When the lock-up period expires, we and our securityholders subject to a lock-up agreement will be able to sell our shares in the public market. In addition, BofA Securities, Inc., J.P. Morgan Securities LLC and Goldman Sachs & Co. LLC may, in their sole discretion, release all or some portion of the shares subject to lock-up agreements at any time and for any reason. See the description of the lock-up agreement with the underwriters in the section titled "Underwriting" for more information. Sales of a substantial number of such shares upon expiration of the lock-up agreement, the perception that such sales may occur, or early release of these agreements, could cause our market price to fall or make it more difficult for you to sell your common stock at a time and price that you deem appropriate.

Moreover, after this offering, holders of an aggregate of 21,904,521 shares of our common stock will have rights, subject to certain conditions, to require us to file registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other stockholders. We also intend to register all shares of common stock that we may issue under our equity incentive plans. Once we register these shares, they can be freely sold in the public market upon issuance, subject to volume limitations applicable to affiliates and the lock-up agreements described in the "Underwriting" section of this prospectus.

Our principal stockholders and management own a significant percentage of our stock and will be able to exert significant control over matters subject to stockholder approval.

Prior to this offering, our executive officers, directors, holders of 5% or more of our capital stock, and their respective affiliates beneficially owned approximately 81.2% of our voting stock and, upon the completion of this offering, that same group will beneficially own approximately 57.3% of our outstanding voting stock (based on the number of shares of common stock outstanding as of December 31, 2025 assuming no exercise of the underwriters' option to purchase additional shares, no exercise of outstanding options, and no purchases of shares in this offering by any of this group), in each case assuming the occurrence of the Preferred Stock Conversion immediately prior to the completion of this offering. After this offering, this group of stockholders will have the ability to control us through this ownership position even if they do not purchase any additional shares in this offering. These stockholders may be able to determine all matters requiring stockholder approval. For example, these stockholders may be able to control elections of directors, amendments of our organizational documents or approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders. The interests of this group of stockholders may not always coincide with your interests or the interests of other stockholders and they may act in a manner that advances their best interests and not necessarily those of other stockholders, including seeking a premium value for their common stock, and might affect the prevailing market price for our common stock.

Certain of our existing stockholders, including entities that are affiliated with certain of our directors and beneficially own more than 5% of our outstanding common stock, may purchase shares of our common stock in this

offering at the initial public offering price. The previously discussed ownership percentage upon completion of this offering does not reflect the potential purchase of any shares in this offering by such stockholders.

We are an "emerging growth company," and a "smaller reporting company," and we cannot be certain if the reduced reporting requirements applicable to emerging growth companies will make our common stock less attractive to investors.

We are an "emerging growth company," as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we intend to take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including:

- being permitted to provide only two years of audited financial statements, in addition to any required unaudited interim financial statements, with correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure in this prospectus;
- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and proxy statements; and
- exemptions from the requirements of holding nonbinding advisory stockholder votes on executive compensation and stockholder approval of any golden parachute payments not previously approved.

We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

We will remain an emerging growth company until the earliest to occur of: (1) the last day of the fiscal year in which we have more than $1.235 billion in annual revenue; (2) the date we qualify as a "large accelerated filer," with at least $700.0 million of equity securities held by non-affiliates; (3) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period; and (4) the last day of the fiscal year ending after the fifth anniversary of our initial public offering.

Under the JOBS Act, emerging growth companies can also delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that we (i) are no longer an emerging growth company or (ii) affirmatively and irrevocably opt out of the extended transition period provided in the JOBS Act. As a result, our financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

We are also a "smaller reporting company" as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter.

We have identified a material weakness in our internal control over financial reporting. If we are unable to design and maintain effective internal control over financial reporting, our investors may lose confidence in the accuracy and completeness of our financial reports, which could adversely affect our stock price.

We identified a material weakness in our internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis.

We did not design and maintain effective controls over the review of inputs in the calculation of net loss per share attributable to common stockholders. The material weakness resulted in a revision to the weighted average number of shares and net loss per share attributable to common stock holders within the statement of operations and related disclosures as of and for the year ended December 31, 2025. Additionally, this material weakness could result in misstatements to net loss per share attributable to common stockholders and related disclosures that would result in a material misstatement to the annual or interim financial statements that would not be prevented or detected.

We are taking steps to remediate the material weakness and to strengthen our internal control over financial reporting, including reviewing and prioritizing this control deficiency for remediation. The material weakness will not be considered remediated until management completes the design and implementation of the controls and the controls operate for a sufficient period of time and management has concluded, through testing, that these controls are effective. The measures we will take may not be sufficient to remediate the material weakness we have identified or avoid potential future material weaknesses. If the steps we take do not remediate the material weakness in a timely manner, we will be unable to conclude that we maintain effective internal control over financial reporting. Accordingly, there could continue to be a reasonable possibility that a material misstatement of our financial statements would not be prevented or detected.

Our management will not be required to evaluate the effectiveness of our internal control over financial reporting until our second annual report on Form 10-K after the effectiveness of the registration statement of which this prospectus forms a part. As part of that evaluation, we may identify additional control deficiencies that are determined to constitute one or more material weaknesses. In addition, there can be no assurance that our remediation efforts will be successful, that our internal control over financial reporting will be effective as a result of these efforts, or that any future control deficiencies identified may not be material weaknesses that would be required to be reported in future periods.

We will incur increased costs as a result of operating as a public company, and our management will be required to devote substantial time to new compliance initiatives and corporate governance practices. Additionally, if we fail to maintain effective internal control over financial reporting, our ability to produce accurate financial statements on a timely basis could be impaired.

In connection with the preparation of our financial statements, we identified a material weakness in our internal control over financial reporting. Specifically, we did not design and maintain effective controls over the review of the inputs in the calculation of net loss per share attributable to common stockholders. The material weakness resulted in a revision to the weighted average number of shares and net loss per share attributable to common stockholders within the statement of operations and related disclosures as of and for the year ended December 31, 2025. Additionally, this material weakness could result in misstatements to net loss per share attributable to common stockholders and related disclosures that would result in a material misstatement to the annual or interim financial statements that would not be prevented or detected. We are in the process of implementing remediation measures, including the establishment of a control over the review of the calculation of weighted-average shares outstanding and net loss per share. The material weakness will not be considered remediated until management completes the design and implementation of the controls and the controls operate for a sufficient period of time and management has concluded, through testing, that these controls are effective.

As a public company, we will incur significant legal, accounting, and other expenses that we did not incur as a private company, and these expenses may increase even more after we are no longer an "emerging growth company." We will be subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Protection Act, as well as rules adopted, and to be adopted, by the SEC. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, we expect these rules and regulations to substantially increase our legal and financial compliance costs and to make some activities more time-consuming and costly, which will increase our operating expenses. For example, we expect these rules and regulations to make it more difficult and more expensive for us to obtain director and officer liability insurance and we may be required to incur substantial costs to maintain sufficient coverage. We cannot accurately predict or estimate the amount or timing of additional costs we may incur to respond to these requirements. The impact of these requirements could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees, or as executive officers.

In addition, as a public company we will be required to incur additional costs and obligations in order to comply with SEC rules that implement Section 404 of the Sarbanes-Oxley Act. Under these rules, beginning with our second annual report on Form 10-K after we become a public company, we will be required to make a formal assessment of the effectiveness of our internal control over financial reporting, and once we cease to be an emerging growth company, we will be required to include an attestation report on internal control over financial reporting issued by our independent registered public accounting firm. To achieve compliance with Section 404 within the prescribed period, we will be engaging in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants and adopt a detailed work plan to assess and document the adequacy of our internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are designed and operating effectively, and implement a continuous reporting and improvement process for internal control over financial reporting.

The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing, and possible remediation to meet the detailed standards under the rules. During the course of its testing, our management may identify additional material weaknesses or deficiencies which may not be remedied in time to meet the deadline imposed by the Sarbanes-Oxley Act. Our internal control over financial reporting will not prevent or detect all errors and all fraud. A control system, no matter how well designed and operated, can provide only reasonable, not absolute, assurance that the control system's objectives will be met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud will be detected.

If we are not able to remediate this material weakness and comply with the requirements of Section 404 of the Sarbanes-Oxley Act in a timely manner, or maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our stock could decline and we could be subject to sanctions or investigations by the stock exchange on which our common stock is listed, the SEC or other regulatory authorities.

We will have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

Our management will have broad discretion in the application of the net proceeds from this offering, and you will be relying on the judgment of our management regarding the application of these proceeds. You will not have the opportunity, as part of your investment decision, to assess whether we are using the proceeds appropriately. Our management might not apply the net proceeds in ways that ultimately increase the value of your investment. If we do not invest or apply the net proceeds from this offering in ways that enhance stockholder value, we may fail to achieve expected financial results, which could cause our stock price to decline.

We do not intend to pay dividends on our common stock so any returns will be limited to the value of our stock.

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain future earnings for the development, operation, and expansion of our business and do not anticipate declaring

or paying any cash dividends for the foreseeable future. Any return to stockholders will therefore be limited to any appreciation in the value of their stock. Any future determination related to dividend policy will be made at the discretion of our board of directors, subject to applicable laws, and will depend upon, among other factors, our results of operations, prospects, financial condition, contractual restrictions and capital requirements. In addition, our ability to pay cash dividends on our capital stock is limited by the terms of the Loan and Security Agreement and may be limited by the terms of any future debt or preferred securities we issue or any future credit facilities we enter into. Accordingly, you will have to, for the foreseeable future, rely on sales of your common stock after price appreciation, which may never occur, as the only way to realize any future gains on your investments.

Anti-takeover provisions in our amended and restated certificate of incorporation and amended and restated bylaws, as they will be in effect upon closing of this offering, and Delaware law might discourage, delay, or prevent a change in control of our company or changes in our management and, therefore, depress the market price of our common stock.

Our amended and restated certificate of incorporation and amended and restated bylaws, as we expect they will be in effect upon closing of this offering, will contain provisions that could depress the market price of our common stock by acting to discourage, delay, or prevent a change in control of our company or changes in our management that the stockholders of our company may deem advantageous. These provisions, among other things:

- establish a classified board of directors so that not all members of our board are elected at one time;
- permit only the board of directors to establish the number of directors and fill vacancies on the board;
- provide that directors may only be removed "for cause" and only with the approval of a majority of the voting power of the issued and outstanding capital stock;
- authorize the issuance of "blank check" preferred stock that our board could use to implement a stockholder rights plan (also known as a "poison pill");
- eliminate the ability of our stockholders to call special meetings of stockholders;
- prohibit stockholder action by written consent, which requires all stockholder actions to be taken at a meeting of our stockholders;
- prohibit cumulative voting;
- authorize our board of directors to amend the bylaws;
- establish advance notice requirements for nominations for election to our board or for proposing matters that can be acted upon by stockholders at annual stockholder meetings; and
- require a super-majority vote of stockholders to amend some provisions described above.

In addition, Section 203 of the General Corporation Law of the State of Delaware (DGCL), prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years has owned, 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

Any provision of our amended and restated certificate of incorporation, amended and restated bylaws or Delaware law that has the effect of delaying or preventing a change in control could limit the opportunity for our stockholders to receive a premium for their shares of our capital stock and could also affect the price that some investors are willing to pay for our common stock.

Our amended and restated bylaws that will become effective upon the closing of this offering provide that the Court of Chancery of the State of Delaware and the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated bylaws that will become effective upon the closing of this offering provide that the Court of Chancery of the State of Delaware (or, if the Court of Chancery does not have jurisdiction, another State court in Delaware or the federal district court for the District of Delaware) is the exclusive forum for the following (except for any claim as to which such court determines that there is an indispensable party not subject to the jurisdiction of such court (and the indispensable party does not consent to the personal jurisdiction of such court within 10 days following such determination), which is vested in the exclusive jurisdiction of a court or forum other than such court or for which such court does not have subject matter jurisdiction):

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of fiduciary duty;
- any action asserting a claim against us arising under the DGCL, our amended- and restated certificate of incorporation or our amended and restated bylaws; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction.

Such amended and restated bylaws further provide that the federal district courts of the United States of America will be the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act, against any person in connection with any offering of the Company's securities, including, without limitation and for the avoidance of doubt, any auditor, underwriter, expert, control person, or other defendant.

These exclusive-forum provisions may increase costs for a stockholder to bring a claim and may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage lawsuits against us and our directors, officers and other employees. Any person or entity purchasing or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions. There is uncertainty as to whether a court would enforce such provisions, and the enforceability of similar choice of forum provisions in other companies' charter documents has been challenged in legal proceedings. We also note that stockholders cannot waive compliance (or consent to noncompliance) with the federal securities laws and the rules and regulations thereunder. It is possible that a court could find these types of provisions to be inapplicable or unenforceable, and if a court were to find either exclusive-forum provision in our amended and restated bylaws to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could materially and adversely affect our business.

Our board of directors will be authorized to issue and designate shares of our preferred stock in additional series without stockholder approval.

Our amended and restated certificate of incorporation will authorize our board of directors, without the approval of our stockholders, to issue shares of our preferred stock, subject to limitations prescribed by applicable law, rules, and regulations and the provisions of our amended and restated certificate of incorporation, as shares of preferred stock in series, to establish from time to time the number of shares to be included in each such series and to fix the designation, powers, preferences, and rights of the shares of each such series and the qualifications, limitations or restrictions thereof. The powers, preferences, and rights of these additional series of preferred stock may be senior to or on parity with our common stock, which may reduce its value.

Our disclosure controls and procedures may not prevent or detect all errors or acts of fraud.

Upon the completion of this offering, we will become subject to the periodic reporting requirements of the Exchange Act. We must design our disclosure controls and procedures to reasonably assure that information we must disclose in reports we file or submit under the Exchange Act is accumulated and communicated to management, and recorded, processed, summarized, and reported within the time periods specified in the rules and forms of the SEC. We believe that any disclosure controls and procedures or internal controls and procedures, no matter how well-conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met.

These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. For example, our directors or executive officers could inadvertently fail to disclose a new relationship or arrangement, causing us to fail to make a required related party transaction disclosure. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by an unauthorized override of the controls. Accordingly, because of the inherent limitations in our control system, misstatements due to error or fraud may occur and not be detected.

Investors in this offering will experience immediate and substantial dilution.

The initial public offering price of our common stock is expected to be substantially higher than the pro forma as adjusted net tangible book value per share of our common stock. Therefore, if you purchase shares of our common stock in this offering, you will pay a price per share that substantially exceeds our pro forma as adjusted net tangible book value per share after this offering. Based on the initial public offering price of $15.00 per share, the midpoint of the price range set forth on the cover page of this prospectus, you will experience immediate dilution of $8.86 per share, representing the difference between our pro forma as adjusted net tangible book value per share after giving effect to this offering and the initial public offering price. In addition, purchasers of common stock in this offering will have contributed 40% of the aggregate price paid by all purchasers of our common stock but will own only approximately 30% of our total equity outstanding immediately after this offering. Furthermore, if the underwriters exercise their option to purchase additional shares, or outstanding options and warrants are exercised, you could experience further dilution. For a further description of the dilution that you will experience immediately after this offering, see the section titled “Dilution.”

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements. All statements other than statements of historical facts contained in this prospectus, including statements regarding our future liquidity, business strategy, clinical trials and clinical strategy, prior authorization and reimbursement strategy, real-world patient registries, as well as plans and objectives of management for future operations, are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that are in some cases beyond our control and may cause our actual results, performance, or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

In some cases, you can identify forward-looking statements by terms such as "may," "will," "should," "would," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential," or "continue" or the negative of these terms or other similar expressions. Forward-looking statements contained in this prospectus include, but are not limited to, statements about:

- the expected growth of our business and our organization;
- our ability to continue as a going concern;
- our ability to retain and recruit key personnel, including the continued development of a sales and marketing infrastructure;
- our expectations regarding the potential market size and size of the potential patient populations for Vivistim Therapy and any future products, if approved for commercial use;
- the expected use of our products by physicians and patients;
- our plans to conduct further clinical trials and patient registries;
- our plans and expected timeline related to our products, or developing new products, to address additional indications or otherwise;
- our ability to obtain, maintain and expand regulatory clearances for our products and any new products we create;
- our expected uses of the net proceeds from this offering and our existing cash and cash equivalents;
- our expectations regarding government and third-party payer coverage and reimbursement;
- our ability to purchase sufficient quantities from manufacturers of our products with sufficient quality and at an acceptable price;
- our ability to obtain an adequate supply of materials and components for our products from our third-party suppliers;
- our ability to obtain, maintain and enforce intellectual property protection for our products;
- our ability to expand our business into new geographic markets;
- the outcome of any litigations to which we may become a party;
- our compliance with extensive exchange requirements and government laws, rules, and regulations both in the United States and internationally;
- our estimates of our expenses, ongoing losses, future revenue, and capital requirements, as well as our need for, or ability to obtain, additional financing, and our future financial performance;
- our expectations regarding the time during which we will be an emerging growth company under the JOBS Act;

- our ability to identify and develop new and planned products or acquire new products;
- developments and projections relating to our competitors or our industry; and
- the sufficiency of our existing capital resources to fund our future operating expenses and capital expenditure requirements.

We caution you that the foregoing list does not contain all of the forward-looking statements made in this prospectus.

You should not rely upon forward-looking statements as predictions of future events. We have based the forward-looking statements contained in this prospectus primarily on our current expectations, estimates, forecasts, and projections about future events and trends that we believe may affect our business, financial condition, results of operations, and prospects. Although we believe that we have a reasonable basis for each forward-looking statement contained in this prospectus, we cannot guarantee that the future results, levels of activity, performance, or events and circumstances reflected in the forward-looking statements will be achieved or occur at all. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties, and other factors described in the section titled "Risk Factors" and elsewhere in this prospectus. Moreover, we operate in a very competitive and rapidly changing environment. New risks and uncertainties emerge from time to time, and risks and uncertainties that we currently deem immaterial may also impair our business operations and the market price for our common stock, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this prospectus. The results, events, and circumstances reflected in the forward-looking statements may not be achieved or occur, and actual results, events, or circumstances could differ materially from those described in the forward-looking statements.

The forward-looking statements made in this prospectus relate only to events as of the date on which the statements are made. We undertake no obligation to update any forward-looking statements made in this prospectus to reflect events or circumstances after the date of this prospectus or to reflect new information or the occurrence of unanticipated events, except as required by law. We may not actually achieve the plans, intentions, or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, or investments we may make.

In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date of this prospectus, and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and you are cautioned not to unduly rely upon these statements.

You should read this prospectus and the documents that we reference in this prospectus and have filed as exhibits to the registration statement, of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of the forward-looking statements in this prospectus by these cautionary statements.

USE OF PROCEEDS

We estimate that the net proceeds to us from the sale of the shares of our common stock in this offering will be approximately $134.5 million, or approximately $155.4 million if the underwriters exercise their option to purchase additional shares in full, based upon the assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

Each $1.00 increase (decrease) in the assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the net proceeds to us from this offering by approximately $9.3 million, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. Similarly, each increase (decrease) of 1.0 million shares in the number of shares offered by us would increase (decrease) the net proceeds to us from this offering by approximately $14.0 million, assuming that the assumed initial public offering price remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. We do not expect that a change in the initial public offering price or the number of shares by these amounts would have a material effect on our uses of the proceeds from this offering, although such change may accelerate the time at which we will need to seek additional capital.

The principal purposes of this offering are to obtain additional capital to support our operations, establish a public market for our common stock and facilitate our future access to the public capital markets. We currently intend to use the net proceeds from this offering as follows:

- approximately $93.5 million to expand our direct sales force and commercial organization;
- approximately $18.5 million to continue our research and development activities and our clinical studies and trials; and
- the remainder for working capital and other general corporate purposes.

We may use a portion of the net proceeds we receive from this offering to acquire businesses, products, services, or technologies. We periodically evaluate strategic opportunities; however, we do not have agreements or commitments for any material acquisitions or investments at this time.

The expected use of the net proceeds from this offering represents our intentions based on our current plans and business conditions, which could change in the future as our plans and business conditions evolve. We cannot predict with certainty all of the particular uses for the proceeds of this offering or the amounts that we will actually spend on the uses set forth above. Accordingly, our management will have broad discretion in applying the net proceeds from this offering. The timing and amount of our actual expenditures will be based on many factors, including cash flows from operations and the anticipated growth of our business.

Pending their use, we intend to invest the net proceeds from this offering in a variety of capital-preservation investments, including government securities and money market funds.

DIVIDEND POLICY

We have never declared or paid any cash dividends on our capital stock. We currently intend to retain future earnings, if any, to finance the operation and expansion of our business and do not anticipate paying any cash dividends in the foreseeable future. Any future determinations regarding the payment of dividends or distributions, if any, will be at the discretion of our board of directors, subject to applicable law, and will depend upon then-existing conditions, including our financial condition, results of operations, contractual restrictions, general business conditions, capital requirements, and other factors our board of directors may deem relevant. In addition, the terms of the Loan and Security Agreement restrict our ability to make certain restricted payments, including dividends.

CAPITALIZATION

The following table sets forth our cash, cash equivalents, and capitalization as of December 31, 2025, on:

- an actual basis;
- a pro forma basis to reflect: (i) the Preferred Stock Conversion, (ii) the issuance of the 2026 Convertible Notes and the related Notes Conversion (iii) the Warrant Exercises, (iv) the Warrant Conversion, and (v) the filing and effectiveness of our amended and restated certificate of incorporation; and
- a pro forma as adjusted basis to further reflect our issuance and sale of 10,000,000 shares of common stock in this offering at the assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us.

You should read this information in conjunction with our financial statements and the related notes included elsewhere in this prospectus, as well as the sections of this prospectus titled "Summary Financial Data" and "Management's Discussion and Analysis of Financial Condition and Results of Operations."

	As of December 31, 2025		
(in thousands, except per share data)	**Actual**	**Pro forma**	**Pro forma as adjusted[1]**
Cash and cash equivalents	$ 33,587	$ 73,500	$ 208,000
Notes payable, net of discount and deferred financing costs[2]	$ 7,130	$ 7,130	$ 7,130
Warrant liabilities	$ 865	$ —	$ —
Redeemable Convertible preferred stock, $0.01 par value per share; 67,174,403 shares authorized, 65,591,701 shares issued and outstanding, actual; no shares authorized, issued or outstanding pro forma and pro forma as adjusted	$ 179,773	$ —	$ —
Stockholders' (deficit) equity:			
Preferred stock, $0.01 par value; no shares authorized, issued and outstanding, actual; 50,000,000 shares authorized, no shares issued and outstanding, pro forma and pro forma as adjusted	$ —	$ —	$ —
Common stock, $0.01 par value per share; 86,600,000 shares authorized, 884,030 shares issued and outstanding, actual; 950,000,000 shares authorized, 23,085,391 shares issued and outstanding, pro forma; 950,000,000 shares authorized, 33,085,391 shares issued and outstanding, pro forma as adjusted	$ 9	$ 231	$ 331
Additional paid-in capital	$ 7,007	$ 227,421	$ 361,821
Accumulated deficit	$ (157,789)	$ (157,875)	$ (157,875)
Total stockholders' deficit[3]	$ (150,774)	$ 69,777	$ 204,277
Total capitalization	$ 36,995	$ 76,907	$ 211,407

(1) Each $1.00 increase (decrease) in the assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) our pro forma as adjusted cash and cash equivalents, additional paid-in capital, total stockholders' deficit and total capitalization by approximately $9.3 million, assuming that the number of shares of common stock offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting the estimated underwriting discounts and commissions and estimated offering expenses payable by us. Each increase (decrease) of 1.0 million shares in the number of shares of common stock offered by us would increase (decrease) our pro forma as adjusted cash and cash equivalents, additional paid-in capital, total stockholders' equity and total capitalization by approximately $14.0 million, assuming the assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. The pro forma as adjusted information discussed above is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering determined at pricing.

(2) Actual notes payable, net of discount and deferred financing costs as of December 31, 2025 excludes the 2026 Convertible Notes issued from January 30, 2026 through February 11, 2026, which will automatically convert into shares of our common stock upon completion of

this offering. See "Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources—2026 Convertible Notes."

(3) Amount may not sum due to normal rounding practices.

The number of shares of our common stock to be outstanding immediately after this offering is based on 23,085,391 shares of our common stock outstanding as of December 31, 2025, which reflects (i) the Preferred Stock Conversion, (ii) the issuance of the 2026 Convertible Notes and the related Notes Conversion and (iii) the Warrant Exercises, and excludes the following:

- 29,622 shares of our common stock issuable upon the Warrant Conversion;
- 4,046,266 shares of common stock issuable upon exercise of options to purchase shares of our common stock outstanding as of December 31, 2025, at a weighted-average exercise price of $3.51 per share;
- 524,180 shares of common stock issuable upon exercise of options to purchase shares of our common stock granted after December 31, 2025, at a weighted-average exercise price of $7.91 per share;
- 523,613 shares of common stock reserved for future issuance under the 2022 Plan as of December 31, 2025, provided that we will cease granting awards under the 2022 Plan upon the effectiveness of the 2026 Plan;
- 2,862,590 shares of common stock issuable upon the exercise or vesting, as applicable, of the IPO Grants;
- a number of shares of our common stock reserved for future issuance under the 2026 Plan (which number includes the IPO Grants), which will become effective on the business day immediately prior to the date of effectiveness of the registration statement of which this prospectus forms a part, equal to the sum of (1) a number of shares equal to 14% of the number of fully-diluted shares of our common stock upon the closing of this offering (calculated on an as-converted basis after giving effect to the number of shares of common stock to be sold in this offering and assuming the exercise in full of the underwriters' over-allotment option and including shares subject to outstanding equity awards and the share reserve under the 2026 Plan and the ESPP, plus (2) any shares of common stock remaining available for future issuance under our 2022 Plan as of the effectiveness of the 2026 Plan, which shares will be added to the share reserve under the 2026 Plan upon its effectiveness; and
- a number of shares of common stock reserved for issuance under our ESPP, which will become effective on the business day immediately prior to the date of effectiveness of the registration statement of which this prospectus forms a part, equal to a number of shares equal to 1% of the number of fully-diluted shares of our common stock upon the closing of this offering (calculated on an as-converted basis after giving effect to the number of shares of common stock to be sold in this offering and assuming the exercise in full of the underwriters' over-allotment option and including shares subject to outstanding equity awards and the share reserves under the 2026 Plan and the ESPP).

Each of the 2026 Plan and the ESPP provides for annual automatic increases in the number of shares reserved thereunder, and the 2026 Plan also provides for increases to the number of shares that may be granted thereunder based on awards under the 2022 Plan that expire, are forfeited, or otherwise repurchased by us, as more fully described in the section titled "Executive and Director Compensation —Equity Incentive Plans."

DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock immediately after this offering.

Our historical net tangible book value (deficit) as of December 31, 2025 was approximately $(152.8) million, or $(172.8) per share of our common stock. Our historical net tangible book value (deficit) is the amount of our total tangible assets less our total liabilities and redeemable convertible preferred stock, which is not included within our stockholders' (deficit) equity. Historical net tangible book value per share represents historical net tangible book value (deficit), divided by the number of shares of our common stock outstanding as of December 31, 2025.

Our pro forma net tangible book value (deficit) as of December 31, 2025 was approximately $67.8 million, or $2.94 per share of our common stock. Pro forma net tangible book value represents the amount of our total tangible assets less our total liabilities, after giving effect to (i) the Preferred Stock Conversion, (ii) the issuance of the 2026 Convertible Notes and the related Notes Conversion, (iii) the Warrant Exercises, and (iv) the Warrant Conversion. Pro forma net tangible book value per share represents pro forma net tangible book value, divided by the total number of shares outstanding as of December 31, 2025, after giving effect to (i) the Preferred Stock Conversion, (ii) the issuance of the 2026 Convertible Notes and the related Notes Conversion, and (iii) the Warrant Exercises.

After giving further effect to our sale of 10,000,000 shares of common stock in this offering at the assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, our pro forma as adjusted net tangible book value as of December 31, 2025 would have been approximately $203.2 million, or $6.14 per share. This represents an immediate increase in pro forma as adjusted net tangible book value per share of $3.20 to our existing stockholders and an immediate dilution in pro forma as adjusted net tangible book value per share of $8.86 to new investors purchasing common stock in this offering. Dilution per share to new investors purchasing common stock in this offering is determined by subtracting pro forma as adjusted net tangible book value per share after this offering from the assumed initial public offering price per share paid by new investors.

The following table illustrates this dilution on a per share basis:

Assumed initial public offering price per share		$ 15.00
Historical net tangible book value (deficit) per share as of December 31, 2025	$ (172.82)	
Increase in pro forma net tangible book value per share as of December 31, 2025	175.76	
Pro forma net tangible book value per share as of December 31, 2025	2.94	
Increase in pro forma as adjusted net tangible book value per share attributable to new investors purchasing shares in this offering	3.20	
Pro forma as adjusted net tangible book value per share after this offering		6.14
Dilution per share to new investors purchasing shares in this offering		$ 8.86

The dilution information discussed above is illustrative only and may change based on the actual initial public offering price and other terms of this offering. Each $1.00 increase (decrease) in the assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the pro forma as adjusted net tangible book value per share after this offering by $0.28 per share and the dilution to new investors purchasing common stock in this offering by $0.72 per share, assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. An increase of 1.0 million shares in the number of shares offered by us would increase the pro forma as adjusted net tangible book value per share after this offering by $0.23 and decrease the dilution per share to new investors participating in this offering by $0.23, assuming no change in the assumed initial public offering price and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us. A

decrease of 1.0 million shares in the number of shares offered by us would decrease the pro forma as adjusted net tangible book value per share after this offering by $0.24 and increase the dilution per share to new investors participating in this offering by $0.24, assuming no change in the assumed initial public offering price and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us.

If the underwriters exercise their option to purchase 1,500,000 additional shares of common stock in this offering in full at the assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover of this prospectus and assuming the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same, and after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, the pro forma as adjusted net tangible book value per share after this offering would be $6.48 per share, and the dilution in pro forma as adjusted net tangible book value per share to new investors purchasing common stock in this offering would be $8.52 per share.

The following table summarizes, on a pro forma as adjusted basis, as of December 31, 2025, the number of shares of common stock purchased from us, the total consideration paid and the weighted-average price per share paid, by existing stockholders and by new investors in this offering. The presentation in this table regarding ownership by existing stockholders does not give effect to any purchases in this offering by such investors.

	Shares Purchased		Total Consideration		Weighted-Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders before this offering	23,085,391	70 %	$ 222,527,042	60 %	$ 9.64
Investors participating in this offering	10,000,000	30 %	$ 150,000,000	40 %	$ 15.00
Total	33,085,391	100 %	$ 372,527,042	100 %	$ 11.26

The table above assumes no exercise of the underwriters' option to purchase additional shares in this offering. If the underwriters' option to purchase additional shares is exercised in full, the number of shares of our common stock held by existing stockholders would be reduced to approximately 3% of the total number of shares of our common stock outstanding immediately after this offering, and the number of shares of common stock held by new investors participating in the offering would be increased to approximately 3% of the total number of shares outstanding immediately after this offering.

Each $1.00 increase (decrease) in the assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, would increase (decrease) the total consideration paid by new investors by approximately $10.0 million, assuming that the number of shares offered by us, as set forth on the cover page of this prospectus, remains the same. An increase (decrease) of 1.0 million shares in the number of shares offered by us would increase (decrease) the total consideration paid by new investors by approximately $15.0 million, assuming no change in the assumed initial public offering price.

The number of shares of our common stock to be outstanding immediately after this offering is based on 23,085,391 shares of our common stock outstanding as of December 31, 2025, which reflects (i) the Preferred Stock Conversion, (ii) the issuance of the 2026 Convertible Notes and the related Notes Conversion and (iii) the Warrant Exercises, and excludes the following:

- 29,622 shares of our common stock issuable upon the Warrant Conversion;
- 4,046,266 shares of common stock issuable upon exercise of options to purchase shares of our common stock outstanding as of December 31, 2025, at a weighted-average exercise price of $3.51 per share;
- 524,180 shares of common stock issuable upon exercise of options to purchase shares of our common stock granted after December 31, 2025, at a weighted-average exercise price of $7.91 per share;

- 523,613 shares of common stock reserved for future issuance under the 2022 Plan as of December 31, 2025, provided that we will cease granting awards under the 2022 Plan upon the effectiveness of the 2026 Plan;
- 2,862,590 shares of common stock issuable upon the exercise or vesting, as applicable, of the IPO Grants;
- a number of shares of our common stock reserved for future issuance under the 2026 Plan (which number includes the IPO Grants), which will become effective on the business day immediately prior to the date of effectiveness of the registration statement of which this prospectus forms a part, equal to the sum of (1) a number of shares equal to 14% of the number of fully-diluted shares of our common stock upon the closing of this offering (calculated on an as-converted basis after giving effect to the number of shares of common stock to be sold in this offering and assuming the exercise in full of the underwriters' over-allotment option and including shares subject to outstanding equity awards and the share reserve under the 2026 Plan and the ESPP, plus (2) any shares of common stock remaining available for future issuance under our 2022 Plan as of the effectiveness of the 2026 Plan, which shares will be added to the share reserve under the 2026 Plan upon its effectiveness; and
- a number of shares of common stock reserved for issuance under our ESPP, which will become effective on the business day immediately prior to the date of effectiveness of the registration statement of which this prospectus forms a part, equal to a number of shares equal to 1% of the number of fully-diluted shares of our common stock upon the closing of this offering (calculated on an as-converted basis after giving effect to the number of shares of common stock to be sold in this offering and assuming the exercise in full of the underwriters' over-allotment option and including shares subject to outstanding equity awards and the share reserves under the 2026 Plan and the ESPP).

Each of the 2026 Plan and the ESPP provides for annual automatic increases in the number of shares reserved thereunder, and the 2026 Plan also provides for increases to the number of shares that may be granted thereunder based on awards under the 2022 Plan that expire, are forfeited, or otherwise repurchased by us, as more fully described in the section titled "Executive and Director Compensation —Equity Incentive Plans."

We may choose to raise additional capital through the sale of equity or convertible debt securities due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that any outstanding options to purchase shares of our common stock are exercised or new options are issued under the equity benefit plans, or we issue additional shares of common stock or other securities convertible into or exercisable or exchangeable for shares of our capital stock in the future, there will be further dilution to investors participating in this offering.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes included elsewhere in this prospectus. Some of the information contained in this discussion and analysis are set forth elsewhere in this prospectus, including information with respect to our plans and strategy for our business and related financing, and includes forward-looking statements that involve risks and uncertainties. See the section titled "Special Note Regarding Forward-Looking Statements" appearing elsewhere in this prospectus. As a result of many factors, including those factors set forth in the section of this prospectus titled "Risk Factors," our actual results could differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

Overview

We are a commercial-stage medical device company redefining stroke recovery for survivors living with life-altering motor impairments. Our Vivistim Paired Vagus Nerve Stimulation (Paired VNS) System is the first and only clinically-validated, FDA-approved solution for chronic ischemic stroke survivors with moderate to severe upper extremity impairments. Stroke is one of the leading causes of long-term disability in the United States. While advancements in acute stroke care over the past decade have significantly reduced mortality, innovation for chronic stroke recovery has lagged, resulting in a growing number of stroke survivors living with meaningful impairments. Our breakthrough Vivistim Paired VNS System (Vivistim System) addresses this unmet need. The Vivistim System includes an implanted pulse generator and lead that deliver stimulation to the vagus nerve when activated. During treatment (Vivistim Therapy), intentional bursts of stimulation are delivered during functional movement to increase neuroplasticity and durably restore motor function. Clinical data has demonstrated that Vivistim Therapy delivers meaningful improvements in upper limb function, which can help stroke survivors regain critical capabilities and independence and restore quality of life, regardless of the time elapsed since the patient's stroke. We believe we are setting a new standard of care in chronic stroke recovery, facilitating a new treatment pathway for chronic ischemic stroke survivors with moderate to severe upper extremity impairments. We have experienced rapid growth since our full commercial launch in 2023, and physicians have performed over 1,000 implants, including approximately 700 in 2025.

Chronic stroke recovery presents a significant market opportunity. According to the American Heart Association (AHA), approximately 87% of the strokes in the United States are ischemic. This equates to approximately 9 million ischemic stroke survivors in the United States, of which we estimate that more than 4 million are chronic ischemic stroke survivors living with moderate to severe upper extremity impairment. This population falls within the current on-label indication for the Vivistim System. We believe that an initial market opportunity comprises approximately 1 million of those survivors that demonstrate the requisite overall health, cognition and motivation to participate in therapy and have received some amount of post-stroke therapy, which we estimate represents an initial market opportunity of over $30 billion based on the average selling price of the Vivistim System. Vivistim Therapy is effective for recent stroke survivors as well as patients who initiate treatment many years post-stroke. Based on a report published by the AHA in 2025, we estimate that each year approximately 200,000 new stroke survivors in the United States meet our indication for use, with 50,000 of these survivors representative of our initial market opportunity.

Our commercial strategy is designed to encourage Vivistim Therapy adoption at stroke centers and therapy sites through a coordinated, evidence-based approach. We sell the Vivistim System to customers, primarily stroke hospitals, in the United States, and our commercial organization is responsible for driving adoption of the Vivistim System through customer outreach, education, and relationship management activities. Our team includes Territory Managers (TMs), who support initial customer onboarding efforts at stroke centers and maintain commercial relationships with physicians and administrators, and Therapy Development Specialists (TDSs), who focus on outreach to therapy sites and provide general educational information regarding the clinical use of the Vivistim System. These activities are intended to facilitate customer adoption and utilization of the Vivistim System. Our commercial efforts are currently focused on primary and comprehensive stroke centers, which are hospitals that have cross-functional teams with the capabilities to treat acute stroke at the highest level of care and in compliance with AHA guidelines. These centers see significant volumes of acute stroke patients and are typically surrounded by a

network of therapy sites with neurorehabilitation capabilities, providing the infrastructure necessary for efficient implementation of Vivistim Therapy. We work with these stroke centers to establish Vivistim Therapy as a treatment option for stroke survivors. Over time, we believe these centers will naturally integrate Vivistim Therapy into standard care pathways for stroke survivors upon discharge and establish self-sustaining care programs that use Vivistim Therapy. According to data from the stroke center accreditation organizations, there were approximately 1,500 primary and comprehensive stroke centers in the United States as of December 2025. In addition, according to stroke claims data, approximately 70% of acute strokes in the United States are seen at 900 hospitals.

We rely on third-party contract manufacturers to manufacture the Vivistim System and accessories. We believe this strategy provides the expertise and capacity required to effectively and efficiently scale production based on demand, and helps to reduce our need for capital investment and reduce operational expenses.

To date, our primary sources of capital have been private placements of preferred stock, debt financing arrangements and revenue from sales of our Vivistim System. For the year ended December 31, 2025, we generated revenue of $32.0 million, with a gross margin of 81.1%, and had a net loss of $46.5 million, compared to revenue of $15.6 million, with a gross margin of 79.6%, and a net loss of $24.6 million for the year ended December 31, 2024. As of December 31, 2025, we had cash and cash equivalents of $33.6 million and an accumulated deficit of approximately $157.8 million.

Key Factors and Trends Affecting our Business

We believe that our performance, results of operations and future success depend on several factors, including:

- ***Market development and awareness of Vivistim Therapy.*** Our mission is to redefine stroke recovery for survivors living with life-altering functional impairments by establishing Vivistim Therapy as the standard of care for chronic stroke recovery. As there are currently very limited options to support chronic stroke recovery, we are focused on developing this new market and driving awareness of Vivistim Therapy as a potential treatment option for stroke survivors. To accomplish this, we intend to continue to educate healthcare providers on the capabilities and benefits of Vivistim Therapy, work closely with hospitals to incorporate Vivistim Therapy as a treatment option, and activate care programs that use Vivistim Therapy at stroke centers and therapy sites. In addition, we intend to continue to expand our clinical evidence to support a robust cadence of publications regarding the benefits of Vivistim Therapy. We believe these efforts will support the growth of our business by generating broader awareness, which can support adoption and increase utilization of Vivistim Therapy. Candidates for Vivistim Therapy generally result from three primary sources: physician referrals, therapist referrals, and direct patient engagement. A diverse network of care providers, including stroke interventionalists, neurosurgeons, neurologists, physical medicine and rehabilitation physicians, occupational and physical therapists, stroke coordinators and nurses, support and interact with stroke survivors. We directly engage with each of these stakeholders through our field-based commercial team and specialized events, summits, and conferences. In addition, we engage in direct patient education activities, such as webinars, outreach through support groups, digital advertising and other targeted activities. We believe that establishing strong referral patterns between providers and engaging directly with stroke survivors and their caregivers will help to further market development, awareness and utilization. For example, we believe that as awareness and utilization increase, stroke centers will naturally integrate Vivistim Therapy into standard care pathways for stroke survivors upon discharge and establish self-sustaining care programs that use Vivistim Therapy over time. Our financial performance will be significantly impacted by the extent to which we can increase awareness and utilization, as well as the timing and rate of adoption of our products by healthcare providers.

- ***Growing our commercial organization.*** To promote awareness and utilization, we expect to continue to efficiently grow our commercial organization. For example, our selling, general and administrative expenses were $65.8 million and $32.4 million for the years ended December 31, 2025 and 2024, respectively. We intend to continue to make significant investments in our commercial organization by scaling our team, which we believe will broaden our geographic reach, drive penetration, and increase access to our products. We seek to scale deliberately and efficiently using our scalable commercial model, which initially targets a highly concentrated group of high-volume primary and comprehensive stroke

centers. These stroke centers are typically surrounded by a network of therapy sites with neurorehabilitation capabilities, providing the infrastructure for efficient implementation of Vivistim Therapy. For the years ended December 31, 2025 and 2024, substantially all Vivistim System implants were performed at primary and comprehensive stroke centers. While we aim to expand strategically and efficiently, the rate at which we grow our commercial organization and the speed at which newly hired personnel become effective will impact our revenue growth and our costs incurred in anticipation of such growth.

- ***Reimbursement and expanding payor coverage.*** Healthcare providers generally rely on third-party payors, including Medicare, Medicaid, Medicare Advantage and commercial insurance plans, to cover and reimburse all or part of the cost of the Vivistim System. As a result, demand for our Vivistim System depends in part on the availability of reimbursement from such payors and the rates that such payors reimburse for implantation procedures with the Vivistim System. The Vivistim System implantation procedure falls under a long-established Category 1 CPT code. Effective January 1, 2026, this code was assigned to a New Technology Ambulatory Payment Classification (APC) by CMS, which established an elevated payment level. Future changes in payment levels could have a significant impact on patient access to the Vivistim System, and thus on our revenue, either positively or negatively. Medicare fee-for-service patients can typically access Vivistim Therapy when medically necessary, without prior authorization. Commercial insurance plans, Medicaid and Medicare Advantage generally require prior authorization. Our in-house market access team works to provide support in navigating the prior authorization process and facilitating positive coverage decisions by third-party payors, including by utilizing our robust clinical evidence, demonstrating economic value, and leveraging endorsements from key opinion leaders. Our growth in 2025 was, and our future success will be, driven in part by our ability to facilitate streamlined prior authorization processes and increase coverage by third-party payors, and improve market access.
- ***Expanding our clinical evidence.*** We have built, and remain committed to expanding, a robust body of clinical evidence demonstrating the safety, efficacy and durability of Vivistim Therapy. We believe the extent of our clinical evidence is important for increasing awareness and adoption of, and driving broader coverage decisions for the Vivistim System. We are actively enrolling patients in our GRASP registry and plan to publish 12-, 24-, and 36-month outcomes. We anticipate that our real-world evidence will also support a robust cadence of publications in the future that will further validate our clinical trials and the direct experiences of patients and healthcare providers. We plan to build our base of clinical evidence by supporting new clinical studies.
- ***Continued investment in research and development.*** We focus on innovation to develop new products and product enhancements, including to improve clinical outcomes, optimize patient experience, enhance physician usability, increase utilization, and increase patient engagement. We expect to continue to invest in supporting these initiatives. Our near-term research and development activities are primarily directed toward continued technological advancement of the Vivistim System, and development of a next-generation Vivistim System with enhanced features. We also expect to invest in exploring expansions into other functional impairments (e.g., lower limb) or stroke etiologies (e.g., intracerebral hemorrhage).

Components of our Results of Operations

Revenue

We currently generate all of our revenue from the sale of our Vivistim System to customers, mainly primary and comprehensive stroke centers, in the United States. Our customers typically purchase an initial stocking order and then reorder replenishment product as procedures are performed. No single customer accounted for 10% or more of our revenue during the years ended December 31, 2025 or 2024. We expect revenue to increase as we expand our commercial organization and sales territories, add customers and expand patient and customer awareness. We have expanded our commercial organization to help us drive and support revenue growth and intend to continue this expansion. We also expect that demand, and thus revenue growth, will be positively impacted by, and to the extent that, we obtain additional positive coverage policies with payors. While we have experienced strong revenue growth, our revenue may fluctuate from quarter to quarter due to a variety of factors.

Cost of goods sold and gross margin

Cost of goods sold primarily consists of acquisition costs of finished goods and components, depreciation, warranty costs to replace aged, damaged or unusable items, product replacement costs, shipping costs, packaging costs, and allocated costs including facilities and information technology. We expect cost of goods sold to increase in absolute terms as our revenue grows.

We calculate gross margin as gross profit divided by revenue. Our gross profit has been and will continue to be affected by a variety of factors, including sales volumes, purchase volumes of inventory, cost of goods sold, tariffs, inflation, and product yields. Our gross margin will likely fluctuate from quarter to quarter.

Research and development expenses

Research and development expenses primarily consist of costs related to product development, engineering, clinical studies related to new clinical indications, regulatory expenses, testing, consulting services and other costs associated with product improvements and next generation versions of our products. Other research and development costs include salaries, employee benefits, stock-based compensation and other headcount-related costs, depreciation expense and allocated costs related to facilities and information technology. We expect our research and development expenses to increase in absolute dollars in the future as we pursue product development initiatives, including product improvements and next-generation versions of our products, and continue to expand our clinical data. We expect research and development expenses as a percentage of revenue to vary over time depending on the level and timing of initiating product development efforts and clinical development activities.

Selling, general and administrative expenses

Selling, general and administrative expenses primarily consist of compensation for personnel, including salaries, employee benefits, stock-based compensation, commissions associated with our commercial organization, spending related to sales and marketing, finance, information technology and human resource functions, expenses related to clinical studies and our registry for our current clinical indication, legal expenses related to regulatory matters, and training. Other expenses include travel expenses, advertising, conferences, trade shows, consulting and professional services fees, insurance costs, and general corporate expenses, including facilities-related expenses. The activities of our TMs and TDSs to facilitate customer adoption and utilization of the Vivistim System, and of our in-house market access team in facilitating the administrative prior authorization process, are included in selling, general and administrative expenses and do not represent contractual obligations or services provided to customers after product delivery. We expect selling, general and administrative expenses to continue to increase in absolute dollars as we expand our commercial organization, including with respect to TMs and TDSs, to both drive and support our planned growth in revenue, fund clinical studies and our registry for our current clinical indication, and incur additional expenses associated with operating as a public company, including costs related to legal, accounting, insurance, compliance with exchange listing and Securities and Exchange Commission requirements, and investor relations. We also expect an increase in our stock-based compensation expense with the establishment of a new equity plan associated with this offering and related grants either in the form of restricted stock or options. However, we expect selling, general and administrative expenses to decrease as a percentage of revenue primarily as, and to the extent, our revenue grows.

Other income (expense), net

Other income (expense), net consists primarily of interest expense on our debt obligations, including our Loan and Security Agreement, as well as amortization of debt issuance costs, interest income on our cash and cash equivalents and fair value adjustments related to our redeemable convertible preferred stock warrants and redeemable convertible preferred stock tranche liability. We expect our other income (expense), net to vary in future periods depending on the extent of our debt obligations.

Provision for income taxes

Provision for income taxes consists of income taxes in the United States and includes deferred taxes on temporary differences for tax and financial statement purposes.

Results of Operations

Comparison of years ended December 31, 2025 and 2024

The following table summarizes our results of operations for the years ended December 31, 2025 and 2024.

	Year ended December 31,		Change	
(in thousands, except percentage)	**2025**	**2024**	**$**	**%**
Revenue	$ 32,041	$ 15,644	$ 16,397	104.8 %
Cost of goods sold	6,066	3,193	2,873	90.0 %
Gross profit	25,975	12,451	13,524	108.6 %
Operating expenses:				
Research and development costs	6,515	4,243	2,272	53.5 %
Selling, general and administrative expenses	65,828	32,444	33,384	102.9 %
Total operating expenses	72,343	36,687	35,656	97.2 %
Loss from operations	(46,368)	(24,236)	(22,132)	91.3 %
Other income (expense):				
Interest expense	(967)	(970)	3	(0.3)%
Other income, net	842	617	225	36.5 %
Total other expense, net	(125)	(353)	228	(64.6)%
Loss before provision for income taxes	(46,493)	(24,589)	(21,904)	89.1 %
Provision for income taxes	(5)	(14)	9	(64.3)%
Net loss	$ (46,498)	$ (24,603)	$ (21,895)	89.0 %

Revenue

Revenue increased by $16.4 million, or 104.8%, to $32.0 million for the year ended December 31, 2025, compared to $15.6 million for the year ended December 31, 2024. The increase was driven entirely by higher adoption of the Vivistim System. Units of IPGs, a primary component of the Vivistim System, sold increased by 108.1% during the period. This revenue growth reflects our continued efforts to increase awareness and expand our commercial organization while maintaining a consistent average selling price of the Vivistim System.

Cost of goods sold and gross margin

Cost of goods sold increased by $2.9 million, or 90.0%, to $6.1 million for the year ended December 31, 2025, compared to $3.2 million for the year ended December 31, 2024. While the cost per unit of the underlying product remained relatively consistent year over year, the increase in cost of goods sold was primarily driven by higher sales volume of Vivistim Systems, as well as an increase in freight and tariff costs during the year ended December 31, 2025. Gross margin increased to 81.1% in 2025, from 79.6% in 2024. Gross margin improved as lower overhead costs and lower product warranty expense as a percentage of revenue more than offset higher freight costs and tariffs in 2025, while per-unit product costs remained relatively consistent.

Research and development expenses

Research and development expenses increased by $2.3 million, or 53.5%, to $6.5 million for the year ended December 31, 2025, compared to $4.2 million for the year ended December 31, 2024. The increase was primarily due to an increase of $1.8 million of expenses related to product development efforts including external development services, and $0.5 million of expenses related to increased headcount and related expenses.

Selling, general and administrative expenses

Selling, general and administrative expenses increased by $33.4 million, or 102.9%, to $65.8 million for the year ended December 31, 2025, compared to $32.4 million for the year ended December 31, 2024. The increase was primarily due to an increase of $21.3 million of personnel-related expenses as a result of increased headcount in our commercial organization, increased commissions and an increase in the number of Vivistim Systems sold, increases of $4.4 million in marketing and market access-related costs, $3.5 million related to travel, meetings and conferences and $1.2 million related to professional services, as well as certain other expenses related to supplies, materials, software and our ongoing registry and monitoring for our current clinical indication.

Total other expense, net

Total other expense, net was $0.1 million for the year ended December 31, 2025, compared to total other expense, net of $0.4 million for the year ended December 31, 2024. The increase was primarily due to the recording of $0.2 million related to our Series F preferred stock tranche liability, partially offset by a $0.3 million increase in interest income.

Provision for income taxes

Provision for income taxes decreased by $8,463 for the year ended December 31, 2025 compared to the year ended December 31, 2024, and primarily represents minimum state taxes due.

Quarterly Results of Operations Data

The following table sets forth certain unaudited quarterly information for the periods presented. The unaudited quarterly information set forth below has been prepared on a basis consistent with our audited annual financial statements included elsewhere in this prospectus and includes, in our opinion, all normal recurring adjustments necessary for the fair statement of the results of operations for the periods presented. Our historical unaudited quarterly results are not necessarily indicative of the results that may be expected in the future. The following unaudited quarterly financial information should be read in conjunction with our audited financial statements and related notes thereto included elsewhere in this prospectus.

	For the three months ended							
(in thousands)	March 31, 2024	June 30, 2024	September 30, 2024	December 31, 2024	March 31, 2025	June 30, 2025	September 30, 2025	December 31, 2025
Revenue	$ 3,098	$ 4,034	$ 4,133	$ 4,380	$ 5,661	$ 6,674	$ 9,012	$ 10,694
Cost of goods sold	616	719	860	998	1,015	1,185	1,836	2,031
Gross profit	2,482	3,315	3,273	3,382	4,646	5,489	7,176	8,663
Operating Expenses								
Research and development costs	998	875	975	1,395	1,354	1,418	1,605	2,138
Selling, general and administrative expenses	7,611	7,515	8,370	8,949	13,596	14,532	16,828	20,872
Total operating expenses	$ 8,609	$ 8,390	$ 9,345	$ 10,344	$ 14,950	$ 15,950	$ 18,433	$ 23,010
Loss from operations	$ (6,127)	$ (5,075)	$ (6,072)	$ (6,962)	$ (10,304)	$ (10,461)	$ (11,257)	$ (14,347)
Other income (expense)								
Interest expense	(232)	(232)	(235)	(271)	(239)	(241)	(244)	(244)
Other income (expense), net	110	150	110	248	(109)	214	79	659
Total other income (expense), net	$ (122)	$ (82)	$ (125)	$ (23)	$ (348)	$ (27)	$ (165)	$ 415
Loss before provision for income taxes	$ (6,249)	$ (5,157)	$ (6,197)	$ (6,985)	$ (10,652)	$ (10,488)	$ (11,422)	$ (13,932)
Provision for income tax				(14)	(1)	(1)	(1)	(1)
Net loss attributable to common stockholders	$ (6,249)	$ (5,157)	$ (6,197)	$ (6,999)	$ (10,653)	$ (10,489)	$ (11,423)	$ (13,933)

Liquidity and Capital Resources

Overview

To date, our primary sources of capital have been private placements of preferred stock, debt financing arrangements and revenue from sales of our Vivistim System. As of December 31, 2025, we had cash and cash equivalents of $33.6 million and an accumulated deficit of approximately $157.8 million. In the first quarter of 2026, we issued convertible promissory notes to certain investors in an aggregate principal amount of $40.0 million.

Funding Requirements

We expect our operating expenses to continue to increase for the foreseeable future as we continue to make significant investments in our commercial organization, seek to expand our marketing programs to help facilitate further awareness and adoption of our Vivistim System, continue to make investments in research and development, including regulatory affairs and clinical studies, and as we continue to scale our infrastructure. Moreover, we expect to incur additional expenses associated with operating as a public company, including costs related to legal, accounting, insurance, exchange listing and Securities and Exchange Commission requirements, and investor relations.

Our future liquidity and capital requirements will depend on numerous factors, including:

- our revenue growth;
- the market awareness and adoption of Vivistim Therapy, including by patients and our customers;
- the scope, timing and costs of supporting the growth and expansion of our commercial organization and efforts;
- the availability and amount of reimbursement for procedures using our products;
- the adoption of private payor coverage of our products;
- changes in the acquisition costs of finished goods and components used in our products;
- the costs associated with securing additional suppliers and service providers;
- the timing and costs of our research and development efforts;
- the scope, rate of progress and costs of our current or future clinical trials and registries as well as costs associated with complying with regulatory requirements;
- the cost and timing of additional regulatory clearances or approvals;
- the costs of attaining, defending, and enforcing our intellectual property rights;
- whether we acquire third-party products or technologies;
- litigation or other claims against us for intellectual property infringement or otherwise;
- the emergence of competing or complementary technologies;
- our ability to raise additional funds to finance our operations;
- debt service requirements;
- our need to implement additional infrastructure and internal systems;
- general economic, industry and market conditions or extraordinary external events, such as a recession;
- the rate at which we expand internationally;

- the cost associated with being a public company;
- our reputation among physicians, hospitals, therapists and patients; and
- whether we are required by the FDA or comparable non-U.S. regulatory authorities to conduct additional clinical trials for future or current indications.

We have concluded that our history of continued operating losses and negative cash flow from operations and accumulated deficit raise substantial doubt about our ability to continue as a going concern. See Note 2 to our financial statements for the fiscal year ended December 31, 2025 included elsewhere in this prospectus for additional information on our assessment. Similarly, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements as of and for the fiscal year ended December 31, 2025 included elsewhere in this prospectus, describing the existence of substantial doubt about our ability to continue as a going concern. Based on our current operating plan, we do not expect that our cash and cash equivalents will be sufficient to fund our operations for at least 12 months after the date of these financial statements are issued without raising additional capital through equity or debt financing, or potential collaboration proceeds. We believe that the actions presently being taken to further implement our business plan, generate revenues, and raise additional capital provide the opportunity for us to continue as a going concern. While we believe in the viability of our strategy to generate revenues and in our ability to raise additional funds, there can be no assurances that we will be successful in these efforts and the substantial doubt will be alleviated.

However, based on our current operating plan, we believe that the estimated net proceeds from this offering, together with our existing cash and cash equivalents, will be sufficient to fund our planned operating expenses for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could deplete our capital resources sooner than we expect. Our ability to continue as a going concern is dependent upon our ability to successfully secure sources of financing and ultimately achieve profitable operations.

If these sources are insufficient to satisfy our liquidity requirements, we may seek additional financing or to raise any necessary additional capital through public or private equity offerings or debt financings, credit or loan facilities or a combination of one or more of these or other funding sources. Additional funds may not be available to us on acceptable terms or at all. If we fail to obtain necessary capital when needed on acceptable terms, or at all, we could be forced to delay, limit, reduce or terminate our commercial efforts, product development programs or other operations, and such failure would have a negative impact on our financial condition and our ability to execute our business plan. If we raise additional funds by issuing equity securities or convertible debt, our stockholders will suffer dilution and the terms of any financing may adversely affect the rights of our stockholders. In addition, as a condition to providing additional funds to us, future investors may demand, and may be granted, rights superior to those of existing stockholders. If we raise additional capital through collaboration agreements, licensing arrangements or marketing and distribution or other similar arrangements, we may have to relinquish valuable rights, future revenue streams, research programs or product or grant licenses that may not be favorable to us. Debt financing, if available, is likely to involve restrictive covenants limiting our flexibility in conducting future business activities, and, in the event of insolvency, debt holders would be repaid before holders of our equity securities received any distribution of our corporate assets.

Cash Flows

The following table summarizes our cash flows for the years ended December 31, 2025 and 2024:

	Year ended December 31,	
(in thousands)	**2025**	**2024**
Net cash used in operating activities	$ (45,695)	$ (24,315)
Net cash used in investing activities	(364)	(41)
Net cash provided by financing activities	65,026	15,658
Net (decrease) increase in cash and cash equivalent	$ 18,967	$ (8,698)

Operating Activities

Net cash used in operating activities was $45.7 million for the year ended December 31, 2025. This was primarily due to net losses incurred during the period of $46.5 million. The cash used in operating activities for the year ended December 31, 2025 was also affected by increases in other assets of $2.6 million, inventory of $2.0 million, and accounts receivable of $1.6 million. These changes were offset by increases in accrued liabilities (for accruals in commissions, bonuses and product warranty reserves) of $4.2 million and accounts payable of $1.1 million, as well as non-cash share-based compensation of $1.4 million.

Net cash used in operating activities was $24.3 million for the year ended December 31, 2024. This was primarily due to net losses incurred during the period of $24.6 million, as well as an increase in accounts receivable of $1.4 million. These changes were offset by increases in accrued liabilities (for accruals in commissions, bonuses and product warranty reserves) of $1.4 million, as well as non-cash stock-based compensation of $0.8 million.

Investing activities

Net cash used in investing activities was $0.4 million for the year ended December 31, 2025, consisting of purchases of property and equipment.

Net cash used in investing activities was $40,848 for the year ended December 31, 2024, consisting of purchases of property and equipment.

Financing activities

Net cash provided by financing activities was $65.0 million for the year ended December 31, 2025, attributable primarily to net proceeds of $64.7 million received from the issuance of Series F redeemable convertible preferred stock and $0.3 million received upon the issuance of shares of our common stock following the exercise of stock options.

Net cash provided by financing activities was $15.7 million for the year ended December 31, 2024, attributable to net proceeds of $15.0 million received upon the issuance of shares of our Series E-2 redeemable convertible preferred stock and $0.7 million received upon the issuance of shares of our common stock following the exercise of stock options.

Loan and Security Agreement with Horizon

On December 29, 2023, we entered into a Loan and Security Agreement (the Loan and Security Agreement) with Horizon Technology Finance Corporation. On June 1, 2024, Horizon Technology Finance Corporation assigned all of its right, title and interest in and to the loans outstanding under the Loan and Security Agreement and related warrants to Horizon Funding II, LLC, its wholly-owned subsidiary (together with Horizon Technology Finance Corporation, Horizon). The Loan and Security Agreement provides for term loans of up to an aggregate principal amount of $30.0 million, available in four equal tranches of $7.5 million. Each tranche comprises two equal loans of $3,750,000. As of December 31, 2025, there was $7.5 million outstanding under the Loan and Security Agreement, representing the full available aggregate principal amount under the Loan and Security Agreement, and no additional tranches are available to draw down under the Loan and Security Agreement in the future.

The tranches are subject to various conditions and requirements set out in the Loan and Security Agreement. The availability of the first tranche was subject to, among other things, our completing an equity offering of at least $15.0 million on or before December 31, 2023. We satisfied the conditions of the first tranche and drew down $7.5 million in December 2023. The availability of the second tranche was subject to, among other things, our completing an equity offering of at least $15.0 million on or before December 31, 2024. We did not draw down this second tranche. The availability of the third tranche was subject to, among other things, (i) our achievement of at least $20.0 million of trailing 12-month revenue as of the funding date and (ii) our completing an equity offering of at least $30.0 million on or before June 20, 2025. We did not draw down this third tranche. The availability of the fourth tranche is subject to, among other things, (i) our achievement of at least $25.0 million of trailing 12-month revenue

as of the funding date and (ii) our completing an equity offering of at least $30.0 million on or before December 31, 2025. We did not draw down this fourth tranche. Our ability to draw additional loans under the Loan and Security Agreement expired on December 31, 2025.

Pursuant to the Loan and Security Agreement, we are required to issue a warrant to purchase shares of our securities in the event that we draw down a tranche following satisfaction of the applicable conditions. In connection with our draw down of the first tranche under the Loan and Security Agreement, we issued first tranche warrants to purchase such number of securities representing an aggregate of $262,500 to Horizon. The first tranche warrants are exercisable, at the election of Horizon, for (i) shares of Series E-2 redeemable convertible preferred stock at an exercise price of $2.5443 per share or (ii) shares of Series F redeemable convertible preferred stock at an exercise price of $2.6317 per share, and expire ten years from the date of issuance.

The Loan and Security Agreement matures on January 1, 2029. Borrowings under the Loan and Security Agreement accrue interest at an annual rate equal to the greater of (i) The Wall Street Journal (or any successor thereto) prime rate (subject to a floor of 8.50%) plus 3.75% and (ii) 12.25%. We are required to make monthly payments of interest only through January 1, 2028. Following such date, we are required to make monthly payments of principal and accrued interest through maturity. The unpaid balance of principal and accrued interest is due at maturity.

The Loan and Security Agreement provides that we can at any time prepay, in whole but not in part, amounts outstanding under the Loan and Security Agreement, subject to a prepayment premium on the outstanding principal amount of the loans being repaid equal to (i) 3.0% if such prepayment occurs on or prior to the second anniversary of the Loan and Security Agreement; (ii) 2.0% if such prepayment occurs after the second anniversary, and on or prior to the fourth anniversary, of the Loan and Security Agreement; and (iii) 1.0% if such prepayment occurs after the fourth anniversary of the Loan and Security Agreement and prior to maturity.

We are required to make a final payment of $131,250 for each loan funded on the earlier of (i) the date that we prepay all of the outstanding principal of such loan, (ii) the date of acceleration of the balance of such loan by the Lender, and (iii) the maturity.

Amounts outstanding under the Loan and Security Agreement are secured by substantially all of our assets, excluding intellectual property.

The Loan and Security Agreement includes customary affirmative and negative covenants and events of default. Upon the occurrence and continuance of an event of default, Horizon may demand immediate repayment of all principal and unpaid interest under the Loan and Security Agreement, and exercise remedies against us and the collateral securing our obligations under the Loan and Security Agreement. Events of default under the Loan and Security Agreement include, among other things: (i) insolvency, bankruptcy or similar proceedings subject to a certain grace period in respect of any involuntary insolvency, bankruptcy or similar proceedings; (ii) failure to pay any debts due under the Loan and Security Agreement or other indebtedness on a timely basis; (iii) failure to observe any covenant or other terms under the Loan and Security Agreement or the other Loan Documents (as defined in the Loan and Security Agreement), some of which are subject to a certain cure period; (iv) occurrence of a material adverse change; (v) material misrepresentations; and (vi) entry of certain final, non-appealable judgments against us in excess of $250,000 not paid or bonded within 10 days of such entry.

As of December 31, 2025, we were in compliance with all covenants contained in the Loan and Security Agreement.

2026 Convertible Notes

From January 30, 2026 through February 11, 2026, we issued convertible promissory notes to certain investors in an aggregate principal amount of $40.0 million (2026 Convertible Notes). The 2026 Convertible Notes mature on January 30, 2028 (Maturity Date). The 2026 Convertible Notes bear no interest for the first six months following the date of issuance (Interest Free Period). Following such Interest Free Period, the 2026 Convertible Notes accrue interest at a rate of 7.0% per annum through the Maturity Date, which interest payments shall be paid in kind. Immediately prior to the closing of this offering, the 2026 Convertible Notes and any accrued interest will

automatically convert into shares of our common stock at the applicable conversion price. The conversion price is the lower of (a) 80% of the initial public offering price per share in this offering and (b) the valuation of the Company immediately prior to the closing of this offering divided by the number of fully diluted shares of capital stock (on an as-converted basis) outstanding immediately prior to this offering but excluding the 2026 Convertible Notes (Fully Diluted Capitalization), provided, that in no event shall such conversion price be less than the quotient obtained by dividing $226.0 million by the Fully Diluted Capitalization or greater than the quotient obtained by dividing $750.0 million by the Fully Diluted Capitalization. Based on an assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and without giving effect to accrued interest (if any), the 2026 Convertible Notes will automatically convert into an aggregate of 3,333,324 shares of our common stock immediately prior to the closing of this offering.

Critical Accounting Estimates

The preparation of our financial statements in conformity with GAAP requires us to make estimates and judgments that affect the amounts reported in the financial statements and related notes thereto. Critical accounting estimates are those estimates that, in accordance with GAAP, involve a significant level of estimation uncertainty and have had or are reasonably likely to have a material impact on our financial statements. Management has determined that our most critical accounting estimates are those relating to stock compensation and valuation of common stock. Although we believe that the estimates we use are reasonable, due to the inherent uncertainty involved in making these estimates, actual results reported in future periods could differ materially from those estimates. The following is a summary of certain accounting estimates we consider critical. For further discussion about our accounting policies, see Note 3 to our financial statements included elsewhere in this prospectus.

Stock-based Compensation and Common Stock Valuation

We measure compensation expense for stock options and other stock-based awards in accordance with ASC 718, *Compensation – Stock Compensation*. Stock-based compensation expense is measured based on the fair value of the awards on the grant date and is recognized over the requisite service period for time-vesting awards or, for awards with a performance condition, over the requisite service period if the performance condition is probable of achievement. Estimating fair value for stock-based awards requires the selection of the appropriate valuation model based on the specific terms and conditions of each grant. For stock options, the Black-Scholes option-pricing model is used to calculate the grant date fair value.

The Black-Scholes model relies on subjective assumptions to determine the fair value of stock-based awards, including:

- *Expected Term*—The expected term represents the period that stock-based awards are expected to be outstanding. The expected term for employee stock options is estimated using the "simplified" method, whereby the expected term equals the average of the award's weighted-average vesting period and contractual term.
- *Expected Volatility*—Since we have been privately held and do not have any trading history for our common stock, we estimated the expected volatility based on the average volatility for comparable publicly traded companies over a period equal to the expected term of the stock option grants.
- *Risk-Free Interest Rate*—The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award.
- *Expected Dividend Yield*—We have never paid dividends on our common stock and have no plans to pay dividends on our common stock. Therefore, we used an expected dividend yield of zero.
- *Fair Value of Common Stock*—Because our common stock is not yet publicly traded, we are required to estimate the fair value of our common stock, as discussed below.

We will continue to use judgment in evaluating the assumptions related to our stock-based compensation on a prospective basis. As we continue to accumulate additional data related to our common stock, we may refine our estimation process, which could materially impact our future stock-based compensation expense.

Common Stock Valuation

Prior to this offering, given the absence of a public trading market for our common stock, our board exercised reasonable judgment and considered a combination of objective and subjective factors to determine the best estimate of the fair value of our common stock at each grant date, including:

- independent third-party valuations of our common stock;
- the prices of recent issuances of redeemable convertible preferred stock by us to investors in arm's-length transactions;
- the rights, preferences, and privileges of our redeemable convertible preferred stock relative to our common stock;
- our current business condition, financial performance, and growth projections;
- our performance and market position relative to comparable publicly-traded companies;
- the likelihood and timing of achieving a liquidity event, such as an initial public offering or sale of our company, given prevailing market conditions and company readiness;
- the lack of marketability and liquidity inherent in our common stock; and
- the general economic outlook and macroeconomic conditions.

Independent third-party valuations were performed in accordance with the guidance outlined in the American Institute of Certified Public Accountants and Valuation Guide, *Valuation of Privately Held Company Equity Securities Issued as Compensation*. The methodology to determine the fair value of our common stock included estimating the fair value of the enterprise using a market approach that primarily considered recent arm's-length transactions in our equity securities and other relevant market data. The resulting equity value was then used as a basis for determining the fair value of our common stock.

Our historical valuations have primarily used the subject company transaction method and the subject company transaction method with market adjustment to equity value. The subject company transaction method involves examining our prior equity transactions and considering these transactions as relevant inputs for the equity value. The subject company transaction method with market adjustment to equity value involves examining our prior equity transactions, in conjunction with a market adjustment to equity value to account for changes at our company, in our industry and in the economy since the most recent equity transaction. For example, recent valuations examined our Series F redeemable convertible preferred stock financing, which held closings in March 2025 and October 2025, as a key valuation input.

For valuations prior to December 2025, these independent third-party valuations then allocated the equity value of the business to our common stock using the option-pricing model (OPM). Under the OPM, shares are valued by creating a series of call options with exercise prices based on the liquidation preferences, participation rights, dividend policy, and conversion terms of each equity class. The values of the preferred and common stock are inferred by analyzing these options, and the common stock has value only if the funds available for distribution to stockholders exceed the value of the liquidation preferences at the time of a liquidity event.

For the valuations performed since December 2025, these independent third-party valuations utilized the probability-weighted expected return method (PWERM). The PWERM is a forward-looking valuation methodology that estimates the fair value of equity securities by considering multiple potential future outcomes for the Company and assigning probability weightings to each scenario. In connection with the December 2025 valuation, the analysis considered two primary potential outcomes: (i) a potential initial public offering and (ii) a scenario in which the

Company would continue operating as a privately held company. For each scenario, the valuation firm estimated the Company's enterprise value based on the applicable valuation methodologies and market inputs, and then allocated that value across the Company's capital structure to determine the implied value of the Company's common stock. The resulting common stock values under each scenario were then probability-weighted based on management's assessment of the likelihood of each outcome as of the valuation date to determine the estimated fair market value of the Company's common stock.

Application of these approaches involves the use of estimates, judgment, and assumptions that are complex and subjective, including assumptions regarding the expected timing of a liquidity event, risk-free interest rates, expected equity volatility, discount rates, market multiples, the selection of comparable companies, forecast revenue, the probability of possible events, discount for lack of marketability, our capital structure and the rights and preferences of our outstanding securities, including liquidity preferences.

For valuations after the completion of this offering, the fair value of each share of underlying common stock will be based on the closing price of our common stock as reported by primary stock exchange where our common stock is traded on the applicable grant date.

Recent Accounting Pronouncements

See Note 3 to our audited financial statements included elsewhere in this prospectus for more information.

Quantitative and Qualitative Disclosures About Market Risk

Interest rate risk

The primary risk associated with fluctuating interest rates is related to our debt. Borrowings under the Loan and Security Agreement accrue interest at an annual rate equal to the greater of (i) The Wall Street Journal (or any successor thereto) prime rate (subject to a floor of 8.50%) plus 3.75% and (ii) 12.25%. In addition, we hold cash and cash equivalents as well as marketable securities, all of which may generate interest income. The primary objectives of our investment activities are to preserve principal and provide liquidity. Since our results of operations are not dependent on investments, we believe the risk associated with fluctuating interest rates is limited. We do not believe that a hypothetical 10% increase or decrease in interest rates during any of the periods presented would have had a material effect on our financial statements included elsewhere in this prospectus. We do not currently use or plan to use financial derivatives in our investment portfolio and we do not currently engage in hedging transactions to manage our exposure to interest rate risk.

Financial Institution Risk

As of December 31, 2025, our cash and cash equivalents were maintained with two financial institutions in the United States, and our deposits are generally in excess of insured limits. Cash amounts held at financial institutions are insured by the Federal Deposit Insurance Corporation up to $250,000. We do not believe we are exposed to any significant credit risk. Our cash equivalents are invested in highly rated money market funds.

Inflation Risk

Inflation generally affects us by increasing our cost of labor. Inflationary and supply chain pressures may adversely impact our future financial results. Our operating costs have increased and may continue to increase because of these pressures, and we may not be able to fully offset these cost increases by raising prices for products or other mitigation efforts, which could result in downward pressure on margins.

Foreign currency exchange risk

Our business is primarily conducted in U.S. dollars. Any transactions that may be conducted in foreign currencies are not expected to have a material effect on our results of operations, financial position or cash flows.

Emerging Growth Company and Smaller Reporting Company Status

We are an emerging growth company, as defined in the JOBS Act. The JOBS Act permits an "emerging growth company" such as us to take advantage of an extended transition period for complying with new or revised accounting standards. This provision allows an emerging growth company to delay the adoption of some accounting standards until those standards would otherwise apply to private companies. We have elected to use the extended transition period for any other new or revised accounting standards during the period in which we remain an emerging growth company; however, we may adopt certain new or revised accounting standards early. As a result, we will not be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies and our financial statements may not be comparable to other public companies that comply with new or revised accounting pronouncements as of public company effective dates. The JOBS Act also exempts us from having to provide an attestation and report from our independent registered public accounting firm on the assessment of our internal control over financial reporting pursuant to the Sarbanes-Oxley Act.

We will remain an emerging growth company until the earliest of: (i) the last day of the fiscal year following the fifth anniversary of the consummation of this offering; (ii) the last day of the fiscal year in which we have total annual gross revenue of at least $1.235 billion; (iii) the last day of the fiscal year in which we are deemed to be a "large accelerated filer" as defined in Rule 12b-2 under the Exchange Act, which would occur if the market value of our common stock held by non-affiliates exceeded $700.0 million as of the last business day of the second fiscal quarter of such year; or (iv) the date on which we have issued more than $1.0 billion in non-convertible debt securities during the prior three-year period.

We are also a "smaller reporting company" as defined in the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates is less than $250.0 million measured on the last business day of our second fiscal quarter, or our annual revenue is less than $100.0 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is less than $700.0 million measured on the last business day of our second fiscal quarter. We cannot predict if investors will find our shares of common stock less attractive because we may rely on these exemptions. If some investors find our shares of common stock less attractive as a result, there may be a less active trading market for shares of our common stock and our share price may be more volatile.

BUSINESS

Overview

We are a commercial-stage medical device company redefining stroke recovery for survivors living with life-altering motor impairments. Our Vivistim Paired Vagus Nerve Stimulation (Paired VNS) System is the first and only clinically-validated, FDA-approved solution for chronic ischemic stroke survivors with moderate to severe upper extremity impairments. Stroke is one of the leading causes of long-term disability in the United States. While advancements in acute stroke care over the past decade have significantly reduced mortality, innovation for chronic stroke recovery has lagged, resulting in a growing number of stroke survivors living with meaningful impairments. Our breakthrough Vivistim Paired VNS System (Vivistim System) addresses this unmet need. The Vivistim System includes an implanted pulse generator and lead that deliver stimulation to the vagus nerve when activated. During treatment (Vivistim Therapy), intentional bursts of stimulation are delivered during functional movement to increase neuroplasticity and durably restore motor function. Clinical data has demonstrated that Vivistim Therapy delivers meaningful improvements in upper limb function, which can help stroke survivors regain critical capabilities and independence and restore quality of life, regardless of the time elapsed since the patient's stroke. We believe we are setting a new standard of care in chronic stroke recovery, facilitating a new treatment pathway for chronic ischemic stroke survivors with moderate to severe upper extremity impairments. We have experienced rapid growth since our full commercial launch in 2023, and physicians have performed over 1,000 implants, including approximately 700 in 2025.

In the United States, a stroke occurs every 40 seconds and approximately 800,000 strokes occur annually, according to a report published by the American Heart Association (AHA) in 2025. Stroke occurs when blood flow to a region of the brain is suddenly interrupted, either because an artery becomes blocked in the case of an ischemic stroke, or because a weakened blood vessel ruptures in the case of a hemorrhagic stroke. For stroke survivors, the interruption of blood flow to the brain can result in lasting motor, cognitive, visual, and language impairments, including weakness or hemiparesis affecting the extremities. Based on a report published by the AHA in 2025, we estimate that there are currently approximately 10 million stroke survivors in the United States, the majority of whom are living with chronic impairments.

Chronic ischemic stroke is a serious medical condition characterized by physical and cognitive impairments that persist beyond the first three to six months post-stroke. These impairments can materially diminish a patient's independence and quality of life. According to a report published by the AHA in 2025, ischemic stroke is a leading cause of serious long-term impairment for adults in the United States and has an estimated annual healthcare burden of more than $25 billion.

Chronic stroke recovery presents a significant market opportunity. According to the AHA, approximately 87% of the strokes in the United States are ischemic. This equates to approximately 9 million ischemic stroke survivors in the United States, of which we estimate that more than 4 million are chronic ischemic stroke survivors living with moderate to severe upper extremity impairment. This population falls within the current on-label indication for the Vivistim System. We believe that an initial market opportunity comprises approximately 1 million of those survivors that demonstrate the requisite overall health, cognition and motivation to participate in therapy and have received some amount of post-stroke therapy, which we estimate represents an initial market opportunity of over $30 billion based on the average selling price of the Vivistim System. Vivistim Therapy is effective for recent stroke survivors as well as patients who initiate treatment many years post-stroke. Based on a report published by the AHA in 2025, we estimate that each year approximately 200,000 new stroke survivors in the United States meet our indication for use, with 50,000 of these survivors representative of our initial market opportunity.

There is no standard of care for motor recovery in the chronic stage of stroke. After the initial three- to six-month sub-acute phase post-stroke, we believe patients typically reach a functional plateau with conventional physical rehabilitation and have limited options to continue improving. As a result, we believe that there is a large population of highly motivated stroke survivors who have few proven options.

Our breakthrough Vivistim System is the first and only FDA-approved solution for chronic ischemic stroke survivors with moderate to severe upper extremity impairments. The Vivistim System facilitates Vivistim Therapy,

which has been clinically proven to significantly improve upper limb function and help patients regain critical capabilities and independence. Vivistim Therapy leverages neuroplasticity – the ability of the nervous system to adapt and reorganize its connections – to improve upper limb function in patients with chronic stroke. The Vivistim System includes an implantable device that stimulates the vagus nerve only when intentionally activated, triggering the release of neuromodulators. These neuromodulators create a heightened state of plasticity in the brain, such that neural networks can more readily adapt and reform in response to stimuli. When functional movements, such as goal- or task-oriented exercises and movements, are performed in the presence of these increased neuromodulators, the brain can create new neural connections and strengthen existing connections to a degree that would otherwise not be possible, enabling lasting improvements in motor pathways and creating greater potential for recovery.

Shortly after device implantation, patients begin Vivistim Therapy with a physical or occupational therapist. This therapy does not require patient-specific programming. In the clinic, the therapist uses a remote to activate the Vivistim System during task-specific practice, such as reaching for and grasping objects. Patients continue Vivistim Therapy at home, both during their in-clinic therapy protocol and, if desired, in the months and years that follow. At home, patients easily activate stimulation sessions by swiping the Vivistim magnet over the Vivistim IPG implant site, which initiates 30 minutes of periodic stimulation pulses. Patients can perform this therapy at home or during their activities of daily living to further reinforce their neural retraining. We believe the ability for patients to observe real, tangible improvements in their ability to perform activities of daily living can encourage ongoing engagement with at-home therapy, helping patients to sustain their efforts and achieve meaningful, lasting functional improvement over time.

We believe we are setting a new standard of care in chronic stroke recovery, facilitating a new treatment pathway for chronic ischemic stroke patients with moderate to severe upper extremity impairment. We believe Vivistim Therapy offers these patients a number of key benefits, including the first and only FDA-approved device clinically proven to deliver significant improvements in upper limb function; significant clinical improvement even for patients who initiate treatment many years post-stroke; durable improvements underpinned by a clinically proven mechanism of action; high patient and therapist satisfaction; and a safe and minimally invasive outpatient procedure.

We are building a robust body of clinical evidence supporting the safety, efficacy, durability, and well-understood mechanism of action of Vivistim Therapy, with additional trials ongoing and planned in 2026 and beyond. In our pivotal, triple-blind, randomized, sham-controlled VNS-REHAB trial, Vivistim Therapy resulted in an approximately two-times greater, as measured by Fugl-Meyer Assessment of Upper Extremity (FMA-UE), and approximately three-times greater, as measured by Wolf Motor Function Test (WMFT), improvement in hand and arm function compared to intensive rehabilitation alone, at the end of the in-clinic and at-home therapy protocol. Data from the trial also demonstrated a favorable safety profile, with no severe adverse events, serious adverse events or unanticipated adverse events associated with the Vivistim System. While implantation can result in procedure-related complications, such as post-operative pain and infection, the rate of surgical complications that did not resolve within a few weeks was less than 1% in the VNS-REHAB trial. These results highlight Vivistim Therapy's distinctive ability to drive substantial neuroplastic adaptations and functional gains, which we believe sets it apart as the only therapy with robust clinical evidence for effective post-stroke motor recovery. Looking ahead, our GRASP registry is collecting real-world evidence to reinforce the durable benefits of Vivistim Therapy. We believe patient access is key to gaining market acceptance, and we remain committed to expanding patient access by developing additional evidence that further validates the benefits of Vivistim Therapy, accelerates market adoption, strengthens proof of its clinical utility, and supports broader reimbursement coverage decisions.

We continue to optimize our commercial model to support the adoption of Vivistim Therapy and gain further market acceptance. Our strategy is tailored to our unique patient and customer dynamics. Stroke survivors living with life-altering functional impairment can self-identify and are highly motivated to seek effective, long-lasting solutions. These patients are often supported by dedicated advocates who create a strong network of care and commitment. Our target customer base consists of a highly concentrated group of approximately 1,500 primary and comprehensive stroke centers in the United States. These stroke centers, which are typically surrounded by a network of therapy sites with neurorehabilitation capabilities, provide the infrastructure for efficient implementation of Vivistim Therapy.

As a novel treatment, expanding market acceptance depends in part upon our ability to educate healthcare providers and others as to the distinctive characteristics, clinical and benefits, safety, durability and ease of use of Vivistim Therapy. We believe we have implemented highly effective initiatives for generating a consistent funnel of Vivistim Therapy candidates through physician and therapist referrals, as well as direct patient engagement. Stroke survivors interact with a diverse network of care providers who help identify and evaluate candidates. We directly engage each of these stakeholders through specialized events, summits, and conferences as well as through our field-based commercial team. Our commercial organization is responsible for driving adoption of the Vivistim System through customer outreach, education, and relationship management activities. Our team includes Territory Managers (TMs), who support initial customer onboarding efforts at stroke centers and maintain commercial relationships with physicians and administrators, and Therapy Development Specialists (TDSs), who focus on outreach to therapy sites and provide general educational information regarding the clinical use of the Vivistim System. These activities are intended to facilitate customer adoption and utilization of the Vivistim System.

We have designed a differentiated, purpose-built technology uniquely engineered to enable Vivistim Therapy. The Vivistim System delivers intentional bursts of stimulation paired with salient, goal-oriented exercises—an approach clinically proven to promote neuroplasticity and improve motor recovery. This innovative therapeutic method is protected by a robust patent portfolio. Our breakthrough technology, combined with our robust intellectual property protection, creates meaningful barriers to entry and reinforces our first-mover advantage.

Our commitment to offering life-changing treatments drives our passion for innovation through continuous research and development. We commenced development efforts in 2007 with an aim to pursue initial research from the University of Texas regarding the effects of vagus nerve stimulation. By early 2013, we began focusing on paired vagus nerve stimulation therapy for stroke recovery, working with a small team of fewer than ten engineers, clinicians and scientists. Over several years, this work led to the development and clinical testing of our Vivistim System, including through our feasibility, pilot and pivotal trials from 2014 to 2021. Following the results of our pivotal trial, we submitted a premarket approval (PMA) application to the FDA in March 2021. The Vivistim System received PMA approval from the FDA in 2021 and is classified by the FDA as a Class III device. In 2021, the Vivistim System was granted breakthrough device status under the FDA's Breakthrough Devices Program. We aim to build upon these development efforts and leverage our internal expertise, clinical insights and experience gained from developing the Vivistim System to assess and prioritize research and development initiatives.

The Vivistim System implantation procedure falls under a long-established Category 1 CPT code. Effective January 1, 2026, this CPT code was assigned to a New Technology Ambulatory Payment Classification (APC) by the Centers for Medicare and Medicaid Services (CMS), establishing an elevated payment level that we believe will support sustainable access for Medicare beneficiaries. Coverage for Vivistim Therapy varies by payor. As there are currently no national coverage determinations or local coverage determinations specific to Vivistim Therapy, coverage for Medicare fee-for-service patients is made on a case-by-case basis and patients are typically able to access Vivistim Therapy when medically necessary, without prior authorization. Currently, most commercial insurers have determined that Vivistim Therapy is experimental or investigational and therefore, not covered. To that end, commercial insurance, Medicaid and Medicare Advantage generally require prior authorization. Our in-house market access team supports providers by facilitating administrative aspects of the prior authorization process, including assisting with documentation and submissions to payors in advance of implantation. As part of our longer term strategy, our market access team plans to continue to engage with payors to communicate clinical and health economic data which may impact coverage policies. We believe that expanded payor coverage will facilitate broader patient access to Vivistim Therapy.

We have experienced rapid growth since our full commercial launch in 2023. We recognized revenue of $32.0 million for the year ended December 31, 2025, compared to revenue of $15.6 million for the year ended December 31, 2024, representing 104.8% year-over-year growth. For the year ended December 31, 2025, we recognized a gross margin of 81.1% and a net loss of $46.5 million, compared to a gross margin of 79.6% and a net loss of $24.6 million for the year ended December 31, 2024. As of December 31, 2025, we had an accumulated deficit of approximately $157.8 million.

Our Success Factors

We believe the continued growth of our company will be driven by the following success factors:

- ***First and only FDA-approved solution establishing a new standard of care in chronic stroke recovery.*** We are redefining chronic stroke recovery with a novel and clinically validated therapy. Stroke impairment is one of the leading causes of serious long-term impairment for adults in the United States. While advances in acute stroke care over the past decade have significantly reduced mortality, innovation for chronic stroke recovery has lagged, resulting in a growing number of stroke survivors living with life-altering motor impairments. Conventional treatment consists of physical or occupational therapy, which is generally performed in the first three to six months following a stroke, after which it has very limited effectiveness. Thus, patients are left with few clinically proven options beyond that point. Our breakthrough Vivistim System addresses this unmet need and is the first and only FDA-approved solution for chronic ischemic stroke survivors with moderate to severe upper extremity impairments. During Vivistim Therapy, intentional bursts of stimulation are delivered during functional movement to increase neuroplasticity and durably restore motor function. Vivistim Therapy has demonstrated efficacy and durability even years after a stroke, offering hope and meaningful recovery where none existed before. For example, clinical data demonstrated meaningful improvements in upper limb function. Based on published case studies involving patients that received Vivistim Therapy, improvements in upper limb function following Vivistim Therapy can further enable patients to perform activities of daily living, such as dressing independently, preparing meals, folding laundry, and eating (Saylor A, Patrick L, Reddy CG, Gandhi R., *Vagus Nerve Stimulation Paired With Upper Extremity Rehabilitation for Chronic Stroke: Real-World Implementation and Outcomes*. Arch Rehabil Res Clin Transl. (2026)). We believe this proven therapy helps restore quality of life and sets a new standard of care in chronic stroke recovery.

- ***Large and untapped market opportunity with significant unmet need.*** Stroke is a major health burden, with someone in the United States experiencing a stroke every 40 seconds. Ischemic stroke is a leading cause of serious long-term impairment for adults in the United States and has an estimated annual healthcare burden of more than $25 billion. Nearly two-thirds of stroke survivors are left with long-term disabilities including, but not limited to, impaired motor function, speech and language difficulties, and cognitive impairments that significantly impact quality of life. We estimate there are about 9 million ischemic stroke survivors in the United States, of which more than 4 million live with moderate to severe upper extremity impairment. This population falls within the current on-label indication for the Vivistim System. We believe that our initial market opportunity comprises approximately 1 million of those survivors, which we estimate represents an initial market opportunity of over $30 billion based on the average selling price of the Vivistim System. Since Vivistim Therapy is clinically proven to be effective regardless of time since stroke, eligible Vivistim System candidates include patients who have lived with chronic stroke-related impairments for many years, as well as recent stroke survivors. Based on a report published by the AHA in 2025, we estimate that each year approximately 200,000 new stroke survivors in the United States meet our indication for use, with 50,000 of these survivors representative of our initial market opportunity.

- ***Compelling body of clinical data demonstrating the significant and sustained benefits of Vivistim Therapy.*** We have built a robust body of clinical data demonstrating the safety, efficacy, durability, and well-understood mechanism of action of Vivistim Therapy and have additional studies ongoing and planned in 2026 and beyond. Our pivotal VNS-REHAB trial, a triple-blind, sham-controlled, randomized controlled trial (RCT), proved the efficacy and safety of Vivistim Therapy in ischemic stroke survivors with moderate to severe upper extremity impairment 9 months to 10 years after stroke. Published in *The Lancet* in 2021, this landmark trial showed an approximately two-times greater, as measured by FMA-UE, and approximately three-times greater, as measured by WMFT, improvement in hand and arm function compared to intensive rehabilitation alone, at the end of the in-clinic and at-home therapy protocol (Dawson, Jesse et al., *Vagus nerve stimulation paired with rehabilitation for upper limb motor function after ischaemic stroke (VNS-REHAB): a randomised, blinded, pivotal, device trial*, The Lancet, Volume 397, Issue 10284, 1545-1553 (2021)). These findings have been reinforced by subsequent publications, including a 2024 publication in *Neurorehabilitation and Neural Repair*, which confirmed consistent

outcomes across subgroups, including age, time since stroke, and baseline severity (Lin, Shiyu et al., *Vagus Nerve Stimulation Paired With Upper Extremity Rehabilitation for Chronic Ischemic Stroke: Contribution of Dosage Parameters*, Neurorehabilitation and Neural Repair, Volume 38, Issue 8, 607-615 (2024)). A 2025 publication in *Stroke* demonstrated that the functional gains were sustained at one-year follow-up (Kimberley, Teresa et al., *Long-Term Outcomes of Vagus Nerve Stimulation Paired With Upper Extremity Rehabilitation After Stroke*, Stroke, Volume 56, Number 8, 2255-2265 (2025)). Looking ahead, our GRASP registry is collecting real-world evidence to reinforce the durable benefits of Vivistim Therapy. Our strong body of clinical data demonstrates the significant safety and efficacy of Vivistim Therapy in its indication, and we remain committed to expanding our evidence base to reinforce Vivistim Therapy's value, accelerate market adoption, and strengthen proof of its clinical utility.

- ***Unique customer and patient dynamics to support a scalable commercial model.*** Our market development and patient engagement strategy is tailored to our unique patient and customer dynamics. Stroke survivors living with life-altering functional impairment can self-identify and are highly motivated to seek effective, long-lasting solutions. These patients are often supported by dedicated advocates who create a strong network of care and commitment. Our target customer base consists of a highly concentrated group of approximately 1,500 primary and comprehensive stroke centers in the United States. These centers treat a high proportion of the stroke survivor population. In addition, according to stroke claims data from Definitive Healthcare, approximately 70% of acute strokes are seen at 900 hospitals. Additionally, these stroke centers are typically surrounded by a network of therapy sites with neurorehabilitation capabilities, providing the infrastructure necessary for efficient implementation of Vivistim Therapy. This unique market concentration sets the foundation for an efficiently scalable commercial model.

- ***Favorable coding and payment dynamics with dedicated in-house market access team supporting patients and providers.*** The Vivistim System implantation procedure falls under a long-established Category 1 CPT code. Effective January 1, 2026, this CPT code was assigned to a New Technology APC by the CMS, establishing an elevated payment level that we believe will support sustainable access for Medicare beneficiaries. Medicare fee-for-service patients can typically access Vivistim Therapy when medically necessary, without prior authorization. Commercial insurance, Medicaid and Medicare Advantage generally require prior authorization. We believe we have implemented a highly effective process to guide patients from initial consultation through implantation of the Vivistim System. Our in-house market access team supports providers by facilitating administrative aspects of the prior authorization process, including assisting with documentation and submissions to payors in advance of implantation. Beyond individual case support, our market access team proactively works to influence payor coverage decisions by utilizing our robust clinical evidence, demonstrating economic value, and leveraging endorsements from key opinion leaders. This team is central to reducing friction across the patient journey and serves as a cornerstone of our strategy to expand payor coverage, which we believe will significantly increase patient market access of Vivistim Therapy.

- ***Differentiated purpose-built technology for Vivistim Therapy protected by robust IP portfolio.*** We have designed a differentiated, purpose-built technology uniquely engineered to enable paired vagus nerve stimulation therapy. The Vivistim System delivers intentional bursts of stimulation paired with salient, goal-oriented exercises—an approach clinically proven to promote neuroplasticity and improve motor recovery. This innovative therapeutic method is protected by a robust patent portfolio. Our breakthrough technology, combined with our robust intellectual property protection, creates meaningful barriers to entry and reinforces our first-mover advantage.

- ***Seasoned executives with extensive Med Tech commercialization expertise and a proven track record of value creation.*** Our management team is comprised of seasoned executives with decades of experience across commercialization, marketing, operations, and engineering. Our leadership team has a proven track record of successfully scaling large and small businesses, both public and private, in the medical technology space. Our team understands the requirements of technological development, regulatory approval and commercial execution for new and transformative medical devices and has a history of driving rapid commercial growth. Our expertise is further strengthened by an experienced board and world-

class investors who provide blue-chip leadership. These investors have supported the growth of numerous publicly traded companies and bring deep knowledge of medical technology and healthcare broadly.

Our Growth Strategies

Our mission is to redefine stroke recovery for survivors living with life-altering functional impairments by establishing Vivistim Therapy as the standard of care for chronic stroke. The key elements of our growth strategy include:

- ***Expand our market development efforts to broaden awareness and access to Vivistim Therapy.*** Since our commercial launch, we have continuously developed and refined the optimal commercial model to support the adoption of Vivistim Therapy and have established a methodical approach to market development across the key stakeholders in stroke recovery. Through our comprehensive Vivistim Therapy program, we educate providers on how to identify, screen, refer and treat stroke survivors, and work closely with hospitals to incorporate Vivistim Therapy as a treatment option. We plan to build on this foundation of commercial learning to accelerate adoption nationwide by activating Vivistim Therapy initiatives at stroke centers and therapy sites while deepening engagement within existing accounts. To broaden geographic reach and drive penetration, we will strategically expand our commercial organization and territory coverage by adding highly qualified personnel. By scaling our skilled direct sales force, we believe we can significantly increase access to Vivistim Therapy and deliver meaningful impact to patients nationwide.

- ***Driving utilization of Vivistim Therapy by promoting awareness among patients, caregivers and healthcare providers.*** We have developed highly effective initiatives for generating a consistent funnel of Vivistim Therapy candidates from three primary sources: physician referrals, therapist referrals, and direct patient engagement. Stroke survivors interact with a diverse network of care providers, including stroke interventionalists, neurosurgeons, neurologists, physical medicine and rehabilitation physicians, occupational and physical therapists, stroke coordinators and nurses. Each of these providers can play a role in identifying and evaluating potential Vivistim Therapy candidates. We directly engage each of these stakeholders through our field-based commercial team, as well as through specialized events, summits, and conferences. In each geography, our teams also work to establish strong referral patterns between these providers to ensure that potential candidates can be efficiently evaluated and receive Vivistim Therapy. Additionally, since stroke survivors and their caregivers are a highly motivated population, we engage in direct patient education activities. These initiatives include patient webinars, outreach through support groups, digital advertising, and other targeted activities. We believe that as Vivistim Therapy awareness and utilization increases, stroke centers will naturally integrate Vivistim Therapy into standard care pathways for stroke survivors upon discharge and establish self-sustaining care programs that use Vivistim Therapy over time.

- ***Building upon our strong base of clinical evidence to support adoption and expand payor coverage.*** We have built, and remain committed to expanding, a robust body of clinical evidence demonstrating the safety, efficacy and durability of Vivistim Therapy. We are actively enrolling patients in our GRASP registry, a real-world study generating evidence of the therapy's significant and sustained benefits. We plan to publish 12-, 24-, and 36-month outcomes, supporting a steady cadence of publications. Our market access team works to ensure that this growing body of clinical data, along with the therapy's health economic benefits, and strong support from key opinion leaders, is communicated effectively to payors to inform positive coverage decisions. We believe that expanding payor coverage will be a key driver of increased utilization and improved access for stroke survivors living with life-altering impairments.

- ***Investing in research and development to drive continuous innovation, better outcomes, and improved user experience.*** Our commitment to offering life-changing treatments for stroke survivors drives our passion for innovation through continuous research and development. We intend to invest in existing and next-generation technologies to further improve our products and clinical outcomes, optimize patient experience, increase utilization, and increase patient engagement. Our near-term research and development activities are primarily directed toward continued technological advancement of the Vivistim System, and development of a next-generation Vivistim System with enhanced features.

- ***Expanding clinical indications to benefit a broader patient population.*** With its unique and clinically validated mechanism of action, we believe Vivistim Therapy has the potential to address additional clinical indications within stroke recovery. We are committed to better serving this population by exploring expansions into other functional impairments (e.g., lower limb) or stroke etiologies (e.g., intracerebral hemorrhage).
- ***Continue to evaluate expansion into geographies outside of the United States.*** While our current commercial efforts are focused on the significant opportunity nationwide, we will continue to evaluate expansion into select geographies outside the United States. Over time, we intend to strategically invest in markets with a high stroke burden and favorable commercial dynamics, enabling patients worldwide to benefit from Vivistim Therapy.

Overview of Chronic Stroke Impairment

Stroke occurs when blood flow to a region of the brain is suddenly interrupted, either because an artery becomes blocked in the case of an ischemic stroke, or because a weakened blood vessel ruptures in the case of a hemorrhagic stroke. The leading causes of stroke are high blood pressure, high cholesterol, and certain lifestyle choices. A stroke deprives brain cells of oxygen, and they begin to die within minutes. Every second without oxygen can lead to serious brain damage, long-term disability, or death if not treated promptly. For survivors, the interruption of blood flow to the brain can result in lasting motor, cognitive, visual, and language impairments, including weakness or hemiparesis affecting the extremities. In the United States, a stroke occurs every 40 seconds, and approximately 800,000 strokes occur annually, according to a report published by the AHA in 2025. Based on the same report, we estimate that there are approximately 10 million stroke survivors in the United States, the majority of whom are living with chronic impairments.

Chronic ischemic stroke is a serious medical condition characterized by physical and cognitive impairments that persist beyond the first three to six months post-stroke. The first three to six months after a stroke are commonly referred to as the sub-acute phase. These impairments can materially diminish a patient's independence and quality of life. According to a report published by the AHA in 2025, ischemic stroke is a leading cause of serious long-term impairment for adults in the United States and has an estimated annual healthcare burden of more than $25 billion.

While advancements in acute stroke care have helped to significantly reduce the stroke mortality rate in the United States over time, effective therapeutic options for post-stroke recovery have not advanced, and there is no standard of care for motor recovery in the chronic stage of stroke. The standard of care for post-stroke recovery in the sub-acute phase consists of several weeks or months of conventional occupational or physical rehabilitation therapy, although many patients do not receive any rehabilitation therapy at all due to lack of access or motivation. While stroke patients can, and often do, make some physical and cognitive improvements during the acute and sub-acute phases when neuroplasticity is the highest, a substantial proportion of patients continue living with long-term motor impairments and associated complications. We believe there is limited data demonstrating the clinical efficacy of conventional rehabilitation therapy beyond the sub-acute phase, leaving many patients with chronic deficits in functionality (Grefkes, C. and Fink, G.R., *Recovery from stroke: current concepts and future perspectives*, Neurological Research and Practice, Volume 2, Number 17 (2020)). In addition, we believe conventional rehabilitation therapy has experienced limited adoption or continuation in the chronic phase. One study published in *Stroke* in 2023 concluded that the delivery rate of such therapy during the first year following a stroke is low and decreases over time, with 51% of patients receiving conventional occupational therapy during the first three months following a stroke and 21% of patients receiving such therapy during the three to six months following a stroke (Young, Bittany et al., *Rehabilitation Therapy Doses Are Low After Stroke and Predicted by Clinical Factors*, Stroke, Volume 54, Number 3, 831-839 (2023)). In the same study, approximately one third of stroke patients received no therapy in the year following a stroke. As such, we believe these patients have generally not had an effective therapeutic option for continued recovery.

Chronic Upper Extremity Impairment

Chronic upper extremity impairment is among the most common and disabling consequences of stroke, with millions of survivors experiencing weakness, loss of coordination, reduced dexterity, and impaired function in the

arm and hand, persisting for more than three to six months post-stroke. These impairments significantly limit the patients' ability to perform activities of daily living, such as eating, dressing, bathing, and personal care, can impede a survivor's ability to return to their profession, and can have a profound impact on functional independence and quality of life.

Our Market Opportunity

Based on a report published by the AHA in 2025, we estimate that there are currently approximately 10 million stroke survivors in the United States. According to the AHA, approximately 87% of strokes are ischemic. This equates to approximately 9 million ischemic stroke survivors in the United States. Based on our analysis of third party publications, we estimate that more than 4 million of these survivors are chronic ischemic stroke survivors living with moderate to severe upper extremity impairment. For example, according to several third-party publications, up to two-thirds of stroke survivors continue to experience upper extremity disability at six months post-stroke (*e.g.*, Lang CE, et al., *Observation of amounts of movement practice provided during stroke rehabilitation*, Arch Phys Med Rehabil. 2009 Oct;90(10):1692-8; and Kwakkel G, Kollen BJ, van der Grond J, Prevo AJ., *Probability of regaining dexterity in the flaccid upper limb: impact of severity of paresis and time since onset in acute stroke*, Stroke, Volume 34, Number 9, 2181-6 (2003), and approximately 81% of stroke survivors with upper extremity disability after six months post-stroke have moderate to severe upper extremity impairment (Woytowicz E, et al., *Determining Levels of Upper Extremity Movement Impairment by Applying a Cluster Analysis to the Fugl-Meyer Assessment of the Upper Extremity in Chronic Stroke*, Archives of Physical Medicine and Rehabilitation, 2016; 98, 456-462). We expect this large prevalence population to continue to grow over time, driven by, among others, increasing stroke survival rates due to improvements in acute thrombectomy therapies and increasing stroke incidence rates among young adults.

Based on our FDA-approved, on-label indication for the Vivistim System, we estimate that our total addressable market opportunity in the United States consists of the approximately 4 million chronic ischemic stroke survivors living with moderate to severe upper extremity impairment. While we are pursuing this total addressable market, we believe an initial market opportunity comprises stroke survivors that demonstrate the requisite overall health, cognition and motivation to participate in therapy and have received some amount of post-stroke therapy. According to the AHA, two-thirds of stroke survivors receive rehabilitation therapy following a stroke. This rate of therapy generally decreases over time, with one study published in *Stroke* in 2023 concluding that the rate of conventional occupational therapy decreases to 21% in the three to six months following a stroke (Young, Bittany et al., *Rehabilitation Therapy Doses Are Low After Stroke and Predicted by Clinical Factors*, Stroke, Volume 54, Number 3, 831-839 (2023)). Based on these patient factors and post-stroke therapy rates, we estimate that this initial market opportunity comprises approximately 1 million stroke survivors within our total addressable market. We believe this patient population represents an initial market opportunity of over $30 billion based on the average selling price of the Vivistim System.

Vivistim Therapy has demonstrated meaningful clinical improvements in upper extremity function independent of the time elapsed since stroke. As such, Vivistim Therapy is appropriate for patients who initiate treatment many years post-stroke as well as more recent stroke survivors. Based on a report published by the AHA in 2025, we estimate that each year approximately 200,000 new stroke survivors in the United States meet our indication for use, with 50,000 of these survivors representative of our initial market opportunity.

While our initial focus is on ischemic stroke survivors with moderate to severe upper extremity impairment within the United States due to the large unmet need and prevalence pool, we believe our technology is well-suited to address additional indications within stroke, including but not limited to lower extremity impairment and chronic hemorrhagic stroke. We expect to explore targeted indication and geographic expansion opportunities in the future.

The market share we ultimately achieve is subject to a number of assumptions, risks and uncertainties, including the market acceptance of Vivistim Therapy and our ability to execute on our commercial strategy. As a novel treatment, market acceptance depends, in part, on our ability to raise awareness, the adoption of Vivistim Therapy by hospitals, healthcare providers, therapists, patients, caregivers and adequate payor coverage and reimbursement, and the acceptance of Vivistim Therapy as safe, effective and cost-effective. We may be unsuccessful in attaining significant market acceptance or such acceptance may take longer or be more costly than anticipated. For more

information, please see the section titled "*Risk Factors — Risks Related to Our Business and Industry — The commercial success of Vivistim Therapy depends upon attaining significant market acceptance of our products by hospitals, healthcare providers, therapists, patients, caregivers and payors" and " — The size of our market opportunity has not been established with precision and may be smaller than we estimate, possibly materially.*"

Patient Journey: Conventional Rehabilitation during the Sub-Acute Phase

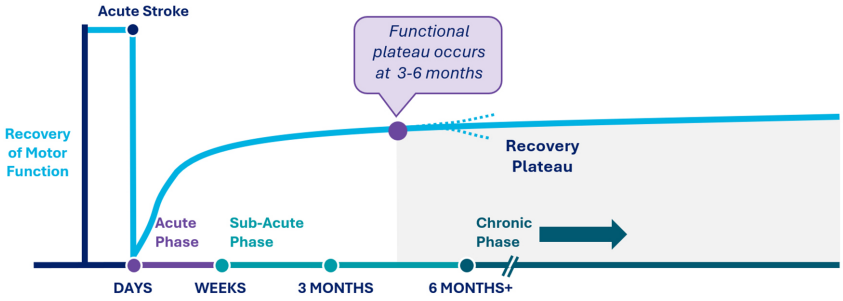
For stroke survivors who are discharged home with moderate to severe upper extremity impairment, the standard of care for rehabilitation during the sub-acute phase involves physical and/or occupational therapy several times per week, generally for several weeks or months. However, many patients do not receive any rehabilitation therapy due to lack of access, poor care coordination, or lack of social support. Conventional rehabilitation programs are generally delivered during the first several weeks to months after a stroke when neuroplasticity is highest and functional gains are the most achievable.

Physical therapy aims to improve gross motor skills (e.g., stretching to improve arm movement), while occupational therapy aims to improve fine motor skills, like those associated with activities of daily living such as bathing and eating. Many patients undergo a combination of both physical and occupational therapy.

During the sub-acute phase, patients may also explore other rehabilitation techniques including but not limited to: neurological rehabilitation therapy, which involves practicing everyday activities (e.g., cutting a banana or folding cloths); Constraint-Induced Movement therapy, which focuses on constraining the non-affected side from moving; and Mental Practice, where patients mentally rehearse a physical movement or task without actually performing it. Although alternative therapy delivery methods such as virtual reality or video games may be helpful for increasing the amount of movement practice a patient undergoes, there is limited and low-quality clinical evidence about their benefits. Assistive tools – such as splints, braces, muscle stimulators, have been used in conjunction with therapy and adaptive equipment (e.g., one handed kitchen tools), may also be used to help patients compensate for their impairments. Importantly, while these adjunctive therapies can help improve a patient's ability to participate in therapy during the sub-acute phase, they have not been clinically proven to provide meaningful functional gains in the chronic phase.

Lack of Effective Treatments for Chronic Upper Extremity Impairments

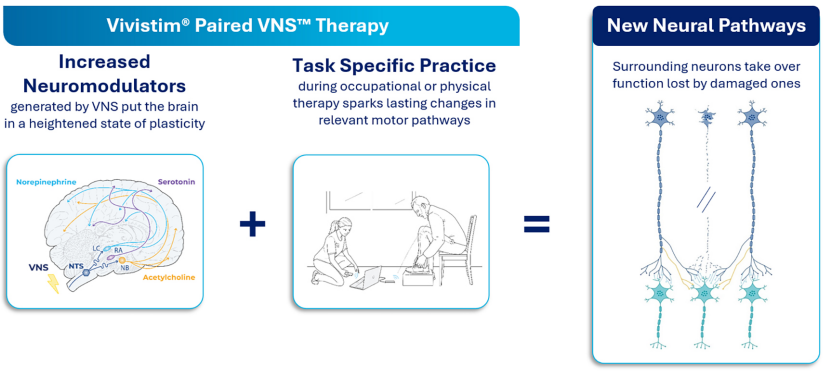
There is no standard of care for motor recovery in the chronic stage of stroke. After the initial three- to six-month period post-stroke, patients typically reach a functional plateau with conventional physical rehabilitation and have limited options to continue improving their recovery. As a result, we believe that there is a large population of highly motivated stroke survivors who have few proven options. The image below presents an overview of the patient journey and conventional rehabilitation windows through the acute, sub-acute and chronic phases.



Given the lack of therapies that are clinically proven to improve motor function in the chronic phase of recovery, there is a compelling need for a scalable and clinically validated solution that delivers measurable functional gains and improves quality of life for these highly motivated patients that are actively seeking a solution.

Our Solution

Our breakthrough Vivistim System is the first and only FDA-approved solution for chronic ischemic stroke survivors with moderate to severe upper extremity impairments. The Vivistim System facilitates Vivistim Therapy, which has been clinically proven to significantly improve upper limb function and help patients regain critical capabilities and independence. Vivistim Therapy leverages neuroplasticity – the ability of the nervous system to adapt and reorganize its connections – to improve upper limb function in patients with chronic stroke. The Vivistim System includes an implantable device that stimulates the vagus nerve only when intentionally activated, triggering the release of neuromodulators, including acetylcholine, norepinephrine, and serotonin. These neuromodulators create a heightened state of plasticity in the brain, such that neural networks can more readily adapt and reform in response to stimuli. When functional movements, such as goal- or task-oriented exercises and movements, are performed in the presence of these increased neuromodulators, the brain can create new neural connections and strengthen existing connections to a degree that would otherwise not be possible, enabling lasting improvements in motor pathways and creating greater potential for recovery. The image below provides an overview of the mechanism of action of Vivistim Therapy.



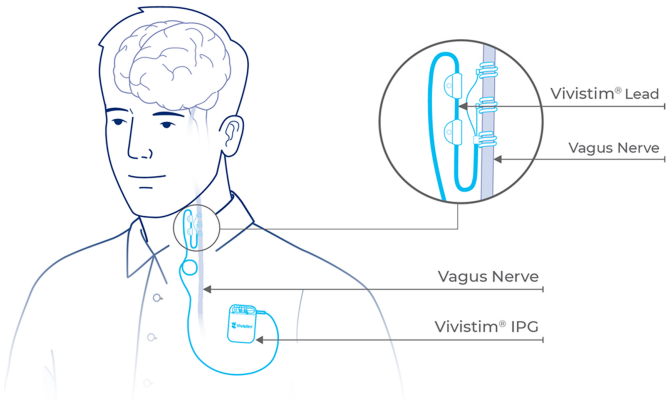
The Vivistim System received PMA approval from the FDA in 2021 to reduce upper extremity motor deficits and improve motor function in chronic ischemic stroke patients with moderate to severe upper extremity impairments. Moderate to severe upper extremity impairment can be classified based on a clinical evaluation or functional assessment, such as the FMA-UE. FMA-UE scores can range from 0 (most impairment) to 66 (no impairment), and scores between 15 and 55 generally correspond to moderate to severe impairment. The system is classified by the FDA as a Class III device. Class III devices require approval of a PMA and are devices deemed by the FDA to pose the greatest risks, such as implantable devices, devices that have a new intended use, or devices that use advanced technology that is not substantially equivalent to that of a legally marketed device.

The Vivistim System was granted breakthrough device status under the FDA's Breakthrough Devices Program in 2021, because it is intended to provide more effective treatment of a life-threatening or irreversibly debilitating condition. The FDA implemented the Breakthrough Devices Program to provide patients and health care providers with more timely access to qualifying devices by expediting their development, assessment, and review, while preserving the statutory standards for PMA approval, 510(k) clearance, and *de novo* classification. The program is available for medical devices that meet certain eligibility criteria, including that the device provides more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions.

For more information, please see the section titled "— Government Regulation" for a discussion on the FDA's classification system of medical devices and the Breakthrough Devices Program.

The Vivistim System Procedure

The implantable components of the Vivistim System – namely, the implantable pulse generator (IPG) and lead – are implanted through a safe, minimally invasive outpatient procedure that takes approximately 60 minutes. During the procedure, a surgeon makes a small incision on the left side of the neck to expose and isolate the vagus nerve and creates a pocket in the upper-left chest area for the IPG. The lead is tunneled from the neck incision to the generator pocket, and the helical electrode is carefully placed around the vagus nerve. Vagus nerve stimulation has been used in clinical practice for other conditions for over 25 years and neurosurgeons are well-acquainted with this technique. Patients typically recover quickly and are able to resume normal activities within a few days. The image below depicts the placement of the Vivistim System, including the IPG and lead.



Vivistim Therapy Delivery

Shortly after device implantation, patients begin Vivistim Therapy with a physical or occupational therapist. Vivistim Therapy does not require patient-specific programming but can be adjusted as needed. In the clinic, the therapist uses a remote to activate the Vivistim System during task-specific practice, such as reaching for and grasping objects. This type of therapy is called "task-specific practice" and focuses on practicing meaningful tasks tailored to each patient's recovery objectives and conducting a large number of sequential repetitions of each task. Each session typically involves over 300 task repetitions and is tailored to provide the appropriate level of challenge, with tasks increasing in complexity as the patient's functional abilities improve.

The Vivistim System does not deliver continuous stimulation. During in-clinic therapy, therapists activate stimulation only when paired with intentional, task-specific practice. Therapists generally do not require training on how to administer task-specific practice therapy, only an introduction on how to control and activate the Vivistim System. During each task, the therapist delivers several stimulation pulses activated via the remote control, resulting in several hundred stimulation pulses per therapy session. Therapy sessions are typically 90 minutes each, three times per week for at least six weeks. By pairing precisely-delivered vagus nerve stimulation with intensive task practice, Vivistim Therapy creates and reinforces neural pathways that improve upper limb function.

Patients can continue Vivistim Therapy at home, both during their in-clinic therapy protocol and, if desired, in the months and years that follow. By performing functional movements with the Vivistim System at home, they can further reinforce neural retraining. Patients easily activate stimulation sessions by swiping the Vivistim magnet over the Vivistim IPG implant site, which initiates 30 minutes of periodic stimulation pulses. Patients may initiate up to 8

such stimulation sessions per day, which we determined based on anticipated real world usage and believe is adequate to enable quality functional movement during each session. During this time, patients perform activities of daily living or functional movements recommended by their therapists. Such functional movements could include taking a shower, getting dressed, folding laundry, doing dishes, emptying the dishwasher, preparing or eating meals, or engaging in hobbies. Importantly, the ability for patients to observe real, tangible improvements in their ability to perform activities of daily living encourages ongoing engagement with at-home therapy, helping them to sustain their efforts and achieve meaningful, lasting functional improvement over time.

Setting a New Standard in Chronic Stroke Recovery: The Key Benefits of Vivistim Therapy

We believe Vivistim Therapy offers the first effective therapeutic option for chronic ischemic stroke patients living with moderate to severe upper extremity impairment, with the following key benefits:

- **First and only FDA-approved device clinically proven to deliver significant improvements in upper limb function.** In our pivotal, triple-blind, randomized, sham-controlled VNS-REHAB trial, Vivistim Therapy resulted in an approximately two-times greater, as measured by FMA-UE, and approximately three-times greater, as measured by WMFT, improvement in hand and arm function compared to intensive rehabilitation alone, at the end of the in-clinic and at-home therapy protocol. At such time, the FMA-UE score increased by 5.8 points in the treatment group. These results highlight Vivistim Therapy's distinctive ability to drive substantial neuroplastic adaptations and functional gains, which we believe sets it apart as the only therapy with robust clinical evidence for effective post-stroke motor recovery. Based on published case studies involving patients that received Vivistim Therapy, improvements in upper limb function following Vivistim Therapy can further enable patients to perform activities of daily living, such as dressing independently, preparing meals, folding laundry, and eating (Saylor A, Patrick L, Reddy CG, Gandhi R., *Vagus Nerve Stimulation Paired With Upper Extremity Rehabilitation for Chronic Stroke: Real-World Implementation and Outcomes*. Arch Rehabil Res Clin Transl. (2026)). Even modest gains – particularly in wrist, hand, and finger function – can impact dignity, independence, and quality of life.

- **Significant clinical improvement even for patients who initiate treatment many years post-stroke.** Unlike conventional rehabilitation therapies, which have shown benefits during the sub-acute phase of stroke recovery but not in the chronic phase, Vivistim Therapy has demonstrated clinically meaningful improvements for patients even years after their stroke. We observed significant functional improvements in all cohorts of our pivotal clinical trial, with participants averaging 3.3 years post-stroke at the time of treatment and a range from nine months to 10 years into their recovery. Commercially, we have treated patients many years post-stroke, including up to 45 years, who have achieved meaningful clinical benefit, demonstrating that improvement with Vivistim Therapy is possible regardless of time elapsed since stroke and offering hope to a large population of chronic stroke survivors.

- **Durable improvements underpinned by a clinically proven mechanism of action.** The functional gains achieved with Vivistim Therapy are long-lasting, providing durable, life-changing outcomes for stroke survivors. Clinical data has demonstrated sustained motor improvements, measured out to one year in our pivotal trial and three years in our pilot trial. This lasting effect is enabled by the unique mechanism of action underlying Vivistim Therapy, which creates durable neural pathways that enable motor improvements.

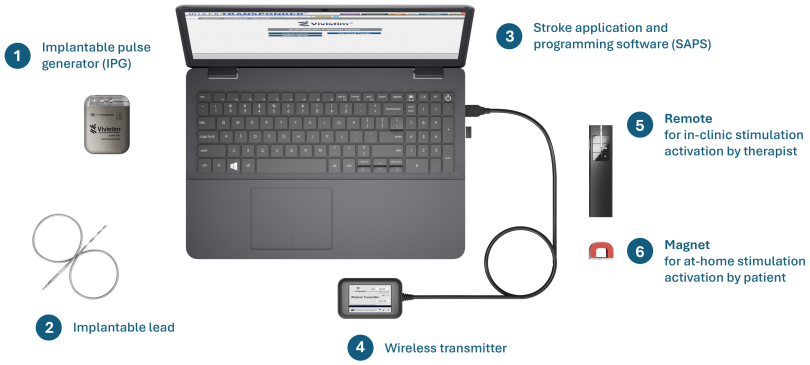
- **High patient and therapist satisfaction, with consistently positive feedback.** Based on a survey we conducted in connection with our VNS-REHAB trial, 98% of patients that received Vivistim Therapy were satisfied with their experience. In addition, based on a commercial survey conducted by us, 98% of therapists would recommend Vivistim Therapy to suitable candidates. We believe the high satisfaction rate reflects the profound impact of these functional gains on patients' lives, and the differentiation of functional gains enabled by Vivistim Therapy.

- **Safe and minimally invasive outpatient procedure.** The IPG and lead are placed via a simple, 60-minute procedure using two small incisions, allowing patients to return home on the same day and quickly resume activities of daily living. This type of procedure has been safely performed by neurosurgeons, who are

trained on it in their residency programs, and other qualified surgeons for over 25 years to treat other medical conditions and is considered safe and reliable. Our clinical results have validated the safety of the system and therapy, with no severe adverse events, serious adverse events or unanticipated adverse events associated with the Vivistim System in our VNS-REHAB trial. Our clinical results have also validated the safety of the procedure with a low complication rate. In our VNS-REHAB trial, the rate of surgical complications that did not resolve within a few weeks was less than 1%.

Components of the Vivistim Paired VNS System

The Vivistim Paired VNS System consists of the following six components:



1. **Implantable Pulse Generator (IPG):**

The IPG is a primary cell (non-rechargeable) device placed under the skin in the upper-left pectoral region, either subcutaneously or sub-muscularly. It serves as the system's power source, delivering controlled electrical pulses to stimulate the vagus nerve during therapy. The IPG battery has an indicated service life under continuous use conditions of five years. After its end of service, the IPG can be surgically replaced for continued use. The actual rate of battery depletion will be impacted by the rate of utilization of the Vivistim System. See "Risk Factors—Risks Related to Our Business and Industry—Adverse events, product recalls, or other complications or customer satisfaction issues associated with Vivistim Therapy, including regarding the finite IPG battery life, could limit its adoption."

2. **Implantable Lead:**

The lead features a helical electrode coil on one end that wraps around the left vagus nerve in the neck, and a connector on the other end that connects to the IPG. It establishes reliable and safe contact with the vagus nerve to deliver stimulation pulses.

3. **Stroke Application & Programming Software (SAPS):**

SAPS serves as the interface for controlling the Vivistim System. Using SAPS, clinicians and therapists can set and adjust the IPG stimulation parameters if needed, including amplitude, frequency, and pulse width, during and after surgery. The software also enables clinicians and therapists to check the IPG battery status and lead impedance

(a measure of the lead's resistance to current), ensuring optimal device performance and safety. Additionally, SAPS records data on stimulations delivered, whether activated by a therapist's remote or a patient's magnet, allowing for tracking of therapy utilization. SAPS is provided to clinicians pre-installed on a secure laptop. Our device manual includes detailed instructions regarding the use of SAPS, and a team of field-based clinical engineers are available to provide remote and in-person support to clinicians and therapists using our SAPS.

4. Wireless Transmitter (WT):

The WT physically connects to SAPS and communicates wirelessly between SAPS and the implanted IPG. Any programming changes initiated in SAPS are communicated to the IPG via the WT. Similarly, all usage, battery, and impedance data extracted from the IPG is transferred to SAPS via the WT.

5. Remote Control:

Used by therapists during in-clinic therapy sessions, the remote control allows for the immediate and precise activation of vagus nerve stimulation. Each press of the remote delivers a half-second pulse of stimulation, synchronizing stimulation precisely with functional movement to strengthen neural connections.

6. Magnet:

The magnet is provided to patients for at-home therapy, and it is swiped over the Vivistim IPG implant site to activate a 30-minute stimulation session. During this session, the Vivistim System delivers half-second pulses of stimulation every 10 seconds, providing periodic neurostimulation while patients perform functional movements or activities of daily living. The magnet also serves as a safety feature, allowing patients to stop stimulation by holding it over the device.

Our Clinical Results and Studies

We have established a robust body of clinical evidence, including three randomized control trials, supporting the safety, efficacy, durability, and well-understood mechanism of action of Vivistim Therapy. The results of our VNS-REHAB trial, our pivotal, randomized, sham-controlled, triple blinded clinical trial, demonstrated an approximately two-times greater, as measured by FMA-UE, and approximately three-times greater, as measured by WMFT, improvement in hand and arm function compared to intensive rehabilitation alone, at the end of the in-clinic and at-home therapy protocol. The 1-year follow-up of this trial demonstrated that these functional gains were maintained long-term. These results, which were first published in *The Lancet* in 2021, served as the basis for the Premarket Approval (PMA) of Vivistim Therapy in August 2021. The results are further supported by our previous feasibility trial and our pilot trial, which demonstrated a high response rate and meaningful improvement in upper extremity mobility without any significant safety concerns related to Vivistim Therapy. In addition, the pilot trial demonstrated sustained benefits of Vivistim Therapy for up to 3 years. Our body of clinical evidence includes over 20 peer-reviewed clinical publications on the safety, effectiveness, and durability of Vivistim Therapy, as well as the mechanism of action of paired vagus nerve stimulation, most of which were co-authored by our clinical and scientific teams.

We are continuing to develop clinical and real-world evidence to further demonstrate the safety, efficacy and sustained benefits of Vivistim Therapy. We established our GRASP registry to collect real-world evidence with the objective to support future publications, payor coverage, inclusion in clinical guidelines and accelerate market adoption. As of December 31, 2025, we had enrolled 255 participants in our GRASP registry. We are also conducting the VNS-REHAB At-Home Study, which is designed to assess the feasibility of therapist-directed Vivistim Therapy at home instead of in clinic for participants. Initial results from the first 11 participants enrolled in the VNS-REHAB At-Home Study indicate that Vivistim Therapy can be effectively delivered at home, presenting the opportunity for greater convenience for participants than driving or finding transportation to a therapy site.

The primary efficacy endpoints in our trials assess various participant outcome measurements related to motor function and recovery primarily based on the FMA-UE score and WMFT functional score. FMA-UE is considered the gold standard for measuring motor impairment in the arm, hand, and wrist; participants perform specific movements and are scored on a 3-point scale (0, 1, or 2), with the total upper extremity motor score ranging from 0

to 66, and lower scores indicating a more severe impairment. Impairments of the fingers and hands typically have the most significant impact on quality of life, but make up just a small portion of the total FMA-UE score. Therefore, even a small improvement in FMA-UE score, if localized in the fingers and hand, can have a significant impact on overall function and independence. In a WMFT assessment, participants are scored on 15 standardized movements (e.g., lifting objects, reaching, and manipulating items), with performance measured by both time and functional ability. Each movement is scored on a scale of 0 to 5, then an overall average is taken to produce a total score from 0 to 5, with higher scores indicating higher function.

VNS-REHAB Trial

Overview

Our pivotal trial, the VNS-REHAB trial, was a randomized, sham-controlled, triple-blinded trial conducted at 19 sites in the United States and United Kingdom. Participants were enrolled from October 2017 to September 2019. We evaluated 108 participants between the age of 22 and 80 years old, who had a history of ischemic stroke occurring between nine months and 10 years prior to randomization as well as moderate-to-severe upper extremity impairment, as defined by an FMA-UE score between 20 and 50. The mean FMA-UE baseline score ranged between 34.4 (Vivistim Therapy group) and 35.7 (control group) and WMFT score between 2.71 (Vivistim Therapy group) and 2.83 (control group). The primary objectives were to provide evidence of efficacy as well as to assess the safety of Vivistim Therapy.

All participants in the trial underwent vagus nerve stimulation implant surgery, at which time they were randomly assigned (1:1) to either functional movement and exercise paired with vagus nerve stimulation (Vivistim Therapy group, n=53) or functional movement and exercise paired with sham stimulation (control group, n=55). All efficacy and safety analyses were performed on intention-to-treat population (combined n=108), defined as all participants who have any surgical portion of the implant procedure attempted, regardless of the treatment to which they were assigned, and regardless of the amount of intervention completed.

Both Vivistim Therapy and control groups received six weeks of intensive in-clinic therapy of 90 minutes, three times per week, for a total of 18 sessions. Each in-clinic therapy session consisted of 300 to 500 repetitions of tasks as part of task-specific practice. The Vivistim Therapy group received active stimulation with Vivistim Therapy during the in-clinic therapy period, and the control group received sham stimulation. There was no in-home therapy during this period. Following the six weeks of in-clinic therapy, all participants in both groups began daily therapist-prescribed home exercises which were performed for 90 days. Participants were instructed to activate stimulation during prescribed home exercises and received 30 minutes of either active (Vivistim Therapy group) or sham (control group) stimulation during each session.

Participants and investigators were unblinded after the 90-day period of prescribed home exercises, at which time participants in the Vivistim Therapy group entered the long-term phase of the trial and participants in the control group entered the crossover phase. During this phase, participants in the crossover group received an additional 18 sessions (3 times per week for 6 weeks) of in-clinic therapy paired with active stimulation with Vivistim Therapy. Following this six week period of in-clinic therapy, participants began daily therapist-prescribed home exercises for 90 days. Participants were instructed to activate stimulation during prescribed home exercises and received 30 minutes of active stimulation during each session. Thereafter, control participants progressed to the long-term phase of the trial.

In the long-term phase of the trial, all participants continued therapist-prescribed home exercises with self-initiated active stimulation for 1 year following completion of the in-clinic protocol. In addition, participants were encouraged to activate stimulation before undertaking daily living activities that engage the upper extremities, such as washing dishes or folding laundry. During the long-term phase, participants attended one to three in-clinic therapy visits. These visits were scheduled at least 1 month before the 6- or 12-month assessment.

The primary outcome measurement was change in FMA-UE score from baseline to the first day following the completion of in-clinic therapy (First Day Post In-Clinic). Secondary outcome measurements consisted of clinically meaningful response on FMA-UE score at 90 days following the completion of in-clinic therapy (Day 90 Post In-Clinic) and change in each of FMA-UE score and WMFT functional score relative to baseline at Day 90 Post In-

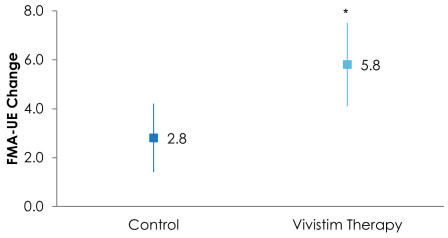
Clinic. Based on research published in *Physical Therapy*, a peer reviewed medical journal and the official scientific journal of the American Physical Therapist Association, which showed that a 5.25-point improvement was associated with an excellent improvement (greater than 50% improvement) in arm function. In our VNS-REHAB trial, we defined a clinically meaningful response as a 6-point or greater improvement in FMA-UE score. In addition, p-values from the trial are an indication of statistical significance reflecting the probability of an observation occurring due to chance alone. A clinical trial result is statistically significant if it is unlikely to have occurred by chance, and the statistical significance of clinical trial results is determined by a widely used statistical method that establishes the p-value of the results. Under this method, a p-value of $p<0.05$ or less typically represents a 95% probability that the results did not occur by chance alone, and are generally considered statistically significant results. For purposes of the trial results, a clinically meaningful response is intended to represent an improvement in function, as measured by change in FMA-UE score, that would be clinically important and meaningful to people living with stroke, and a statistically significant result indicates that such improvement or other outcome measurement is likely due to the Vivistim Therapy as opposed to chance.

Results

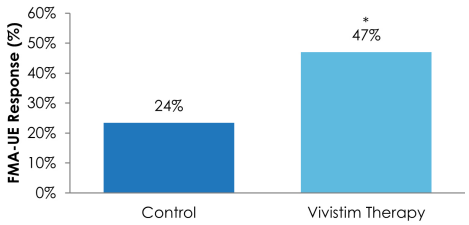
The results of the VNS-REHAB trial, published in April 2021 in *The Lancet*, showed statistically significant and clinically meaningful improvements for the Vivistim Therapy group versus the control group on the primary and all secondary outcome measures (Dawson, Jesse et al., *Vagus nerve stimulation paired with rehabilitation for upper limb motor function after ischaemic stroke (VNS-REHAB): a randomised, blinded, pivotal, device trial*, The Lancet, Volume 397, Issue 10284, 1545-1553 (2021)). For the primary efficacy outcome measurement of change in FMA-UE score at First Day Post In-Clinic Therapy, the mean FMA-UE score increased by 5.0 points in the Vivistim Therapy group compared to 2.4 points in the control group ($p=0.0014$), demonstrating an approximate two times greater improvement. For the secondary outcome measurements of change in each of FMA-UE score and WMFT functional score at Day 90 Post In-Clinic Therapy, the mean FMA-UE score increased 5.8 points in the Vivistim Therapy group compared to 2.8 points in the control group ($p=0.0077$), demonstrating an approximate two times greater improvement, and the mean WMFT functional score increased by 0.46 points in the Vivistim Therapy group compared to 0.16 points in the control group ($p<0.0001$), demonstrating an approximate three times greater improvement. A clinically meaningful response on the FMA-UE score at Day 90 Post In-Clinic Therapy occurred in the Vivistim Therapy group at approximately twice the rate of the control group, with 47% of participants achieving this response in the Vivistim Therapy group compared to 24% in the control group ($p=0.0098$), based on a rigorous response threshold of greater than 6-point improvement in FMA-UE. A clinically meaningful response on the WMFT functional score at Day 90 Post-In-Clinic Therapy was also observed, with 57% of participants achieving this response in the Vivistim Therapy group compared to 22% in the control group ($p<0.0001$). The results were consistent across participant subgroups and characteristics, demonstrating efficacy independent of time since stroke as well as age, ethnicity and gender.

The charts below show the primary and secondary efficacy measures for both the Vivistim Therapy group and for the control group. In the first and third charts below, the squares represent the mean group value and the vertical lines denote 95% confidence intervals. The * in each chart denotes $p<0.05$, the significance level used to measure the difference between Vivistim Therapy and control groups.

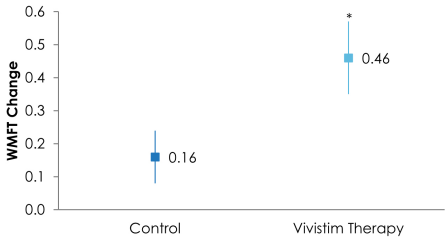
Change in FMA-UE – Baseline to Day 90 Post In-Clinic



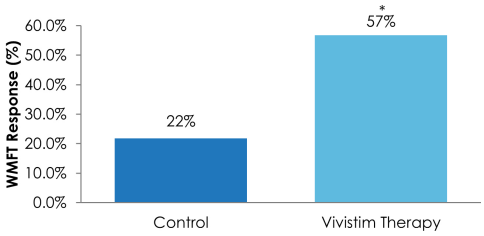
FMA-UE Response Rate at Day 90 Post In-Clinic



Change in WMFT – Baseline to Day 90 Post In-Clinic



WMFT Response Rate at Day 90 Post In-Clinic



The effectiveness of Vivistim Therapy was further demonstrated by the results of the crossover phase of the trial. In the crossover group, FMA-UE improved from baseline by a mean of 6.13 and 5.64 points at first day following the completion of crossover in-clinic therapy (First Day Post Cross-Over In-Clinic) and at 90 days following the completion of crossover in-clinic therapy (Day 90 Post Cross-Over In-Clinic), respectively. WMFT functional scores also improved by a mean of 0.42 and 0.41 at First Day Post Cross-Over In-Clinic and Day 90 Post Cross-Over In-Clinic, respectively. The magnitude of the improvement after Vivistim Therapy was similar in the crossover group to that of the original Vivistim Therapy group, which we believe suggests that functional gains are consistent and repeatable.

Safety

Participants from the trial reported various adverse events, typically mild or moderate. There were five severe events reported (three in the Vivistim Therapy group and two in the control group). Severe adverse events in the

Vivistim Therapy group included urinary tract infection, hyponatremia and insomnia. None of the severe adverse events were reported as related to the Vivistim System and the events were generally similar between Vivistim Therapy group and control group. There was one case of vocal cord palsy following device implantation in a control participant, which resolved after five weeks. There were no serious adverse events or unanticipated adverse events associated with the Vivistim System reported during this trial.

Long-Term Follow-Up

The long-term results from our VNS-REHAB trial, which were published in May 2025 in *Stroke*, support the long-term effectiveness of Vivistim Therapy (Kimberley, Teresa et al., *Long-Term Outcomes of Vagus Nerve Stimulation Paired With Upper Extremity Rehabilitation After Stroke*, Stroke, Volume 56, Number 8, 2255-2265 (2025)). One-year follow-up data were available for 74 of the original 108 participants in the VNS-REHAB trial. This data demonstrated that FMA-UE scores were maintained for at least one year following the completion of in-clinic therapy, with a mean FMA-UE score increase of 5.23 from baseline. The WMFT functional score increased by a mean of 0.5 from baseline at one year, indicating that improvements in WMFT functional scores were maintained to at least one year. Side of stroke, age, time since stroke, and sex did not significantly impact FMA-UE or WMFT outcomes at one year. Overall, 66% of participants achieved a response to Vivistim Therapy as measured by increase in either FMA-UE or WMFT score. Serious events were reported in four participants after the blinded phase and before one-year follow-up (three in the Vivistim Therapy group and one in the control group), none of which were related to the therapy or stimulation.

Pilot Trial

We conducted a pilot trial prior to our VNS-REHAB trial. Our pilot trial was a randomized, multisite, double-blinded, sham-controlled trial. Participants were enrolled from three sites in the United Kingdom and one site in the United States from 2014 to 2017. People between the age of 30 and 80 years old, who had a history of ischemic stroke occurring between four months and five years prior to enrollment, and an FMA-UE score between 20 and 50 were eligible for inclusion. Seventeen participants were implanted with the Vivistim System and randomly assigned to either rehabilitation with active vagus nerve stimulation (Vivistim Therapy group, n=8) or rehabilitation with sham stimulation (control group, n=9). The trial was not powered for statistical significance.

Participants, therapists and outcome assessors were all blinded to group allocation, and a true sham-control arm was used. Both Vivistim Therapy and control groups received six weeks of in-clinic rehabilitation, three times per week, for a total of 18 sessions. The Vivistim Therapy group received active stimulation with Vivistim Therapy during rehabilitation, and the control group received sham stimulation. Following the six weeks of rehabilitation, all participants in both groups began daily therapist-prescribed home exercises which were performed for 90 days. Participants were instructed to activate stimulation during prescribed home exercises and received either active (Vivistim Therapy group) or sham (control group) stimulation during each session.

After the 90-day period of prescribed home exercises, participants in the Vivistim Therapy group entered the long-term phase of the trial and participants in the control group entered the crossover phase. During this phase, participants in the crossover group received an additional 18 sessions (three times per week for six weeks) of in-clinic rehabilitation paired with active stimulation with Vivistim Therapy. Thereafter, control participants progressed to the long-term phase of the trial which included home rehabilitation and self-administered active stimulation.

The primary safety endpoint was the number of serious adverse events related to the device or therapy and the main feasibility measure was the number of participants who completed the minimum of 12 visits. Given this was a pilot trial, no primary or secondary efficacy endpoints were designated. However, efficacy outcomes included assessments of FMA-UE score and WMFT functional score, among others.

All 17 participants completed the trial up to 90 days post completion of in-clinic therapy. At day 1 after the completion of in-clinic therapy, mean FMA-UE scores increased 7.6 points from baseline in the Vivistim Therapy group, compared to 5.3 points in the control group. At 90 days, mean FMA-UE scores increased 9.5 points from baseline in the Vivistim Therapy group, compared to 3.8 in the control group. In addition, at 90 days post the completion of in-clinic therapy, we observed a clinically meaningful response (defined as a 6-point or greater

improvement in FMA-UE score from baseline) in 88% participants in the Vivistim Therapy group, compared to 33% in the control group.

Participants in our pilot trial were followed for a period of three years, during which the ongoing use of Vivistim Therapy demonstrated long-term efficacy, including a sustained average increase in FMA-UE score of 9.2 points at one year (based on data available for 15 participants), 11.4 points at two years (based on data available for 14 participants) and 14.8 points at three years (based on data available for 14 participants), in each case as compared to baseline. Our pilot trial found that the significant effects of Vivistim Therapy at 90 days post completion of in-clinic therapy were not only maintained out to three years, but further improved in measures of impairment and function over the course of the three years. Additionally, participants in the crossover group, who began in the control group, responded similarly to participants in the original Vivistim Therapy group after receiving active VNS therapy.

There were three serious adverse events related to implantation surgery, including one implantation wound infection requiring treatment with intravenous antibiotics but resolved; one case of shortness of breath and dysphagia, likely because of intubation, which recovered; and one case of hoarseness because of vocal cord palsy. There were no serious adverse events related to stimulation.

Feasibility Trial

Our initial feasibility trial was a randomized, controlled trial at two stroke centers in the United Kingdom from 2013 to 2015. In this trial, we evaluated 20 participants who had suffered ischemic stroke more than six months prior to enrollment, and had moderate to severe upper-limb impairment. Nine participants were randomized to rehabilitation with active vagus nerve stimulation (Vivistim Therapy group) and 11 participants were randomized to rehabilitation alone with no Vivistim System implant (control group). Investigators, therapists and participants were not blinded, but outcome assessors were blinded, and there was no sham-control arm. Only participants in the Vivistim Therapy group received the implantation. The trial was not powered for statistical significance.

The primary endpoints were safety (the number of serious adverse events related to therapy) and feasibility (the number of participants who completed the therapy protocol). The main efficacy endpoint was the change in FMA-UE score between baseline and the first post-therapy visit. We also assessed whether participants improved by a minimum clinically meaningful difference in the FMA-UE score (defined as 6-point or greater improvement in FMA-UE score).

In the per-protocol analysis, there was a difference in change in FMA-UE score, with the mean FMA-UE score increase being 9.6 points in the Vivistim Therapy group compared to 3.0 points in the control group. Additionally, six participants achieved a clinically meaningful response on the FMA-UE score in the Vivistim Therapy group compared to four in the control group. One participant had transient vocal cord palsy and dysphagia after implantation, and five had minor adverse device effects; there were no serious adverse device effects. All participants completed the therapy protocol. Overall, the trial suggested that VNS paired with therapy is feasible and did not raise safety concerns.

Vivistim Therapy GRASP Patient Registry

We established our GRASP registry to track real world outcomes for participants who have received Vivistim Therapy. As of December 31, 2025, we had enrolled 255 participants across 59 sites. We expect to collect real-world evidence from 500 or more participants through the GRASP registry to further demonstrate and reinforce the effectiveness and durability of Vivistim Therapy and to help support additional publications, payor coverage decisions and inclusion in clinical guidelines. The GRASP registry includes participant assessments of functional outcomes, participant-reported outcomes, adherence, performance on varying therapy regimes (*i.e.* number and length of therapist-supervised sessions) as well as participant medical histories.

VNS-REHAB At-Home Study

Overview

We are conducting the VNS-REHAB At-Home Study, which is a post-market study designed to assess the feasibility and implementation of therapist-directed Vivistim Therapy at home instead of in clinic. The primary objective of the study is to assess compliance with the therapy protocol and acceptance of home therapy by people implanted with the Vivistim System, and it is intended to provide real-world evidence and data that at-home therapist directed Vivistim Therapy (therapy provided at the participant's home by a therapist) is feasible. The primary endpoint is percent of participants who receive at least 24 hours of therapy at home by a therapist. Other endpoints will analyze changes in assessment measures over time compared to the participant's own baseline.

The study has two distinct stages. In the first stage, participants receive 36 hours of therapist-directed in-home therapy over 18 weeks, with two or more visits per week. On days without therapist-led sessions, participants will complete in-home exercises and functional activities on their own with self-activated Vivistim Therapy. In the second stage, following the initial 18-week period, participants continue to perform therapist-prescribed functional tasks at home with self-activated Vivistim Therapy for a follow-up period of up to two years. Enrollment has ended and we expect that approximately 25 patients will be implanted and provide data for final analysis. Initial results from the first 11 participants enrolled indicate that Vivistim Therapy initially implemented in the home environment is safe and effective and that participants can achieve high levels of compliance. Participants experienced a mean improvement in FMA-UE score of 7.0 points from baseline after 36 hours of therapist-directed in-home Vivistim Therapy. No serious adverse events occurred that were due to Vivistim Therapy.

Other Publications

In addition to our clinical results and studies, the mechanism of action underlying Vivistim Therapy has been discussed and validated by a number of peer-reviewed industry journals. Some of the studies underlying such publications were preclinical, conducted with small sample sizes, did not control for clinical variables, or had other design limitations (*e.g.*, they are not randomized controlled trials). As a result, while we believe certain publications provide helpful context, it is important to consider this information in light of the totality of available information. We believe the following publications provide additional helpful context regarding the mechanism of action:

- An article published in 2019 in *Frontiers in Neuroscience* summarized the neurobiological rationale underlying the mechanism of action for Vivistim Therapy (Engineer, Navzer, et al., *Targeted Vagus Nerve Stimulation for Rehabilitation After Stroke, Frontiers in Neuroscience*, Volume 13 (2019)). The article notes historical animal and human studies demonstrating links between neurological modulation and plasticity, which served as the basis for conducting our clinical trials. The article summarizes the mechanism of action, noting that stimulation of the vagus nerve triggers release of plasticity promoting neuromodulators in the brain, and that engagement of neuromodulators concurrent with motor training drives task-specific plasticity in the motor cortex to improve function. We supported this work and the authors of the article were employees of our company at the time of publication.
- A preclinical study published in 2018 in *Stroke* documented the use of paired vagus nerve stimulation to promote generalization, long-lasting recovery, and structural plasticity in motor networks in rats administered with ischemic lesions (Meyers, Eric et al., *Vagus Nerve Stimulation Enhances Stable Plasticity and Generalization of Stroke Recovery*, Stroke, Volume 49, Number 3, 710–717 (2018)). In the study, rats receiving vagus nerve stimulation paired with a trained behavioral task demonstrated better rehabilitative training with long-lasting recovery. The study noted that it provided some of the first evidence that vagus nerve stimulation paired with rehabilitative training after stroke can improve long-lasting recovery on a complex task, improve recovery on a simple motor task as compared to the same task without vagus nerve stimulation, and enhance structural plasticity in motor networks. We believe this study represents evidence of vagus nerve stimulation-directed plasticity as a potential treatment pathway. We did not provide support for this study but one of the authors was a consultant and shareholder of our company at the time of publication. This study did not use the Vivistim System.

Sales and Marketing

Our commercial strategy is designed to encourage Vivistim Therapy adoption at stroke centers and therapy sites through a coordinated, evidence-based approach. We sell the Vivistim System to customers, primarily stroke hospitals, in the United States, and our commercial organization is responsible for driving adoption of the Vivistim System through customer outreach, education, and relationship management activities. Our TMs and TDSs work collaboratively within each of our sales territories to create and build sustainable care programs that use Vivistim Therapy and drive adoption at hospitals. TMs sell the Vivistim System primarily to stroke hospitals and engage stroke interventionalists, neurosurgeons, neurologists, stroke program administrators and executives at hospitals to establish new, coordinated pathways for chronic stroke care. TDSs focus on outreach to therapy sites and provide general educational information regarding the clinical use of the Vivistim System. These activities are intended to facilitate customer adoption and utilization of the Vivistim System.

Our TMs generally have substantial experience in medical device markets that require program development, early-stage technology adoption, and/or neuromodulation expertise. Our TDSs are licensed occupational or physical therapists and generally have prior leadership roles or experience using Vivistim Therapy.

Our commercial efforts are currently focused on primary and comprehensive stroke centers, which are hospitals that have cross-functional teams with the capabilities to treat acute stroke at the highest level of care and in compliance with AHA guidelines. These centers see significant volumes of acute stroke patients and are typically surrounded by a network of therapy sites with neurorehabilitation capabilities, providing the infrastructure necessary for efficient implementation of Vivistim Therapy. We work with these stroke centers to establish Vivistim Therapy as a treatment option for stroke survivors. Over time, we believe these centers will naturally integrate Vivistim Therapy into standard care pathways for stroke survivors upon discharge and establish self-sustaining care programs that use Vivistim Therapy. According to data from the stroke center accreditation organizations, there were approximately 1,500 primary and comprehensive stroke centers in the United States as of December 2025. In addition, according to stroke claims data from Definitive Healthcare, approximately 70% of acute strokes in the United States are seen at 900 hospitals.

We have developed marketing programs to promote awareness of Vivistim Therapy among patients, caregivers and healthcare providers. Stroke survivors and their families interact with a diverse network of care providers, including stroke interventionalists, neurosurgeons, neurologists, physical medicine and rehabilitation physicians, occupational and physical therapists, stroke coordinators and nurses. Each of these providers can play a role in identifying and evaluating potential Vivistim Therapy candidates, and we directly engage each of these stakeholders through our direct sales force and awareness events, which include webinars for stroke survivors or healthcare professionals, therapy education summits targeted at healthcare professionals involved in chronic stroke care, and physician conferences and society meetings. We also educate neurologists and physical medicine and rehabilitation physicians in private practices and hospitals. In select territories, we also conduct targeted direct-to-patient digital advertising. We have also established a patient education team to assist prospective patients in learning about the therapy and connect them with relevant providers for further evaluation. These efforts are designed to establish and maintain a consistent funnel of chronic stroke patients who may seek a Vivistim System implant at one of our established centers.

Research & Development

Our commitment to offering life-changing treatments for stroke survivors drives our passion for innovation through continuous research and development. Our research and development team has significant experience in designing innovative medical devices, including active implantable neuromodulation devices. We leverage our internal expertise, clinical insights and experience gained from developing the Vivistim System to assess and prioritize research and development initiatives.

We are currently focused on research and development efforts that can improve clinical outcomes, optimize patient experience, enhance physician usability, increase utilization, and increase patient engagement. Our near-term research and development activities are primarily directed toward continued technological advancement of the Vivistim System, and development of a next-generation Vivistim System with enhanced features.

While our current commercial and development efforts are focused on chronic ischemic stroke survivors with moderate to severe upper extremity impairments, we believe the Vivistim System has the potential to address additional clinical indications within stroke recovery, including but not limited to lower extremity impairment and chronic hemorrhagic stroke. We intend to explore this potential over time, leveraging our research and development expertise to inform areas of investment and focus. Any expansion into new indications would require additional regulatory approvals and may involve additional clinical trials or modifications to the Vivistim System. There can be no assurance that such efforts will be successful.

For the years ended December 31, 2025 and 2024, research and development expenses were $6.5 million and $4.2 million, respectively.

Coverage and Reimbursement

We sell the Vivistim System and its accessories to customers, primarily to stroke hospitals, in the United States. These customers in turn bill third-party payors for the cost required to treat each patient. Our device is treated as a general supply utilized in the implantation procedure and, if covered by third-party payors, is paid for as part of such procedure. The Vivistim System is typically implanted in the hospital outpatient setting, and all items and services paid under the Medicare hospital outpatient prospective payment system (OPPS) are assigned to payment groups called Ambulatory Payment Classifications (APCs), which group together items and services that are similar clinically and in terms of resource use. Effective January 1, 2026, CPT code 64568 is assigned to New Technology APC 1580 with a national average facility payment under OPPS of $45,000. Reimbursement for professional services performed by physicians are reported using CPT codes and based on a different payment methodology. Implantation of the Vivistim System falls under CPT Code 64568 (Incision for implantation of a cranial nerve (e.g., vagus) neurostimulator electrode array and pulse generator). Under the 2026 Medicare Physician Fee Schedule (MPFS), the national average physician payment is $663. Occupational or physical therapy services provided to patients using the Vivistim System are billed by therapy providers using standard therapy codes.

Coverage for Vivistim Therapy varies by payor. Because there are currently no national coverage determinations issued by the CMS or local coverage determinations by Medicare administrative contractors specific to Vivistim Therapy, coverage determinations are made on a case-by-case basis under medical necessity standards, without the need for prior authorization. Medicaid programs are funded by both federal and state governments, and coverage and reimbursement policies vary from state to state and from year to year. Effective July 1, 2023, the New York State Medicaid fee-for-service program covers FDA-cleared vagus nerve stimulator devices used for stroke therapy in conjunction with rehabilitation to recover function in hands and arms after an ischemic stroke. Currently, most commercial insurers have determined that Vivistim Therapy is experimental or investigational and therefore, not covered. Patients with commercial insurance, Medicaid, or Medicare Advantage generally require prior authorization. Our in-house market access team assists patients and providers throughout the prior authorization process, from preparing required documentation, submitting approval requests, and managing appeals when needed. Although the prior authorization process can take several weeks, based on our experience to date, we are confident that our support can help lead to prior authorization approvals for many patients. As part of our longer term strategy, our market access team will continue to engage with payors to communicate clinical and health economic data which may impact coverage policies. We believe that expanded payor coverage will facilitate broader patient access to Vivistim Therapy.

Manufacturing and Supply Chain

We rely on third-party contract manufacturers to manufacture the Vivistim System and accessories. We believe this strategy provides the expertise and capacity required to effectively and efficiently scale production based on demand, and helps to reduce our need for capital investment and reduce operational expenses. We believe the capacity of our current manufacturing and supply chain network is sufficient to meet anticipated demand and can be scaled to meet future demand.

We carefully select our suppliers and require each of our suppliers to meet stringent technical and quality requirements that satisfy our product specifications. We employ a rigorous supplier assessment, qualification, and selection process that is aligned with FDA and International Organization for Standardization requirements and

supported by internal policies and procedures. All critical suppliers are required to maintain quality systems compliant with applicable FDA regulations and international standards, including ISO 13485. We maintain oversight of these suppliers through supplier controls, routine audits, periodic reviews, qualification activities, quality agreements, and manufacturing record inspections.

All of the critical components of the Vivistim System, such as the IPG and lead, are supplied to us from single sources that are qualified medical device contract manufacturers and suppliers. We seek to manage single-source supplier risk by regularly assessing the quality and capacity of our suppliers, implementing supply and quality control protocols where appropriate and actively managing lead times and inventory levels. We generally seek to maintain sufficient inventory levels to support continued operations in the event of supply interruptions or terminations and to enable us to find and qualify other sources of supply if necessary. We manage these inventory levels through contractual and operational controls and strategies. For example, we work with our suppliers on inventory forecasting based on anticipated future demand and monitoring production. We intend to evaluate alternative manufacturing and sourcing structures, such as dual- or second-sourcing and multi-site manufacturing, over time to strengthen our manufacturing and supply chain.

We generally do not have long-term contracts with our suppliers, and our supply arrangements generally do not include minimum manufacturing or purchase obligations. For these arrangements, we primarily order products through the use of purchase orders, do not have any obligation to purchase any given quantity of products, and our suppliers generally have no obligation to sell to us or to manufacture for us any given quantity of our products or components of our systems. Certain supplier arrangements include non-cancelable purchase commitments and binding forecast obligations. For these arrangements, we primarily order products through the use of purchase orders that are generally non-cancelable once accepted by the respective supplier.

We operate a distribution facility in Minnesota to warehouse and distribute our implant systems in the United States. We believe this facility is sufficient to meet our current and anticipated needs in the near term and that suitable additional space is available as needed to accommodate expansion of our operations and distribution activities.

IPG Supply Agreements

We entered into supply agreements with Integer Holdings Corporation (Integer), pursuant to which Integer agreed to manufacture our IPG component for us. Our first supply agreement with Integer provides that we may order from Integer on a non-exclusive, purchase order basis with no minimum purchase requirements. The agreement includes, among other provisions, customary representations and warranties by the parties, ordering and payment and shipping terms, customary provisions with respect to the ownership of any intellectual property and customary confidentiality provisions. The agreement continues until termination by the parties. Either party may terminate the agreement upon written notice in the event of a material breach that is not cured within 30 days of the other party's written notice of such breach; upon bankruptcy, insolvency or reorganization that has not been dismissed within 30 days after commencement; or in the event that the other party commits a crime, intentionally imparts material information or misappropriates intellectual property. In addition, we may terminate the agreement if Integer fails to meet our specifications or is unable to manufacture products, or for our convenience if we are current in our payment obligations to Integer.

To further support our anticipated growth and IPG supply needs, we also entered into a second supply agreement (the IPG Supply Agreement), effective September 24, 2024, with Greatbatch Ltd., a subsidiary of Integer. The IPG Supply Agreement contains, among other provisions, customary representations and warranties by the parties, ordering and payment and shipping terms, customary provisions with respect to the ownership of any intellectual property created during the term of the IPG Supply Agreement, certain indemnification rights in favor of both parties, limitations of liability and customary confidentiality provisions, and minimum purchase requirements. The minimum purchase requirements are expected to commence in 2028. Under the minimum purchase requirements, we are obligated to purchase a high double-digit fixed percentage of our IPG supply requirements from Integer and must purchase a minimum number of IPGs from Integer per year. The aggregate minimum purchase obligation for the initial five-year period is approximately $5.8 million. The IPG Supply Agreement has an initial five-year term commencing upon the first commercial shipment of product, and will automatically renew for

one-year periods unless either party delivers a notice of non-renewal prior to the renewal date. Either party may terminate the IPG Supply Agreement upon written notice in the event of a material breach of the IPG Supply Agreement that is not cured within 60 days of the other party's written notice of such breach, subject to certain conditions; or upon bankruptcy, insolvency or reorganization that has not been dismissed within 60 days after commencement. We may terminate the IPG Supply Agreement if Integer fails to adequately supply non-defective products, if the products are subject to repeating failures over time that fail to meet our specifications, or if Integer is unable to manufacture products for a specified period of time.

Competition

The Vivistim System is the first and only FDA-approved solution for chronic ischemic stroke survivors with moderate to severe upper extremity impairments. While a range of therapies and tools are available to support post-stroke motor recovery in the sub-acute phase post-stroke, there are very limited options that address motor recovery in the chronic phase, and we do not believe we have any direct competitor for Vivistim Therapy at this time. For example, conventional treatment consists of physical or occupational therapy, which is generally performed in the sub-acute phase and has limited utility in the chronic phase. Stroke survivors may use rehabilitation therapy and/or assistive devices, such as splints, braces, orthoses, muscle stimulators or EEG-powered devices, in the chronic phase to attempt to improve their chronic stroke impairments, however, we are not aware of meaningful clinical evidence supporting their effectiveness or durability. Further, such therapy and assistive devices may be used in conjunction with Vivistim Therapy if desired.

We are differentiated in our approach because of our focus on care for chronic ischemic stroke survivors. We are developing the market for these survivors, and are engaging key stroke care stakeholders, including stroke interventionalists, neurosurgeons, neurologists, and therapists, through our specialized direct sales force. Overall, our position in our market is dependent upon a number of competitive factors, including: our market development efforts; our ability to establish chronic stroke programs and care pathways for stroke survivors; patient outcomes and demonstrated safety and efficacy in patients several years post-stroke, including from robust clinical trials; durability of functional improvement following treatment; a mechanism of action that enables restoration of native function, rather than assistance or compensation; ease of integration into standard therapy workflows; patient experience and product ease of use; and reimbursement and payor support.

We operate in a competitive industry that is subject to technological change and significantly affected by new product introductions and market activities of other industry participants. For example, industry participants include medical device manufacturers and robotics companies, including a significant number of companies focused on stroke prevention and acute stroke care. To the extent these companies decide to focus on longer term stroke care, particularly in the chronic phase, we may face increased competition. Many of these companies have longer, more established operating histories, and significantly greater name recognition and financial, technical, marketing, sales, distribution and other resources. In addition, certain companies have several competitive advantages, including significant scale and established relationships with healthcare providers and third-party payors. Irrespective of their current focus, we also compete with these companies for personnel, including qualified personnel that are necessary to grow our business, including TMs and TDSs.

Intellectual Property

Intellectual property, including patents, trade secrets, trademarks and copyrights, is important to our business. Our commercial success depends in part on our ability to obtain and maintain proprietary intellectual property protection for our current products as well as for future products, product development technologies, and know-how. Our commercial success also depends in part on our ability to operate without infringing the proprietary rights of others and to prevent others from infringing our proprietary rights. We seek to maintain our proprietary position by, among other means, filing United States and foreign patent applications to obtain issued patents with claims directed to our products, products in development, technology, inventions, and improvements that are important to the development and implementation of our business. We may also license from third parties certain patent rights and proprietary know-how that we believe to be necessary or useful to our business. Additionally, we protect our proprietary know-how that may not be patentable, and other confidential information, by maintaining and implementing appropriate policies and procedures with respect to secrecy and confidentiality. We are currently

seeking and maintaining patent protection in the United States and key foreign jurisdictions where we may market our products in the future, and plan to do so with respect to any of our future product candidates.

Our patent portfolio includes a combination of patents and pending patent applications (i) solely owned by us, (ii) exclusively licensed from the University of Texas at Dallas (UT), and (iii) jointly owned by us and UT or owned by UT, in each case, exclusively licensed to us from UT.

As of December 31, 2025, our owned patent estate contained 1 patent family comprising 1 issued U.S. patent, which was solely owned by us. This patent relates to electrode technology for the current Vivistim Therapy. The issued U.S. patent is expected to expire in 2039, after accounting for potentially available patent term adjustments or extensions and term-limiting effects of terminal disclaimers, and assuming payment of appropriate maintenance, renewal, annuity and other governmental fees.

As of December 31, 2025, our exclusively licensed patent estate from UT contained 1 patent family comprising 12 issued U.S. patents, 13 issued foreign patents, 1 pending U.S. non-provisional patent application and 1 pending foreign patent application. These patents and patent applications relate to various aspects of the current Vivistim Therapy and primarily consist of method patents. The issued U.S. patents are expected to expire between 2029 and 2032, after accounting for potentially available patent term adjustments or extensions and term-limiting effects of terminal disclaimers, and assuming payment of appropriate maintenance, renewal, annuity and other governmental fees. Any patents that may issue from the pending U.S. patent applications are expected to expire in 2029, without accounting for potentially available patent term adjustments or extensions, term-limiting effects of terminal disclaimers and assuming payment of appropriate maintenance, renewal, annuity and other governmental fees. The issued foreign patents include one or more issued patents in jurisdictions such as Germany and the United Kingdom, and are expected to expire between 2029 and 2041, without accounting for potentially available patent term extensions and assuming payment of appropriate maintenance, renewal, annuity and other governmental fees. The pending foreign patent applications include one or more applications filed with the European Patent Office, and are expected to expire in 2029, without accounting for potentially available patent term adjustments or extensions and assuming payment of appropriate maintenance, renewal, annuity and other governmental fees.

Calculation of the expiration of issued patents is complex, varies by country and is based upon many factors. In most countries in which we file, including the United States, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, the term of a patent may be reduced due to terminal disclaimer made to overcome a double patenting rejection, or may be lengthened by patent term adjustment, which permits patent term restoration as compensation for delays incurred at the USPTO during the patent prosecution process. The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. The relevant patent laws and their interpretation outside of the United States is also uncertain.

The table below sets forth information regarding the patents and pending patent applications (i) solely owned by us, (ii) exclusively licensed from the University of Texas at Dallas (UT), and (iii) jointly owned by us and UT or owned by UT, in each case, exclusively licensed to us from UT:

Country	Status (Issued or Pending)	Application No.	Patent No.	Estimated Expiration	Types (Devices, Methods or Devices and Methods)	Related Technology	Owner (Mobia, University of Texas at Dallas (UT) or jointly between Mobia and UT)
US	Issued	12/485,040	9089707	6/15/2029	Method	Motor Deficit	UT
US	Issued	13/651,349	8700145	6/15/2029	Method	Motor Deficit	UT
US	Issued	14/252,727	9522272	6/15/2029	Method & Devices	Motor Deficit	UT
US	Issued	14/538,400	9522273	6/15/2029	Method	Motor Deficit	UT
US	Issued	14/538,421	9474904	6/15/2029	Method	Motor Deficit	UT
US	Issued	14/538,457	9504831	6/15/2029	Method	Motor Deficit	UT
US	Issued	14/550,286	9522274	1/17/2032	Method	Motor Deficit	UT
US	Issued	14/550,357	9533152	6/15/2029	Method	Motor Deficit	UT
US	Issued	14/560,735	9333355	6/15/2029	Device	Motor Deficit	UT
US	Issued	15/382,970	11638824	6/15/2029	Method	Motor Deficit	UT
US	Issued	15/496,766	11116933	6/15/2029	Method	Motor Deficit	UT
US	Issued	18/310,935	12151104	6/15/2029	Method	Motor Deficit	UT
US	Pending	18/959,959	NA	NA	Method	Motor Deficit	UT
EPO	Issued	12778023.7	2766089	10/12/2032	Devices	Motor Deficit	UT & Mobia
EPO	Issued	19192580.9	3593856	10/12/2032	Devices	Motor Deficit	UT & Mobia
EPO	Issued	21214444.8	4032583	10/12/2032	Devices	Motor Deficit	UT & Mobia
EPO	Pending	25186521.8	NA	NA	Devices	Motor Deficit	UT & Mobia
DE	Issued	DE112009001024.5T	DE112009001024	7/1/2029	Devices	Motor Deficit	UT & Mobia
UK	Issued	12778023.7	2766089	10/12/2032	Devices	Motor Deficit	UT & Mobia
UK	Issued	19192580.9	3593856	12/12/2032	Devices	Motor Deficit	UT & Mobia
UK	Issued	21214444.8	4032583	10/12/2032	Devices	Motor Deficit	UT & Mobia
FR	Issued	12778023.7	2766089	10/12/2032	Devices	Motor Deficit	UT & Mobia
FR	Issued	19192580.9	3593856	10/12/2032	Devices	Motor Deficit	UT & Mobia
FR	Issued	21214444.8	4032583	10/12/2032	Devices	Motor Deficit	UT & Mobia
AUS	Issued	2009267051	2009267051	6/30/2029	Devices	Motor Deficit	UT & Mobia
US	Issued	16/018,975	11167130	1/2/2039	Devices	Cuff	Mobia

There is no active patent litigation involving any of our patents and we have not received any notices of any patent infringement.

We have and will continue to pursue trademark protection for our product branding. As of December 31, 2025 we owned 7 registered trademarks and had 1 pending trademark application in the United States and foreign jurisdictions, including the registered trademarks VIVISTIM and MICROTRANSPONDER (which is registered solely on the supplemental registry) in the United States and VIVISTIM in foreign jurisdictions.

See the section titled “Risk Factors—Risks Related to Intellectual Property” for information regarding risks related to our intellectual property portfolio and their potential effect on us.

University of Texas at Dallas License Agreement

On July 23, 2007, we entered into a license agreement with the Board of Regents of the University of Texas System, on behalf of UT, which was amended and restated on March 4, 2008 and again on April 28, 2014 (as amended and restated and subsequently amended, the License Agreement). Pursuant to the License Agreement, UT granted us an exclusive, worldwide and sublicensable (subject to prior approval by UT) license under certain UT patents and know-how relating to vagus nerve stimulation–based therapies or arising from research programs conducted by certain UT personnel and funded by us (collectively, the Licensed IP), to make, have made, copy, use, sell, offer for sale, make derivative works, import and transfer products and processes covered by or incorporating the Licensed IP.

UT retains the right to practice the Licensed IP for non-commercial research and educational purposes, with the right to sublicense through one tier to any successor of UT. We will solely own any improvements to the Licensed IP developed by us and UT will have the right to practice such improvements for non-commercial research and educational purposes. The License Agreement is subject to U.S. government march-in rights. We must obtain UT's prior consent if we seek to sublicense our rights under the License Agreement to our affiliates or third parties.

We must use reasonable efforts to develop and commercialize one or more licensed products or licensed processes. Pursuant to the License Agreement, we previously issued to UT an immaterial number of shares of our common stock and agreed to pay the patent prosecution fees associated with the licensed patents.

Unless earlier terminated in accordance with the terms therein, the License Agreement shall continue until the expiration of the last-to-expire licensed patent, which is currently expected to expire in 2032. We have the right to terminate the License Agreement for convenience upon a specified period of prior written notice. UT may terminate the License Agreement if we commit a material breach and fail to cure such breach within a specified notice-and-cure period, including if we or our successor cease developing and marketing licensed products or licensed processes.

Government Regulation

Our products and our operations are subject to extensive regulation by the U.S. Food and Drug Administration, or FDA, and other federal and state authorities in the United States. Our products are subject to regulation as medical devices in the United States under the Federal Food, Drug, and Cosmetic Act, or FDCA, as implemented and enforced by the FDA.

United States Regulation of Medical Devices

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

FDA Marketing Authorization Requirements

Unless an exemption applies, each medical device commercially distributed in the United States requires either FDA clearance of a premarket notification submitted under Section 510(k) of the FDCA, approval of a premarket approval application, or PMA, or classification under the *de novo* classification process. Under the FDCA, medical devices are classified into one of three classes—Class I, Class II or Class III—depending on the degree of risk associated with each medical device and the extent of manufacturer and regulatory control needed to ensure its safety and effectiveness. Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be assured by adherence to the FDA's General Controls for medical devices, which include compliance with the applicable portions of the Quality System Regulation, or QSR (and once it goes into effect in 2026, the Quality Management System Regulation, or QMSR, which amended the QSR), facility registration and product listing, reporting of adverse medical events, and truthful and non-misleading labeling, advertising, and promotional materials. Class II devices are subject to the FDA's General Controls, and special controls as deemed

necessary by the FDA to ensure the safety and effectiveness of the device. These special controls can include performance standards, post-market surveillance, patient registries and FDA guidance documents.

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

510(k) Clearance Marketing Pathway

To obtain 510(k) clearance, a company must submit to the FDA a premarket notification submission demonstrating that the proposed device is "substantially equivalent" to a legally marketed predicate device. A predicate device is a legally marketed device that is not subject to premarket approval, i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required, a device that has been reclassified from Class III to Class II or I, or a device that was found substantially equivalent through the 510(k) process. The FDA's 510(k) clearance process usually takes from three to twelve months, but may take longer. The FDA may require additional information, including clinical data, to make a determination regarding substantial equivalence. In addition, FDA collects user fees for certain medical device submissions and annual fees and for medical device establishments.

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

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

PMA Approval Pathway

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

party manufacturers' or suppliers' manufacturing facility or facilities to ensure compliance with the QSR. PMA applications are also subject to the payment of user fees, which are higher than in the 510(k) process.

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

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

De Novo Classification

Medical device types that the FDA has not previously classified as Class I, II, or III are automatically classified into Class III regardless of the level of risk they pose. The Food and Drug Administration Modernization Act of 1997 established a route to market for low-to-moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, called the "Request for Evaluation of Automatic Class III Designation," or the *de novo* classification procedure. This procedure allows a manufacturer whose novel device is automatically classified into Class III to request down-classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA application. Pursuant to the Food and Drug Administration Safety and Innovation Act, or FDASIA, manufacturers may request *de novo* classification directly without first submitting a 510(k) pre-market notification to the FDA and receiving a not-substantially-equivalent determination.

Under FDASIA, FDA is required to classify the device within 120 days following receipt of the *de novo* request, although the process may take significantly longer. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. If FDA grants the *de novo* request, the device may be legally marketed in the United States. However, the FDA may reject the request if the FDA identifies a legally marketed predicate device that would be appropriate for a 510(k) notification, determines that the device is not low-to-moderate risk, or determines that General Controls would be inadequate to control the risks and/or special controls cannot be developed. After a device receives *de novo* classification, any modification that could significantly affect its safety or efficacy, or that would constitute a major change or modification in its intended use, will require a new 510(k) clearance or, depending on the modification, another *de novo* request or even PMA approval.

Clinical Trials

Clinical trials are almost always required to support a PMA and *de novo* classification, and are sometimes required to support a 510(k) submission. All clinical investigations of devices to determine safety and effectiveness

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

Regardless of the degree of risk presented by the medical device, clinical studies must be approved by, and conducted under the oversight of, an Institutional Review Board, or IRB, for each clinical site. The IRB is responsible for the initial and continuing review of the IDE, and may impose additional requirements for the conduct of the study. If an IDE application is approved by the FDA and one or more IRBs, human clinical trials may begin at a specific number of investigational sites with a specific number of patients, as approved by the FDA. If the device presents a non-significant risk to the patient, a sponsor may begin the clinical trial after obtaining approval for the trial by one or more IRBs without separate approval from the FDA, but must still follow abbreviated IDE requirements, such as monitoring the investigation, ensuring that the investigators obtain informed consent, and complying with labeling and record-keeping requirements. In some cases, an IDE supplement must be submitted to, and approved by, the FDA before a sponsor or investigator may make a change to the investigational plan that may affect its scientific soundness, study plan or the rights, safety or welfare of human subjects.

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

Expedited Development and Review Programs

Following passage of the 21st Century Cures Act, the FDA implemented the Breakthrough Devices Program, which is a voluntary program offered to manufacturers of certain medical devices and device-led combination products that may provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The goal of the program is to provide patients and health care providers with more timely access to qualifying devices by expediting their development, assessment, and review, while preserving the statutory standards for PMA approval, 510(k) clearance, and *de novo* classification. The program is available for medical devices that meet certain eligibility criteria, including that the device provides more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions, and that: (i) the device represents a breakthrough technology, (ii) no approved or cleared alternatives exist, (iii) the device offers significant advantages over existing approved or cleared alternatives, or (iv) the availability of the device is in the best interest of patients. Breakthrough Device Designation provides certain benefits to device developers, including more interactive and timely communications with FDA staff; use of post-market data collection, when scientifically appropriate, to facilitate expedited and efficient development and review of the device; opportunities for more efficient and flexible clinical study design; and prioritized review of premarket submissions. When reviewing Breakthrough Device

Designation requests, the FDA may require a combination of literature or preliminary bench, animal, or clinical data to demonstrate a reasonable likelihood of clinical and technological success. Receiving a Breakthrough Device Designation from the FDA does not guarantee that the FDA will grant marketing authorization for the device.

Post-Market Regulation of Medical Devices

After a product is placed on the market, numerous regulatory requirements continue to apply. These requirements include:

- product listing and establishment registration, which helps facilitate FDA inspections and other regulatory action;
- the QSR, which requires manufacturers, including third-party manufacturers, to follow stringent design, validation, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process, and once it goes into effect, the QMSR;
- labeling regulations and FDA prohibitions against the promotion of products for uncleared or unapproved use or indication;
- authorization of marketing of certain modifications that could significantly affect safety or effectiveness or that would constitute a major change in intended use;
- medical device reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;
- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- post-market restrictions or conditions, including post-market study commitments;
- post-market surveillance regulations, which apply, when necessary, to protect the public health or to provide additional safety and effectiveness data for the medical product;
- the FDA's recall authority, whereby it can ask, or under certain conditions order, device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and
- regulations pertaining to voluntary recalls.

Manufacturing processes for medical devices are required to comply with the applicable portions of the QSR (and once it goes into effect, the QMSR), which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR and QMSR also require, among other things, maintenance of a device master file, device history file, and complaint files. Manufacturers are subject to periodic scheduled and unscheduled inspections by the FDA. Failure to maintain compliance with the QSR and, once in effect, the QMSR requirements could result in the shut-down of, or restrictions on, manufacturing operations and the recall or seizure of marketed products. The discovery of previously unknown problems with any marketed products, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or approval, or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls.

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

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

Coverage and Reimbursement

Our commercial success depends in part on the extent to which governmental authorities, private health insurers and other third-party payors provide coverage for and establish adequate reimbursement levels for the implantation procedures during which our products are used since our devices are generally not separately reimbursed by third-party payors. Failure by physicians, hospitals and other users of our products to obtain sufficient coverage and reimbursement from third-party payors for procedures in which our products are used, or adverse changes in government and private third-party payors' coverage and reimbursement policies.

Based on our experience to date, third-party payors generally reimburse for the surgical procedures in which our products are used only if the patient meets the established medical necessity criteria for surgery. Some payors are moving toward a managed care system and control their healthcare costs by limiting authorizations for surgical procedures, including elective procedures using our devices. Although no uniform policy of coverage and reimbursement among payors in the United States exists and coverage and reimbursement for procedures can differ significantly from payor to payor, reimbursement decisions by particular third-party payors may depend upon a number of factors, including the payor's determination that use of a product is:

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

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

We believe the overall escalating cost of medical products and services being paid for by the government and private health insurance has led to, and will continue to lead to, increased pressures on the healthcare and medical device industry to reduce the costs of products and services. All third-party reimbursement programs are developing increasingly sophisticated methods of controlling healthcare costs through prospective reimbursement and capitation programs, group purchasing, redesign of benefits, requiring second opinions prior to major surgery, careful review of bills, encouragement of healthier lifestyles and other preventative services and exploration of more cost-effective methods of delivering healthcare.

In addition to uncertainties surrounding coverage policies, there are periodic changes to reimbursement levels. Third-party payors regularly update reimbursement amounts and also from time to time revise the methodologies used to determine reimbursement amounts. This includes routine updates to payments to physicians and hospitals for procedures during which our products are used. These updates could directly impact the demand for our products.

Other U.S. Healthcare Laws

Device manufacturers are subject to additional healthcare regulation and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which they conduct their business. Such laws include, without limitation, U.S. federal and state anti-kickback, fraud and abuse, false claims, consumer fraud, and transparency laws and regulations.

For example, the federal Anti-Kickback Statute prohibits, among other things, individuals or entities from knowingly and willfully offering, paying, soliciting or receiving remuneration, directly or indirectly, overtly or covertly, in cash or in kind to induce or in return for purchasing, leasing, ordering or arranging for or recommending the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation.

The federal civil and criminal false claims laws, including the civil False Claims Act, prohibit, among other things, any individual or entity from knowingly presenting, or causing to be presented, a false claim for payment to the federal government or knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act.

The Civil Monetary Penalty Laws impose penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent, or offering or transferring remuneration to a federal healthcare beneficiary that a person knows or should know is likely to influence the beneficiary's decision to order or receive items or services reimbursable by the government from a particular provider or supplier.

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, created additional federal civil and criminal statutes that prohibit, among other things, knowingly and willfully executing a scheme to defraud any healthcare benefit program. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the healthcare fraud statute implemented under HIPAA or specific intent to violate it in order to have committed a violation.

The federal Physician Payments Sunshine Act requires certain manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program, with specific exceptions, to report annually to the CMS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain non-physician practitioners (defined to include physician assistants, nurse practitioners, clinical nurse specialists, certified nurse anesthetists, anesthesiologist assistants and certified nurse midwives) and teaching hospitals, and further requires applicable manufacturers and applicable group purchasing organizations to report annually to CMS ownership and investment interests held by physicians and their immediate family members.

Similar state and local laws and regulations may also restrict business practices in the medical device industries, such as state anti-kickback and false claims laws, which may apply to business practices, including but not limited to, research, distribution, sales and marketing arrangements and claims involving healthcare items or services reimbursed by non-government third-party payors, including private insurers, or by patients themselves; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state laws and regulations that require manufacturers to file reports relating to pricing and marketing information or which require tracking gifts and other remuneration and

items of value provided to physicians, other healthcare providers and entities; and state and local laws that require the registration of sales representatives.

Violation of any of such laws or any other government regulations that apply may result in penalties, including, without limitation, civil and criminal penalties, damages, fines, additional reporting obligations, the curtailment or restructuring of operations, exclusion from participation in government healthcare programs and individual imprisonment.

Healthcare Reform

The United States is considering or has enacted a number of legislative and regulatory proposals to change the healthcare system in ways that could affect our ability to sell our products profitably. Among policy makers and payors in the United States, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality or expanding access. Current and future legislative proposals to further reform healthcare or reduce healthcare costs may limit coverage of or lower reimbursement for the procedures associated with the use of our products. The cost containment measures that payors and providers are instituting and the effect of any healthcare reform initiative implemented in the future could impact our revenue from the sale of our products.

The implementation of the Affordable Care Act, or ACA, in the United States, for example, has changed healthcare financing and delivery by both governmental and private insurers substantially, and affected medical device manufacturers significantly. The ACA imposed, among other things, provided incentives to programs that increase the federal government's comparative effectiveness research, and implemented payment system reforms including a national pilot program on payment bundling to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain healthcare services through bundled payment models. Additionally, the ACA has expanded eligibility criteria for Medicaid programs and created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011, among other things, reduced Medicare payments to providers, effective on April 1, 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2032 unless additional Congressional action is taken. Additionally, the American Taxpayer Relief Act of 2012, among other things, reduced Medicare payments to several providers, including hospitals, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

The Medicare Access and CHIP Reauthorization Act of 2015 repealed the formula by which Medicare made annual payment adjustments to physicians and replaced the former formula with fixed annual updates and a new system of incentive payments which began in 2019 that are based on various performance measures and physicians' participation in alternative payment models, such as accountable care organizations. Each year, CMS updates Medicare payments for physician services and hospital outpatient services through rulemaking, based on parameters established under law.

We expect additional state and federal healthcare reform measures to be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressure.

Data Privacy and Security Laws

Numerous state, federal and foreign laws, regulations and standards govern the collection, use, access to, confidentiality and security of health-related and other personal information, and could apply now or in the future to our operations or the operations of our partners. In the United States, numerous federal and state laws and regulations, including data breach notification laws, health information privacy and security laws and consumer protection laws and regulations govern the collection, use, disclosure, and protection of health-related and other personal information. In addition, certain foreign laws govern the privacy and security of personal data, including health-related data. Privacy and security laws, regulations, and other obligations are constantly evolving, may

conflict with each other to complicate compliance efforts, and can result in investigations, proceedings, or actions that lead to significant civil and/or criminal penalties and restrictions on data processing.

Employees and Human Capital

As of December 31, 2025, we had 167 full-time employees. None of our employees are represented by a labor union or covered under a collective bargaining agreement. We do employ a small number of temporary workers and consultants on an as needed basis.

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

Facilities

We maintain offices in Austin, Texas and Newport Beach, California. In Austin, we lease approximately 350 square feet of office space pursuant to an amended lease agreement that expires on May 1, 2026. In Newport Beach, we lease approximately 4,200 square feet of office space pursuant to a lease agreement that expires on August 31, 2028.

We also operate a distribution facility in Fridley, Minnesota to warehouse and distribute our implant systems in the United States. We lease approximately 14,000 square feet of office and warehouse space pursuant to an amended lease agreement that expires on April 30, 2030.

We believe that our existing facilities are sufficient to meet our current and anticipated needs in the near term and that additional or alternative space would be available as required in the future on commercially reasonable terms.

Legal Proceedings

From time to time, we may become involved in litigation or other legal proceedings. We are not currently a party to any litigation or legal proceedings that, in the opinion of our management, are likely to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on us because of defense and settlement costs, diversion of management resources, and other factors.

MANAGEMENT

Executive Officers, Significant Employees and Directors

The following table sets forth the names, ages, and positions of our executive officers and directors as of the date hereof:

Name	Age	Position
Executive Officers and Significant Employees:		
Richard Foust	52	President, Chief Executive Officer and Director
Nelson Bunker Curnes[4]	43	Chief Financial Officer and Director
Douglas (Doug) Ellison	63	Chief Commercial Officer
Prashant Rawat	52	Chief Operating Officer
Thomas Jordan Curnes II[4]	47	Co-Founder and Director
Chase Leavitt	44	General Counsel and Corporate Secretary
Non-Employee Directors:		
Dana G. Mead, Jr.[2]	67	Chair of the Board
Casey Tansey[2]	68	Director
William (Bill) Harrington[1][2][3]	66	Director
Cynthia Lucchese[1][3]	65	Director
Maxwell Bikoff[1][3]	40	Director
Edward Hanlon[4]	30	Director

(1) Member of the audit committee following this offering.
(2) Member of the compensation committee following this offering.
(3) Member of the corporate governance and nominating committee following this offering.
(4) Expects to resign from our board of directors prior to the closing of this offering.

Executive Officers and Significant Employees

Richard Foust has served as a member of our board of directors and as our Chief Executive Officer since January 2022 and has served as our President and Chief Executive Officer since October 2025. Mr. Foust co-founded 3D Strategy Consulting, LLC, a healthcare consulting services company, and has served as its Chief Executive Officer since February 2015. Mr. Foust previously served as the Chief Commercial Officer at Velano Vascular, Inc., a medical device company, from November 2018 to November 2020, and as the Chief Business Officer at Analyte Health, Inc., a digital health company, from May 2015 to February 2018. Mr. Foust also had escalating roles at Abbott Vascular, Inc., including Senior Director, West Area Endovascular Sales and Senior Director, Endovascular Global Marketing & Bioresorbable Vascular Scaffold. Mr. Foust received a B.S. in Applied Physics from Emory University and an M.S. in Mechanical Engineering with a major in Bioengineering from Georgia Institute of Technology. We believe that Mr. Foust is qualified to serve on our board of directors due to his experience as our President and Chief Executive Officer, and due to his leadership and extensive business experience in the medical device industry.

Nelson Bunker Curnes has served as a member of our board of directors since 2009 and as our Chief Financial Officer since September 2020. Mr. Curnes previously served as the Chief Operating Officer at TEGA Technologies, LLC from June 2015 to January 2016. Mr. Curnes also had escalating roles at The Boston Consulting Group including Principal and Project Leader from August 2010 to March 2015. Mr. Curnes received a B.S. in Mechanical Engineering from the University of Notre Dame and an M.B.A. from the Fuqua School of Business at Duke University. Mr. Curnes expects to resign from our board of directors prior to the closing of this offering.

Douglas (Doug) Ellison has served as our Chief Commercial Officer since January 2023. Previously, Mr. Ellison was Director of Hybrid Therapies at AtriCure, Inc. (Nasdaq: ATRC), a medical device company, from September 2019 to December 2022, overseeing all commercial activities for certain of its product line, and the Vice

President of Sales at SentreHEART, Inc. from April 2012 to September 2019, building out its sales organization and developing its sales process. Mr. Ellison received a B.S. in Engineering from Purdue University.

Prashant Rawat has served as our Chief Operating Officer since June 2022. Previously, Mr. Rawat was the Chief Operating Officer at Mainstay Medical International plc, a medical device firm, from July 2010 to June 2021. Mr. Rawat received a Bachelor of Engineering in Electronics from the Maharaja Sayajirao University of Baroda and an M.S. in Electrical Engineering and Applied Physics at Case Western Reserve University.

Thomas Jordan Curnes II is a co-founder of the Company and has served as a member of our board of directors since 2007. Mr. Curnes previously served as our President from March 2007 to October 2025. Mr. Curnes started his career as staff consultant at Arthur Andersen LLP and served as an associate consultant at Huron Consulting Group. Mr. Curnes received a B.B.A. in Finance from the University of Notre Dame and an M.B.A. from the Fuqua School of Business at Duke University. Mr. Curnes expects to resign from our board of directors prior to the closing of this offering.

Chase Leavitt has served as our General Counsel and Corporate Secretary since February 2026. Previously, Mr. Leavitt served as General Counsel and Corporate Secretary of Oncternal Therapeutics, Inc., a publicly traded biotechnology company, from April 2021 to June 2025. Mr. Leavitt also served as General Counsel and Corporate Secretary of Lineage Cell Therapeutics, Inc. (NYSE: LCTX), a publicly traded biotechnology company, from May 2019 to April 2021. Mr. Leavitt previously served as Vice President of Legal Affairs of Tang Capital Management, LLC, a life sciences-focused investment company, and its affiliate Odonate Therapeutics, Inc., a publicly traded pharmaceutical company, from June 2018 to May 2019. Mr. Leavitt had escalating roles at Switch, Inc., a technology company, from 2014 to 2018, most recently as Deputy General Counsel through the company's initial public offering. Mr. Leavitt was a corporate attorney at Latham & Watkins LLP from 2007 to 2014. Mr. Leavitt received a B.S. in Business Administration and a J.D. from the University of Southern California and is admitted to practice law in the States of California, Washington, and Texas.

Non-Employee Directors

Dana G. Mead, Jr. has served as a member of our board of directors since October 2024 and as the Chair of our board of directors since November 2025. In addition to serving on our board of directors, Mr. Mead has served on the board of directors of Pulmonx Corporation (Nasdaq: LUNG), a commercial-stage medical technology company, since 2010 and as the Chair of its board since 2019, where he also serves on its audit committee. Mr. Mead has also served on the boards of directors of Inspire Medical Systems, Inc. (NYSE: INSP), a medical technology company, since 2008, where he serves on its audit committee and quality, product supply, and technology committee, Cerapedics Inc., a global orthobiologics company, since March 2023, and Calyxo, Inc., a medical device company, since October 2025. Mr. Mead was previously the Chief Executive Officer, President and director of HeartFlow, Inc. (Nasdaq: HTFL), a medical technology company, from May 2019 to February 2021. From November 2016 to May 2019, Mr. Mead served as President and Chief Executive Officer of Beaver-Visitec International, Inc., a surgical device developer and manufacturer. Mr. Mead received a B.A. from Lafayette College and an M.B.A. from the University of Southern California. We believe that Mr. Mead is qualified to serve as a member of our board of directors because of his service on other medical technology company boards, his broad experience in the healthcare industry and the historical knowledge and continuity he brings to our board of directors.

Casey Tansey has served as a member of our board of directors since June 2022. Since 2005, he has served as a General Partner of U.S. Venture Partners, a venture capital firm. From 2001 until 2004, Mr. Tansey served as the Chief Executive Officer and President of Epicor Medical, Inc., a medical device company. Prior to Epicor Medical, Mr. Tansey was Chief Executive Officer and President of Heartport, Inc., a medical device company, which is now part of the Johnson & Johnson family of companies. Prior to that, he was with the cardiovascular division at Baxter Edwards, a medical technology company, for nearly ten years, holding various sales and marketing positions. Mr. Tansey currently serves on the boards of directors of Inspire Medical Systems, Inc. (NYSE: INSP), a medical technology company, where he also serves on its compensation committee, HeartFlow, Inc. (Nasdaq: HTFL), a commercial-stage medical technology company, and Shoulder Innovations (NYSE: SI), a commercial-stage medical technology company. He also serves on the board of directors for a number of U.S. Venture Partners' portfolio of private companies. Mr. Tansey received a B.S. and an M.B.A. from the Notre Dame de Namur University. We

believe that Mr. Tansey is qualified to serve as a member of our board of directors because of his extensive experience as a venture capital investor and as a member of the boards of directors of multiple companies in the medical sector.

William (Bill) Harrington, M.D. has served as a member of our board of directors since June 2022. Dr. Harrington has also served as a Managing Partner at Osage University Partners since 2012, where he oversees investing activities across biotechnology and medical device industries. He currently serves on the boards of directors of Neuros Medical, Inc., Hyalex Orthopedics, Inc., Transposon Therapeutics, Inc. and MediSix Therapeutics Pte. Ltd. Previously, he served on the board of directors of Nevro Corp., a medical device company. Dr. Harrington received a B.S. from Tufts University, an M.D. from Harvard Medical School, and an M.B.A. from the Haas School of Business at University of California, Berkeley. We believe Dr. Harrington is qualified to serve as a member of our board of directors because of his extensive experience as a venture capital investor and as a member of the boards of directors of multiple companies in the medical device industry.

Cynthia Lucchese has served as a member of our board of directors since April 2024. Ms. Lucchese served as the Chief Strategy Officer of Penske Entertainment Corp., a subsidiary of Penske Corporation, from November 2020 to February 2023, and as the Chief Administrative Officer and Chief Financial Officer of Hulman & Company (acquired by Penske Corporation) from November 2014 to November 2020. Prior to this she was the Senior Vice President and Chief Financial Officer of Hillenbrand, Inc. (NYSE: HI), a company with multiple brands that serve a range of industries across the globe, from 2008 to 2014. She also served as the Senior Vice President and Chief Financial Officer of Thoratec Corporation, a medical device company, from 2005 to 2007, and she held various senior financial positions with Guidant Corporation, a formerly public medical device company, from 1994 to 2005. Since October 2022, Ms. Lucchese has also served on the board of directors of The Cooper Companies, Inc. (Nasdaq: COO), a global medical device and healthcare company, where she currently serves as the chair of the corporate governance and nominating committee and a member of the organization and compensation committee. Ms. Lucchese previously served on the boards of directors of Inari Medical, Inc., a formerly public medical device company, from November 2019 to February 2025, where she served as the chair of its nominating & corporate governance committee and its audit committee; Hanger, Inc., a formerly public medical device and services company, from 2015 to October 2022, where she served on its audit and compensation committees; Intersect ENT, Inc., a formerly public medical device company, from 2014 to May 2022, where she served as the chair of its audit committee and a member of its nominating & corporate governance committee; and Brightpoint, Inc., a formerly public company, from 2009 to 2012, where she was the chair of its audit committee and a member of its nominating & corporate governance committee. She also served on the Board of Trustees of Indiana University from December 2021 to June 2025, where she served as vice chair of the board and chair of the finance and audit committee. Ms. Lucchese received a B.S. in accounting and an M.B.A. from Indiana University, Kelley School of Business. We believe Ms. Lucchese is qualified to serve as a member of our board of directors because of her extensive experience as a board member of public companies and experience with the medical device industry.

Maxwell Bikoff has served as a member of our board of directors since March 2025. Mr. Bikoff is a managing director at Longitude Capital, which he joined in 2016, focusing on investments in medical technologies and solutions. Mr. Bikoff served on the board of directors of Kestra Medical Technologies (Nasdaq: KMTS), a commercial-stage, wearable medical device and digital healthcare company, from July 2024 to September 2025, and has served on the board of directors of Polares Medical, a clinical-stage medical device company, since June 2020. Mr. Bikoff previously served as a board observer at Amphora Medical (which has since been acquired), Bolt Medical (which has since been acquired), Ceribell (Nasdaq: CBLL), Eargo (a formerly public medical device company), Endogenex, FIRE1, LimFlow (which has since been acquired), Nalu Medical, and RxSight (Nasdaq: RXST). He was actively involved in Longitude's investments in Axonics Modulation Technologies (Nasdaq: AXNX) and PROCEPT BioRobotics (Nasdaq: PRCT). Mr. Bikoff held a series of strategy, finance, and operating roles at Cardinal Health from 2010 to 2016, including director of Marketing, North America for a portfolio of cardiovascular devices from 2014 to 2016. Mr. Bikoff began his career in Deloitte Consulting's Life Sciences Strategy practice and received a B.S.E. in Biomedical Engineering from Duke University. We believe Mr. Bikoff is qualified to serve as a member of our board of directors based on his background in biomedical engineering and prior experience as a member of the boards of directors of a number of healthcare companies.

Edward Hanlon has served as a member of our board of directors since March 2025. Mr. Hanlon is an investment director at Gilde Healthcare which he joined in February 2020, overseeing investing activities across clinical-stage and growth-stage companies in the medical device industry. Previously, Mr. Hanlon was a senior analyst at Health Advances from September 2017 to February 2020. Mr. Hanlon has served as a member of the board of directors of VS3 Medical, Inc., a medical device company, since February 2025 and previously served as a board observer at Shoulder Innovations (NYSE: SI) from February 2023 to July 2025. Mr. Hanlon received a B.S. in Biology from Duke University. Mr. Hanlon expects to resign from our board of directors prior to the closing of this offering.

Family Relationships

Thomas Jordan Curnes II, our co-founder and a member of our board of directors, is the brother of Nelson Bunker Curnes, our Chief Financial Officer and a member of our board of directors. Aside from the foregoing relationship, there are no family relationships among any of our executive officers or directors.

Board Composition

Director Independence

Our board of directors has determined that Mr. Bikoff, Mr. Hanlon, Dr. Harrington, Ms. Lucchese, Mr. Mead and Mr. Tansey qualify as "independent" directors in accordance with the listing rules (the Listing Rules) of Nasdaq. Mr. Foust, Mr. Thomas Jordan Curnes II and Mr. Nelson Bunker Curnes are not considered independent by virtue of their positions as president and chief executive officer, co-founder, and chief financial officer, respectively. Under the Listing Rules, the definition of independence includes a series of objective tests, such as that the director is not, and has not been for at least three years, one of our employees and that neither the director nor any of his or her family members has engaged in various types of business dealings with us. In addition, as required by the Listing Rules, our board of directors has made a subjective determination as to each independent director that no relationship exists that, in the opinion of our board of directors, would interfere with the exercise of independent judgment in carrying out the responsibilities of a director. In making these determinations, our board of directors reviewed and discussed information provided by the directors and us with regard to each director's business and personal activities and relationships as they may relate to us and our management. Each of Mr. Thomas Jordan Curnes II, Mr. Nelson Bunker Curnes and Mr. Hanlon expects to resign from our board of directors prior to the closing of this offering. As a result, following this offering we expect that five of our six directors will be "independent" directors in accordance with the Listing Rules.

Classified Board of Directors

In accordance with our amended and restated certificate of incorporation, which will be effective immediately prior to the completion of this offering, our board of directors will be divided into three classes with staggered three-year terms. At each annual general meeting of stockholders, the successors to directors whose terms then expire will be elected to serve from the time of election and qualification until the third annual meeting following election. Following this offering, our directors will be divided among the three classes as follows:

- the Class I directors will be Mr. Foust and Mr. Mead, and their terms will expire at the annual meeting of stockholders to be held in 2027;
- the Class II directors will be Mr. Bikoff and Dr. Harrington, and their terms will expire at the annual meeting of stockholders to be held in 2028; and
- the Class III directors will be Ms. Lucchese and Mr. Tansey, and their terms will expire at the annual meeting of stockholders to be held in 2029.

We expect that any additional directorships resulting from an increase in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. The division of our board of directors into three classes with staggered three-year terms may delay or prevent a change of our management or a change in control.

Leadership Structure of the Board

Our amended and restated bylaws and corporate governance guidelines to be in place immediately prior to the consummation of this offering will provide our board of directors with flexibility to combine or separate the positions of Chair of the board of directors and Chief Executive Officer and to implement a lead independent director in accordance with its determination regarding which structure would be in the best interests of our company.

Our board of directors has concluded that our current leadership structure is appropriate at this time. However, our board of directors will continue to periodically review our leadership structure and may make such changes in the future as it deems appropriate.

Role of Board in Risk Oversight Process

Risk assessment and oversight are an integral part of our governance and management processes. Our board of directors encourages management to promote a culture that incorporates risk management into our corporate strategy and day-to-day business operations. Management discusses strategic and operational risks at regular management meetings and conducts specific strategic planning and review sessions during the year that include a focused discussion and analysis of the strategic risks facing us. Throughout the year, senior management reviews these strategic risks with the board of directors at regular board meetings as part of management presentations that focus on particular business functions, operations, or strategies, and presents the steps taken by management to mitigate or eliminate such risks.

Our board of directors does not have a standing risk management committee, but rather administers this oversight function directly through our board of directors as a whole, as well as through various standing committees of our board of directors that address risks inherent in their respective areas of oversight. While our board of directors is responsible for monitoring and assessing strategic risk exposure, our audit committee is responsible for overseeing company-wide and information security risk assessment processes, our major financial risk exposures, regulatory compliance, and the steps our management has taken to monitor and control these risks and exposures. The audit committee then reviews these matters with the full board of directors as part of the audit committee's reports at regular board meetings. The audit committee also approves or disapproves any related-party transactions. Our nominating and corporate governance committee monitors the effectiveness of our corporate governance guidelines and risks related to environmental, social, and governance issues and oversees management succession planning. Our compensation committee assesses and monitors whether any of our compensation policies and programs has the potential to encourage excessive risk-taking.

Board Committees

Our board of directors has established an audit committee, a compensation committee, and a nominating and corporate governance committee. Our board of directors may establish other committees to facilitate the management of our business. The composition and functions of each committee are described below. Members serve on these committees until their resignation or until otherwise determined by our board of directors. Each committee has a written charter that satisfies the applicable rules and regulations of the Securities and Exchange Commission and Listing Rules, which we will post on our website at www.mobia.com upon the completion of this offering. Information contained on, or that can be accessible through, our website is not a part of this prospectus and the inclusion of our website address in this prospectus is an inactive textual reference only.

Audit Committee

Our audit committee oversees our corporate accounting and financial reporting process. Among other matters, the audit committee is responsible for:

- appointing, compensating, retaining, evaluating, terminating, and overseeing our independent registered public accounting firm;
- discussing with our independent registered public accounting firm their independence from management;

- reviewing with our independent registered public accounting firm the scope and results of their audit;
- approving all audit and permissible non-audit services to be performed by our independent registered public accounting firm;
- overseeing the financial reporting process and discussing with management and our independent registered public accounting firm the interim and annual financial statements that we file with the SEC;
- reviewing and monitoring our accounting principles, accounting policies, financial and accounting controls, and compliance with legal and regulatory requirements;
- reviewing our policies on risk assessment and risk strategy and management, including risk policies and risk mitigation strategies by management;
- reviewing related party transactions; and
- establishing procedures for the confidential anonymous submission of concerns regarding questionable accounting, internal controls, or auditing matters.

Following this offering, our audit committee will consist of Ms. Lucchese, Mr. Bikoff, and Dr. Harrington. Our board of directors has determined that all members are independent under the Listing Rules and Rule 10A-3(b)(1) of the Exchange Act. The chair of our audit committee is Ms. Lucchese. Our board of directors has determined that Ms. Lucchese is an "audit committee financial expert" as such term is currently defined in Item 407(d)(5) of Regulation S-K. Our board of directors has also determined that each member of our audit committee can read and understand fundamental financial statements, in accordance with applicable requirements.

Compensation Committee

Our compensation committee oversees policies relating to compensation and benefits of our officers and employees. Among other matters, the compensation committee is responsible for:

- reviewing and approving, or recommending that our board of directors approve, the compensation of our Chief Executive Officer and executive officers;
- appointing and overseeing any compensation consultants;
- reviewing and approving or making recommendations to our board of directors regarding our incentive compensation and equity-based plans;
- reviewing and making recommendations to our board of directors with respect to director compensation;
- reviewing and discussing annually with management our "Compensation Discussion and Analysis" disclosure if and to the extent then required by SEC rules; and
- preparing the compensation committee report if and to the extent then required by SEC rules.

Following this offering, our compensation committee will consist of Ms. Tansey, Dr. Harrington, and Mr. Mead. Our board of directors has determined that all members are independent under the Listing Rules and are non-employee directors, as defined by Rule 16b-3 promulgated under the Exchange Act. The chair of our compensation committee is Mr. Tansey.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee oversees policies relating to our corporate governance. Among other matters, the nominating and corporate governance committee is responsible for:

- identifying individuals qualified to become members of our board of directors, consistent with criteria approved by our board of directors;

- reviewing and making recommendations to our board with respect to management succession planning;
- evaluating the overall effectiveness of our board of directors and its committees; and
- reviewing developments in corporate governance compliance and developing and recommending to our board of directors a set of corporate governance guidelines and principles.

Following this offering, our nominating and corporate governance committee will consist of Dr. Harrington, Mr. Bikoff, and Ms. Lucchese. Our board of directors has determined that all members are independent under the Listing Rules. The chair of our nominating and corporate governance committee is Dr. Harrington.

Compensation Committee Interlocks and Insider Participation

None of the members of our compensation committee is currently, or has been at any time, one of our executive officers or employees. None of our executive officers currently serves, or has served during the last year, as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving as a member of our board of directors or on our compensation committee.

Code of Business Conduct and Ethics

In connection with this offering, our board of directors adopted a written code of business conduct and ethics that applies to all of our directors, officers, and employees, including our principal executive officer, principal financial officer, and principal accounting officer or controller, or persons performing similar functions, and agents and representatives, which will be effective upon the completion of this offering.

The full text of our code of business conduct and ethics will be posted on our website at www.mobia.com upon the completion of this offering. The audit committee of our board of directors will be responsible for overseeing our code of business conduct and ethics and any waivers applicable to any director, executive officer, or employee. We intend to disclose any future material amendments of our code of business conduct and ethics, or waivers of such provisions applicable to our directors, officers, and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions, and agents and representatives, on our website identified above or in public filings. Information contained on, or that can be accessible through, our website is not a part of this prospectus and the inclusion of our website address in this prospectus is an inactive textual reference only.

EXECUTIVE AND DIRECTOR COMPENSATION

This section discusses the material components of the executive compensation program for our named executive officers who are set forth in the 2025 Summary Compensation Table below. We are an "emerging growth company," within the meaning of the JOBS Act, and have elected to comply with the reduced compensation disclosure requirements available to emerging growth companies under the JOBS Act.

In 2025, our named executive officers and their positions were:

- Richard Foust, Chief Executive Officer and President;
- Prashant Rawat, Chief Operating Officer; and
- Douglas (Doug) Ellison, Chief Commercial Officer.

This discussion may contain forward-looking statements that are based on our current plans, considerations, expectations and determinations regarding future compensation programs. Actual compensation programs that we adopt following the completion of this offering may differ materially from the currently planned programs summarized in this discussion.

We will continue to update, in accordance with the rules and regulations of the SEC, information in this section regarding the compensation of our named executive officers.

As an emerging growth company, we have elected to take advantage of exemptions from various reporting requirements that are applicable to public companies that are not emerging growth companies, including reduced disclosure obligations regarding executive compensation in this prospectus and, while an emerging growth company, our future periodic reports and proxy statements.

2025 Summary Compensation Table

The following table sets forth information regarding compensation earned with respect to the fiscal year ended December 31, 2025 by our named executive officers:

Name and Principal Position	Year	Salary ($)	Option Awards ($)[1]	Non-Equity Incentive Plan Compensation ($)[2]	All Other Compensation ($)[3]	Total
Richard Foust	2025	$ 422,708	$ 1,251,585	$ 225,750	$ 6,275	$ 1,906,318
Chief Executive Officer and President						
Prashant Rawat	2025	$ 422,300	$ 374,993	$ 155,952	$ 8,232	$ 961,477
Chief Operating Officer						
Douglas (Doug) Ellison	2025	$ 350,000	$ 339,346	$ 641,503	$ 14,000	$ 1,344,849
Chief Commercial Officer						

(1) Amounts reflect the full grant-date fair value of stock options granted during 2025 computed in accordance with Financial Accounting Standards Board (FASB) Accounting Standards Codification (ASC) Topic 718. We provide information regarding the assumptions used to calculate the value of all option awards made to named executive officers in Note 11 to the consolidated financial statements included in this prospectus. The amounts reported in this column reflect the accounting cost for the stock options and do not reflect the actual economic value that will be realized by our named executive officers upon the vesting or exercise of such awards or the sale of the common stock underlying such awards. For additional information, see the subsection titled "—Narrative to Summary Compensation Table—Equity-Based Incentive Awards" below.

(2) Amounts reflect the annual performance-based bonuses for each of Messrs. Foust and Rawat. For Mr. Ellison, amount reflects (i) the annual performance-based bonus of $110,250 and (ii) the variable cash-based compensation earned by Mr. Ellison of $531,253. For additional information, see the subsection titled "—Narrative to Summary Compensation Table—Cash Incentive Compensation" below.

(3) For each of our named executive officers, amounts reflect the value of 401(k) matching contributions for 2025. For a description of the 401(k) Plan, please see the subsection titled "—Narrative to Summary Compensation Table—401(k) Plan" below.

Narrative to Summary Compensation Table

Elements of Our Executive Compensation Program

For 2025, the primary elements of our named executive officers' compensation were base salary, cash incentive compensation and long-term equity compensation.

Base Salaries

The base salaries of our named executive officers are an important part of their total compensation package and are intended to reflect their respective positions, duties and responsibilities. For 2025, the named executive officers' annual base salaries were:

Named Executive Officer	Annual Base Salary
Richard Foust	$ 430,000
Prashant Rawat	$ 424,360
Douglas (Doug) Ellison	$ 350,000

In 2025, the compensation committee of our board of directors recommended, and our board of directors approved, a two-step salary increase for Mr. Foust with an increase in base salary in each of 2025 and 2026. Prior to the first-step increase in 2025, Mr. Foust's base salary was equal to $386,250, with the first-step increase to the rate reflected in the table above becoming effective as of March 1, 2025. The second-step increase was approved on January 21, 2026, and Mr. Foust's annual base salary was increased to $450,000, effective as of January 1, 2026.

In connection with this offering, our board of directors approved an increase to the base salaries for each of Messrs. Foust and Ellison such that their base salaries will be equal to $575,000 and $400,000, respectively.

Cash Incentive Compensation

In addition to base salaries, our named executive officers are eligible to receive annual performance-based cash bonuses, which are designed to provide appropriate incentives to our executives to achieve annual corporate goals and to reward our executives for individual achievement towards these goals. The annual performance-based bonus each named executive officer is eligible to receive is based on the extent to which we achieve the corporate goals that our board of directors establishes each year. At the end of the year, our board of directors reviews our performance against each corporate goal and determines the extent to which we achieved each of our corporate goals. For 2025, each named executive officer had the following target annual bonus amount, expressed as a percentage of the named executive officer's annual base salary:

Named Executive Officer	2025 Annual Bonus Target
Richard Foust	50 %
Prashant Rawat	35 %
Douglas (Doug) Ellison	30 %

Performance goals for the 2025 bonus program were generally based on a combination of commercial, operating expense, and operational performance criteria. Bonuses, if any, are typically determined and paid during the first quarter of the year following the performance year. The compensation committee of our board of directors did not assign individual quantitative sub-weightings within each category. The relative weighting among the categories for the 2025 annual bonus program were: (i) 60% commercial performance, based on achievement of revenue and other commercial objectives, including overall revenue targets and market performance, (ii) 10% operating expense management, based on effective management and control of operating expenses, including cost discipline and efficient allocation of resources and (iii) 30% operational performance, based on operational execution, including business continuity, operational stability and achievement of clinical and operational initiatives.

The actual amount of annual cash bonuses paid to our named executive officers for the 2025 performance period, based on performance achievement levels of 105% of target, are included in the "Non-Equity Incentive Plan Compensation" column of the 2025 Summary Compensation Table above.

Additionally, Mr. Ellison is eligible to earn a variable cash-based compensation payment based on our realization of certain revenue targets at the end of our fiscal year. For 2025, Mr. Ellison was eligible for a guaranteed variable cash-based payment equal to $200,000, with the ability to earn an additional uncapped amount equal to 5% of the excess of held reorders and revenues actually achieved in fiscal year 2025 that exceeded $28,040,000. The actual amount of the variable cash-based payment paid to Mr. Ellison for fiscal year 2025, based on realization of held reorders and revenues equal to $34,665,078, is included in the "Non-Equity Incentive Plan Compensation" column of the 2025 Summary Compensation Table above.

In connection with this offering, our board of directors approved an increase to the target annual bonus percentages for each of Messrs. Foust and Rawat such that their target annual bonus percentage for 2026 will be equal to 90% and 55%, respectively.

Equity-Based Incentive Awards

Our equity-based incentive awards are designed to align our interests and those of our stockholders with those of our employees, including our named executive officers. The board of directors or an authorized committee thereof is responsible for approving equity grants.

Prior to this offering, we granted stock options pursuant to our 2022 Equity Incentive Plan (the 2022 Plan) which was the successor to our Third Amended and Restated 2007 Stock Option Plan (the 2007 Plan and, collectively with our 2022 Plan, the Prior Plans). Certain of Mr. Foust's outstanding stock options granted in December 2021 were granted pursuant to the 2007 Plan, and all other outstanding stock options held by our named executive officers were granted pursuant to the 2022 Plan. Following this offering, we plan to grant equity-based incentive awards under the terms of the 2026 Plan to be adopted in connection with this offering. The terms of our Prior Plans and the 2026 Plan are described in the subsection titled "—Equity Incentive Plans" below. All options are granted with an exercise price per share that is no less than the fair market value of our common stock on the date of grant of such award as determined by our board of directors based on an independent third-party valuation. Our stock option grants generally vest over a four-year period and may be subject to acceleration of vesting and exercisability under certain termination and change in control events. From time to time, our board of directors may also construct alternate vesting schedules as it determines are appropriate to motivate particular employees.

On each of March 27, 2025, April 25, 2025 and October 17, 2025, we granted Mr. Foust options to purchase 389,423, 63,920 and 167,708 shares of our common stock, respectively, with an exercise price of $3.73, $3.73 and $3.94, respectively, the fair market value on the date of grant as determined by our board of directors based on an independent third-party valuation. Except for the options granted to Mr. Foust in April 2025, the options vest as to 25% of the options on the first anniversary of the vesting commencement date and as to 1/48th of the options on each monthly anniversary of the vesting commencement date thereafter for 36 months, subject to Mr. Foust's continuous service with us as of each such vesting date. Our board of directors determined that applicable corporate objectives in fiscal year 2025 were met, and accordingly the options granted in April 2025 vest as to 25% of the options on the first anniversary of the vesting commencement date and in respect of 1/48th of the total number of options on each monthly anniversary of the vesting commencement date thereafter for 36 months, subject to Mr. Foust's continuous service with us as of each such vesting date. The performance-based corporate objectives for Mr. Foust's options are the same as described above in the subsection titled "—Narrative to Summary Compensation Table—Cash Incentive Compensation" for our annual 2025 bonus program.

On each of March 27, 2025 and October 17, 2025, we granted Mr. Rawat options to purchase 126,825 and 57,084 shares of our common stock, respectively, with an exercise price of $3.73 and $3.94, respectively, the fair market value on the date of grant as determined by our board of directors based on an independent third-party valuation. The options vest as to 25% of the options on the first anniversary of the vesting commencement date and as to 1/48th of the options on each monthly anniversary of the vesting commencement date thereafter for 36 months, subject to Mr. Rawat's continuous service with us as of each such vesting date.

On each of March 27, 2025, April 25, 2025 and October 17, 2025, we granted Mr. Ellison options to purchase 120,583, 14,204 and 34,037 shares of our common stock, with an exercise price of $3.73, $3.73 and $3.94, respectively, the fair market value on the date of grant as determined by our board of directors based on an independent third-party valuation. Except for the options granted to Mr. Ellison in April 2025, the options vest as to 25% of the options on the first anniversary of the vesting commencement date and as to 1/48th of the options on each monthly anniversary of the vesting commencement date thereafter for 36 months, subject to Mr. Ellison's continuous service with us as of each such vesting date. Based on our exceeding a held reorder and revenue target equal to $28,100,000 in fiscal year 2025, the options granted in April 2025 vest as to 25% of the options on the first anniversary of the vesting commencement date and in respect of 1/48th of the total number of options on each monthly anniversary of the vesting commencement date thereafter for 36 months, subject to Mr. Ellison's continuous service with us as of each such vesting date.

In connection with this offering, each of our executive officers will receive an award of stock options on the date on which this registration statement becomes effective with a grant value of (i) $5,500,000 for Mr. Foust, (ii) $1,500,000 for Mr. Rawat, (iii) $1,600,000 for Mr. Ellison, (iv) $1,700,000 for Mr. Bunker Curnes, (v) $900,000 for Mr. Jordan Curnes II and (vi) $1,450,000 for Mr. Leavitt, at an exercise price equal to the initial public offering price in this offering. The number of options granted will be the quotient obtained by dividing (a) the applicable grant value by (b) 55% of the initial public offering price in this offering, with the resulting number of options rounded up to the nearest 10 shares. These stock options will vest as to 25% of the stock options on the first anniversary of the grant date, with the remaining stock options vesting in 36 equal monthly installments thereafter, in each case, subject to the executive officer's continued service through the applicable vesting date.

In connection with this offering, we will also grant stock options and restricted stock units ("RSUs") on the date on which this registration statement becomes effective to our non-executive employees with an aggregate grant value of $8,156,287 and $2,721,250, respectively. The number of options granted will be the quotient obtained by dividing (a) the applicable grant value by (b) 55% of the initial public offering price in this offering, with the resulting number of options rounded up to the nearest 10 shares. These stock options will vest as to 25% of the stock options on the first anniversary of the grant date, with the remaining stock options vesting in 36 equal monthly installments thereafter, in each case, subject to the employee's continued service through the applicable vesting date. The number of RSUs granted will be the quotient obtained by dividing (a) the applicable grant value by (b) the initial public offering price in this offering, with the resulting number of RSUs rounded up to the nearest 10 shares. These RSUs will vest as to 25% of the RSUs on the first four anniversaries of the grant date, subject to the employee's continued service through the applicable vesting date.

Other Elements of Compensation

Health and Welfare Benefits; Perquisites

All of our named executive officers are eligible to participate in our employee benefit plans, including our medical, dental, vision, disability, and life insurance plans, in each case on the same basis as all of our other employees. We generally do not provide perquisites or personal benefits to our named executive officers, except in limited circumstances. Our board of directors may elect to adopt qualified or non-qualified benefit plans in the future if it determines that doing so is in our best interests.

401(k) Plan

Our named executive officers are eligible to participate in a defined contribution retirement plan that provides eligible employees with an opportunity to save for retirement on a tax advantaged basis. Eligible employees may defer eligible compensation on a pre-tax or after-tax (Roth) basis, up to the statutorily prescribed annual limits on contributions under the Code. Contributions are allocated to each participant's individual account and are then invested in selected investment alternatives according to the participants' directions. The 401(k) plan is intended to be qualified under Section 401(a) of the Code with the 401(k) plan's related trust intended to be tax exempt under Section 501(a) of the Code. As a tax-qualified retirement plan, contributions to the 401(k) plan (except for Roth contributions) and earnings on those contributions are not taxable to the employees until distributed from the 401(k) plan. Under the 401(k) plan, we provide matching contributions to all participants (including our named executive

officers) equal to 4% of such participant's annual compensation. Our board of directors may elect to adopt qualified or nonqualified retirement plans in the future, if it determines that doing so is in our best interests.

Employment, Severance or Change in Control Agreements

We expect to enter into restated employment agreements (Restated Employment Agreements) with our named executive officers effective upon the effectiveness of the registration statement relating to this offering. The terms of these Restated Employment Agreements are generally consistent with the terms of each of our named executive officers' employment agreements described below in the section titled "—Pre-IPO Employment Agreements" except that the Restated Employment Agreements do not include severance provisions and instead provide that each of our named executive officers are eligible to participate in our Severance Plan (as defined and described below).

Upon the effectiveness of the Restated Employment Agreements, each of our named executive officers will be entitled to the base salary and annual bonus targets (and, for Mr. Ellison, sales incentive targets) as described above in the sections titled "—Elements of Our Executive Compensation Program—Base Salaries" and "—Elements of Our Executive Compensation Program—Cash Incentive Compensation." Mr. Foust's Restated Employment Agreement provides that, in the event of a Corporate Transaction (as defined below) any then unvested stock options held by Mr. Foust that were granted prior to the consummation of this offering will become fully vested immediately prior to the consummation of such Corporate Transaction. Mr. Foust's Restated Employment Agreement also provides that, upon termination of Mr. Foust's employment by us under circumstances giving rise to severance under the Executive and Key Employee Severance Plan, in addition to the severance benefits thereunder, Mr. Foust will be entitled to accelerated vesting of any then-unvested portion of outstanding equity grants by 12 months from the date of termination.

Executive and Key Employee Severance Plan

In connection with this offering, our board of directors adopted an Executive and Key Employee Severance and Change in Control Severance Plan (the Severance Plan) for the benefit of certain of our executive and key employees employed by us or our subsidiaries who are designated by our compensation committee as eligible to participate in the Severance Plan (the Covered Employees). The severance benefits under the Severance Plan, which will become effective upon the effectiveness of the registration statement relating to this offering, will supersede any severance benefits otherwise payable under the applicable Covered Employee's Pre-IPO Employment Agreement (as defined below), except as expressly provided in the Restated Employment Agreements.

The Severance Plan provides assurances of specified severance benefits to Covered Employees whose employment is subject to involuntary termination by us other than for Cause (as defined below) or due to the Covered Employee's resignation for Good Reason (as defined below) under the circumstances described in the Severance Plan, including, but not limited to, a qualifying termination that occurs following a Change in Control (as defined below). The severance benefits each Covered Employee could be entitled to receive under the Severance Plan are determined pursuant to each Covered Employee's classification as a Tier 1 Covered Employee, a Tier 2 Covered Employee, or a Tier 3 Covered Employee. Mr. Foust has been designated as a Tier 1 Covered Employee and each of our other executive officers has been designated as a Tier 2 Covered Employee.

Pursuant to the Severance Plan, if, at any time before the date of a Change in Control or after the end of the 18-month period beginning on the date of a Change in Control, we (or any of our subsidiaries) terminate a Covered Employee's employment other than for Cause (and other than due to death or Disability (as defined in the Severance Plan)) or the Covered Employee resigns for Good Reason, then the Covered Employee will be entitled to receive the following severance benefits, subject to the Covered Employee's execution of a release of claims and compliance with certain restrictive covenants, including with respect to non-solicitation and non-disparagement:

- In the case of a Tier 1 Covered Employee, an amount equal to the sum of (i) the Covered Employee's annualized base pay for 12 months following termination and (ii) the prorated portion of the Covered Employee's target bonus for the fiscal year in which such termination occurs, paid in a lump sum;
- In the case of a Tier 2 Covered Employee, an amount equal to the Covered Employee's annualized base pay for 12 months following termination, paid in a lump sum; and

- In the case of a Tier 3 Covered Employee, an amount equal to the Covered Employee's annualized base pay for 9 months following termination paid in a lump sum; and
- Company-paid COBRA coverage for 12 months, 12 months, or 9 months following termination in the case of a Tier 1 Covered Employee, a Tier 2 Covered Employee, or a Tier 3 Covered Employee, respectively; and

Pursuant to the Severance Plan, if, at any time within the 18-month period following a Change in Control, we (or any of our subsidiaries) terminate a Covered Employee's employment other than for Cause (and other than due to death or Disability) or the Covered Employee resigns for Good Reason, then the Covered Employee will be entitled to receive the following severance benefits, subject the Covered Employee's execution of a release of claims and compliance with certain restrictive covenants, including with respect to non-solicitation and non-disparagement:

- The following aggregate cash amount, paid in a lump sum:
- In the case of a Tier 1 Covered Employee, the sum of 18 months of the Covered Employee's annualized base pay and 1.5 times the Covered Employee's target bonus;
- In the case of a Tier 2 Covered Employee, the sum of 15 months of the Covered Employee's annualized base pay and 1.25 times the Covered Employee's target bonus; and
- In the case of a Tier 3 Covered Employee, the sum of 12 months of the Covered Employee's annualized base pay and the Covered Employee's target bonus.
- Company-paid COBRA coverage for 18 months, 15 months, or 12 months following termination in the case of a Tier 1 Covered Employee, a Tier 2 Covered Employee, or a Tier 3 Covered Employee, respectively; and
- 100% accelerated vesting of the Covered Employee's time-based equity compensation awards; provided, that any performance-based equity compensation awards will vest assuming "target" level of performance, unless the terms of the applicable equity compensation award agreement provide otherwise, in which case the applicable equity compensation award agreement will govern.

For purposes of the Severance Plan:

- "Cause" means, unless otherwise defined in a Covered Employee's participation agreement, any of the following: (i) the Covered Employee's commission of an act of fraud, embezzlement or dishonesty, or the commission of some other illegal act by you, that has a demonstrable adverse impact on the Company or any successor or affiliate thereof; (ii) the Covered Employee's conviction of, or plea of "guilty" or "no contest" to, a felony or any crime involving fraud, dishonesty or moral turpitude under the laws of the United States or any state thereof (other than traffic violations or other insignificant infractions of law that do not affect the performance of the Covered Employee's duties to the Company); (iii) any intentional, unauthorized use or disclosure by the Covered Employee of confidential information or trade secrets of the Company or any successor or affiliate thereof; (iv) the Covered Employee's gross negligence, insubordination or material violation of any duty of loyalty to the Company or any successor or affiliate thereof, or any other demonstrable material misconduct on the Covered Employee's part; (v) the Covered Employee's ongoing and intentional failure or refusal to substantially perform the Covered Employee's assigned duties or employment obligations (other than as a result of a cause or event outside of the Covered Employee's control) or the Covered Employee's ongoing and repeated failure or refusal to comply with the lawful instructions given to the Covered Employee by our Chief Executive Officer or, with respect to the Chief Executive Officer, our board of directors, which failure, refusal or neglect continues for 30 days following the Covered Employee's receipt of written notice from our board of directors stating with specificity the nature of such failure, refusal or neglect; or (vi) the Covered Employee's willful, material breach of any written Company policy applicable to the Covered Employee or any material provision of any offer or employment letter or any confidential information agreement, proprietary information and inventions agreement to which the Covered Employee is a party;

- "Change in Control" means a "Change in Control" as such term is defined under our 2026 Plan, as described below in the section titled "—Equity Incentive Plans;" and

"Good Reason" means unless otherwise defined in a Covered Employee's participation agreement, the occurrence of any of the following events or conditions without a Covered Employee's written consent: (i) a material reduction or material adverse change in the Covered Employee's authority, duties or responsibilities; (ii) a material diminution in the Covered Employee's base pay or target bonus, unless such a reduction is imposed across-the-board to all senior management of the Company; (iii) a material change in the geographic location at which the Covered Employee must perform the Covered Employee's duties from the location that was designated as the Covered Employee's primary location immediately prior to such change (and the Covered Employee and the Company agree that a change of more than 35 miles shall be material for this purpose, and that the Covered Employee's primary employment location shall be the Covered Employee's home if the Covered Employee is designated as a remote worker); or (iv) any other action or inaction that constitutes a material breach by the Company or any successor or affiliate of its obligations to the Covered Employee under any agreement between the Covered Employee and the Company or any of its affiliates or any plan maintained by the Company or any of its affiliates related to the Covered Employee's employment in which the Covered Employee is a participant. The Covered Executive must provide written notice to the Company of the occurrence of any of the foregoing events or conditions without the Covered Employee's written consent within 60 days of the occurrence of such event. The Company or any successor or affiliate shall have a period of 30 days to cure such event or condition after receipt of written notice of such event from the Covered Employee. The Covered Employee's termination of employment by reason of resignation from employment with the Company for Good Reason must occur within 30 days following the expiration of the foregoing 30-day cure period.

Pre-IPO Employment Agreements

We are party to an employment agreement with each of our named executive officers (the Pre-IPO Employment Agreements), as further described below.

Richard Foust

We have entered into an employment agreement with Mr. Foust (the Foust Employment Agreement). Mr. Foust's employment with us is at-will.

The Foust Employment Agreement provides that Mr. Foust will be entitled to an annual base salary, which will be reviewed on an annual basis for potential increase and, at a minimum, will increase 3% annually as a cost of living increase. The Foust Employment Agreement also provides that Mr. Foust will be entitled to participate in any incentive bonus program we have adopted for executive employees.

The Foust Employment Agreement provides that Mr. Foust will be eligible, at least annually, for stock option grants under the 2007 Plan or 2022 Plan, as applicable. Additionally, in the event of a Corporate Transaction (as defined below) any then unvested stock options held by Mr. Foust will immediately become fully vested immediately prior to the consummation of such Corporate Transaction.

The Foust Employment Agreement also provides that upon termination of Mr. Foust's employment by us without Cause (as defined below) and upon his resignation for Good Reason (as defined below), subject to Mr. Foust's execution and non-revocation of a release of claims, Mr. Foust will be entitled to receive, in addition to any accrued amounts, (i) a lump sum payment equal to (a) his most recent annual base salary *plus* (b) his then annual target bonus amount, prorated for the period of his employment during the year of termination, (ii) the payment of his and his eligible dependents COBRA premium costs (for the lesser of (x) 12 months, (y) the time until Mr. Foust receives coverage through other employment, or (z) Mr. Foust is no longer eligible for COBRA continuation coverage), and (iii) accelerated vesting of any then-unvested portion of outstanding equity grants by 12 months from the date of termination.

As defined in the Foust Employment Agreement, "Cause" generally means any of the following, as determined in good faith by us: (i) Mr. Foust's conviction of a felony involving moral turpitude; (ii) misappropriation, embezzlement or fraud by Mr. Foust in the performance of his duties; (iii) Mr. Foust's willful violation by him of

any material law, regulation or company policy applicable to his work for us; (iv) a material breach by Mr. Foust of his PIIA (as defined below); or (v) Mr. Foust's repeated refusal to perform his material duties; provided that a termination for Cause pursuant to subsection (iv) or (v) may only be effected after Mr. Foust's receipt of specific written notice and failure to cure the claimed violation within thirty (30) days thereafter.

As defined in the Foust Employment Agreement, "Good Reason" generally means any of the following done without Mr. Foust's written consent: (i) a material diminution in his base salary, aggregate cash compensation or target bonus opportunity; (ii) a material diminution in his authority, duties or responsibility; (iii) relocation of the principal geographic location at which he must perform services to a location that is more than 35 miles from the then-current location; (iv) any requirement that he engage in illegal conduct; or (v) a material breach by us of the Foust Employment Agreement or any other agreement between us (or any of our affiliates) and Mr. Foust; provided, however, that Good Reason shall not exist unless Mr. Foust provides us with written notice specifying the claimed grounds for Good Reason within ninety (90) days following the initial existence of such event or condition, and we fail to cure such event or condition within thirty (30) days after the date of the written notice, and provided, further, that Mr. Foust must resign effective within 30 days following our failure to cure such event or condition.

As defined in the Foust Employment Agreement, "Corporate Transaction" generally has the meaning set forth in the 2007 Plan; provided, however, for the purpose of clarity and notwithstanding anything contrary in the 2007 Plan, a SPAC Transaction will constitute a Corporate Transaction under the Foust Employment Agreement. For purposes of the Foust Employment Agreement, "SPAC Transaction" means the consummation of a transaction or series of related transactions by merger, consolidation, share exchange or otherwise of the Company with a publicly traded "special purpose acquisition company" or its subsidiary (collectively, a SPAC), immediately following the consummation of which the common stock, ordinary shares or share capital of the SPAC or its successor entity is listed on the Nasdaq Stock Market, the New York Stock Exchange or another exchange or marketplace approved by the Company's board of directors.

Mr. Foust also entered into a proprietary information and inventions agreement (the PIIA) which includes confidentiality and assignment of intellectual property provisions and certain restrictive covenants, including non-competition and non-solicitation of customers during Mr. Foust's employment and one-year post-employment non-solicitation of employees.

Prashant Rawat

We have entered into an employment agreement with Mr. Rawat (the Rawat Employment Agreement). Mr. Rawat's employment with us is at-will.

The Rawat Employment Agreement provides that Mr. Rawat will be entitled to an annual base salary, which will be reviewed for potential increase no more frequently than once per calendar year. The Rawat Employment Agreement also provides that Mr. Rawat will be eligible to receive up to 35% of his base salary per year in cash which will be dependent upon his and our performance, as determined by our compensation committee in its discretion.

Mr. Rawat also entered into a PIIA which includes confidentiality and assignment of intellectual property provisions.

Douglas (Doug) Ellison

We have entered into an employment agreement with Mr. Ellison (the Ellison Employment Agreement). Mr. Ellison's employment with us is at-will.

The Ellison Employment Agreement provides that Mr. Ellison will be entitled to an annual base salary, which will be reviewed for potential increase no more frequently than once per calendar year. The Ellison Employment Agreement also provides that Mr. Ellison will be eligible to participate in our sales incentive plan adopted for our sales employees with a target variable compensation under such sales incentive plan equal to $200,000 per year, as determined and paid in accordance with the sales incentive plan. Additionally, Mr. Ellison is eligible to receive up to

30% of his base salary per year in cash which will be dependent upon his and our performance, as determined by our compensation committee in its discretion.

Mr. Ellison also entered into a PIIA which includes confidentiality and assignment of intellectual property provisions.

Clawback Policy

In connection with this offering, our board of directors adopted a compensation recovery policy that is compliant with the Listing Rules, as required by the Dodd-Frank Act, to be effective upon the consummation of this offering.

Outstanding Equity Awards at 2025 Fiscal Year-End

The following table presents information regarding the outstanding stock options held by each of our named executive officers as of December 31, 2025:

	Grant Date	Number of Securities Underlying Unexercised Options (#) Exercisable	Number of Securities Underlying Unexercised Options (#) Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options (#)	Option Exercise Price ($)	Option Expiration Date
Richard Foust	April 27, 2021	43,066	—	—	$ 2.90	May 6, 2031
	December 15, 2022	508,839	10,826[1]	—	$ 3.38	December 14, 2032
	March 27, 2025	55,386	334,033[1]	—	$ 3.73	March 26, 2035
	April 25, 2025	—	—	63,920[2]	$ 3.73	April 24, 2035
	October 17, 2025	—	167,708[1]	—	$ 3.94	October 16, 2035
Prashant Rawat	December 15, 2022	172,588	24,655[1]	—	$ 3.38	December 14, 2032
	March 27, 2025	19,301	107,524[1]	—	$ 3.73	March 26, 2035
	October 17, 2025	—	57,084[1]	—	$ 3.94	October 16, 2035
Douglas (Doug) Ellison	March 3, 2023	123,424	45,843[1]	—	$ 3.38	March 2, 2033
	March 27, 2025	16,485	104,098[1]	—	$ 3.73	March 26, 2035
	April 25, 2025	—	—	14,204[3]	$ 3.73	April 24, 2035
	October 17, 2025	—	34,037[1]	—	$ 3.94	October 16, 2035

(1) Amounts reflect the number of stock options outstanding in each tranche as of December 31, 2025. Outstanding stock options vest in respect of 25% of the total number of shares of common stock initially subject to the option on the first anniversary of the vesting commencement date and in respect of 1/48th of the total number of shares of common stock initially subject to the option on each monthly anniversary of the vesting commencement date thereafter for 36 months, subject to the named executive officer's continuous service with us as of each such vesting date.

(2) Amount reflects the number of stock options outstanding as of December 31, 2025. Based upon the achievement of a certain percentage of corporate objectives in fiscal year 2025, the outstanding stock options will vest in respect of 25% of the total number of shares of common stock initially subject to the option on the first anniversary of the vesting commencement date and in respect of 1/48th of the total number of shares of common stock initially subject to the option on each monthly anniversary of the vesting commencement date thereafter for 36 months, subject to the named executive officer's continuous service with us as of each such vesting date.

(3) Amount reflects the number of stock options outstanding as of December 31, 2025. Based upon our achievement of exceeding a held reorder and revenue target equal to $28,100,000 in fiscal year 2025, the outstanding stock options will vest in respect of 25% of the total number of shares of common stock initially subject to the option on the first anniversary of the vesting commencement date and in respect of 1/48th of the total number of shares of common stock initially subject to the option on each monthly anniversary of the vesting commencement date thereafter for 36 months, subject to the named executive officer's continuous service with us as of each such vesting date.

Equity Incentive Plans

The following summarizes the material terms of our Prior Plans, the 2026 Plan and the ESPP. We anticipate that the 2026 Plan will be the long-term equity incentive plan in which our directors and named executive officers will be eligible to participate following the consummation of this offering, subject to the terms and conditions of the 2026 Plan. These summaries are qualified in their entirety by reference to the actual text of the applicable plan, each of which will be filed as an exhibit to the registration statement of which this prospectus is a part.

2026 Incentive Award Plan

Prior to this offering, our board of directors adopted and will ask our stockholders to approve the Mobia Medical, Inc. 2026 Incentive Award Plan (the 2026 Plan), which will become effective in connection with this offering. Under the 2026 Plan, we may grant cash and equity incentive awards to eligible service providers in order to attract, motivate and retain the talent for which we compete. The material terms of the 2026 Plan, as it is currently contemplated, are summarized below.

Eligibility and Administration. Our employees, consultants, and directors, and employees and consultants of our subsidiaries, will be eligible to receive awards under the 2026 Plan. Following this offering, the 2026 Plan will generally be administered by our board of directors with respect to awards to non-employee directors and by our compensation committee with respect to other participants, each of which may delegate its duties and responsibilities to committees of our directors and/or officers (referred to collectively as the plan administrator below), subject to certain limitations that may be imposed under the 2026 Plan, Section 16 of the Exchange Act, applicable law and/or stock exchange rules, as applicable. The plan administrator will have the authority to make all determinations and interpretations under, prescribe all forms for use with, and adopt rules for the administration of, the 2026 Plan, subject to its express terms and conditions. The plan administrator will also set the terms and conditions of all awards under the 2026 Plan, including any vesting and vesting acceleration conditions.

Limitation on Awards and Shares Available. The number of shares initially available for issuance under awards granted pursuant to the 2026 Plan will be the sum of (i) 14% of the number of "pricing date fully-diluted shares" (as defined below), *plus* (ii) any shares of our common stock which, as of the effective date of the 2026 Plan, remain available for issuance under the 2022 Plan, plus (iii) any shares subject to outstanding awards under the Prior Plans as of the effective date of the 2026 Plan that become available for issuance under the 2026 Plan thereafter in accordance with its terms. The number of shares initially available for issuance will be increased on January 1 of each calendar year beginning in 2027 and ending in 2036, by an amount equal to the lesser of (a) 5% of the shares of common stock outstanding on the final day of the immediately preceding calendar year and (b) such smaller number of shares as determined by the plan administrator. No more than 250,000,000 shares of common stock may be issued upon the exercise of incentive stock options under the 2026 Plan (which number gives effect to the reverse stock split expected to be implemented in connection with this offering). Shares issued under the 2026 Plan may be authorized but unissued shares, shares purchased on the open market or treasury shares. For purposes of the 2026 Plan, the "pricing date fully-diluted shares" means, as of the date on which the registration statement of which this prospectus forms a part is declared effective, the sum of (1) the shares of our common stock outstanding on such date (calculated on an as-converted basis after giving effect to the conversion of the Company's outstanding securities into shares in connection with the initial public offering and after giving effect to the issuance of the shares to be sold in this initial public offering and assuming the exercise in full of the underwriters' over-allotment option in such initial public offering), (2) the shares of our common stock subject to compensatory equity awards (including stock options) outstanding on such date (with the number of shares subject to performance-based compensatory equity awards calculated at the "maximum" level of performance), and (3) all shares of common stock available for future issuance under the 2026 Plan and the ESPP as of such date.

If an award under the 2026 Plan or the Prior Plans expires, lapses, or is terminated, exchanged for, or settled in cash, surrendered, repurchased, cancelled without having been fully exercised or forfeited, in any case, in a manner that results in us acquiring shares covered by the award at a price not greater than the price paid by the participant for such shares or not issuing any shares covered by the award, any shares subject to such award will, as applicable, become or again be available for new grants under the 2026 Plan. Awards granted under the 2026 Plan upon the assumption of, or in substitution for, awards authorized or outstanding under a qualifying equity plan maintained by

an entity with which we enter into a merger or similar corporate transaction will not reduce the shares available for grant under the 2026 Plan. Further, shares delivered (either by actual delivery or attestation) to us by a participant to satisfy the applicable exercise or purchase price of an award under the 2026 Plan or the Prior Plans and/or to satisfy any applicable tax withholding obligation (including shares retained by us from the award being exercised or purchased and/or creating the tax obligation) shall become or again be available for the grant of awards under the 2026 Plan.

Awards. The 2026 Plan provides for the grant of stock options, including incentive stock options, or ISOs within the meaning of Section 422 of the Code, and nonqualified stock options, or NSOs; restricted stock; dividend equivalents; restricted stock units, or RSUs; stock appreciation rights, or SARs; and other stock or cash-based awards. Certain awards under the 2026 Plan may constitute or provide for a deferral of compensation, subject to Section 409A of the Code, which may impose additional requirements on the terms and conditions of such awards. All awards under the 2026 Plan will be set forth in award agreements, which will detail the terms and conditions of the awards, including any applicable vesting and payment terms and post-termination exercise limitations. Awards other than cash awards generally will be settled in shares of our common stock, but the plan administrator may provide for cash settlement of any award. A brief description of each award type follows.

- *Stock Options*. Stock options provide for the purchase of shares of our common stock in the future at an exercise price set on the grant date. ISOs, by contrast to NSOs, may provide tax deferral beyond exercise and favorable capital gains tax treatment to their holders if certain holding period and other requirements of the Code are satisfied. The exercise price of a stock option will not be less than 100% of the fair market value of the underlying share on the date of grant (or 110% in the case of ISOs granted to certain significant stockholders), except with respect to certain substitute options granted in connection with a corporate transaction. The term of a stock option may not be longer than ten years (or five years in the case of ISOs granted to certain significant stockholders). Vesting conditions determined by the plan administrator may apply to stock options and may include continued service, performance, and/or other conditions. ISOs generally may be granted only to our employees and employees of our parent or subsidiary corporations, if any.

- *SARs*. SARs entitle their holder, upon exercise, to receive from us an amount equal to the appreciation of the shares subject to the award between the grant date and the exercise date. The exercise price of a SAR will not be less than 100% of the fair market value of the underlying share on the date of grant (except with respect to certain substitute SARs granted in connection with a corporate transaction), and the term of a SAR may not be longer than ten years. Vesting conditions determined by the plan administrator may apply to SARs and may include continued service, performance and/or other conditions.

- *Restricted Stock and RSUs*. Restricted stock is an award of nontransferable shares of our common stock that remain forfeitable unless and until specified conditions are met, and which may be subject to a purchase price. RSUs are contractual promises to deliver shares of our common stock in the future, which may also remain forfeitable unless and until specified conditions are met. Delivery of the shares underlying RSUs may be deferred under the terms of the award or at the election of the participant, if the plan administrator permits such a deferral. Conditions applicable to restricted stock and RSUs may be based on continuing service, the attainment of performance goals and/or such other conditions.

- *Other Stock or Cash-Based Awards*. Other stock or cash-based awards are awards of cash, fully vested shares of our common stock, and other awards valued wholly or partially by referring to, or otherwise based on, shares of our common stock. Other stock or cash-based awards may be granted to participants and may also be available as a payment form in the settlement of other awards, as standalone payments and as payment in lieu of base salary, bonus, fees, or other cash compensation otherwise payable to any individual who is eligible to receive awards. The plan administrator will determine the terms and conditions of other stock or cash-based awards, which may include vesting conditions based on continued service, performance and/or other conditions.

- *Dividend Equivalents*. RSUs or other stock and cash-based awards may be accompanied by the right to receive the equivalent value of dividends paid on shares of our common stock prior to the delivery of the

underlying shares. Such dividend equivalents will be paid out only to the extent that any vesting conditions are subsequently satisfied, unless otherwise determined by the plan administrator. No dividend equivalents will be payable on stock options or SARs.

Performance Awards. Performance awards include any of the foregoing awards that are granted subject to vesting and/or payment based on the attainment of specified performance goals or other criteria the plan administrator may determine, which may or may not be objectively determinable. Performance criteria upon which performance goals are established by the plan administrator may include, but are not limited to: net earnings or losses (either before or after one or more of interest, taxes, depreciation, amortization, and non-cash equity-based compensation expense); gross or net sales or revenue or sales or revenue growth; net income (either before or after taxes) or adjusted net income; profits (including, but not limited to, gross profits, net profits, profit growth, net operation profit, or economic profit), profit return ratios or operating margin; budget or operating earnings (either before or after taxes or before or after allocation of corporate overhead and bonus); cash flow (including operating cash flow and free cash flow or cash flow return on capital); return on assets; return on capital or invested capital; cost of capital; return on stockholders' equity; total stockholder return; return on sales; costs, reductions in costs, and cost control measures; expenses; working capital; earnings or loss per share; adjusted earnings or loss per share; price per share or dividends per share (or appreciation in or maintenance of such price or dividends); regulatory achievements or compliance; implementation, completion, or attainment of objectives relating to research, development, regulatory, commercial, or strategic milestones or developments; market share; economic value or economic value added models; division, group or corporate financial goals; customer satisfaction/growth; customer service; employee satisfaction; recruitment and maintenance of personnel; human capital management (including diversity and inclusion); supervision of litigation and other legal matters; strategic partnerships and transactions; financial ratios (including those measuring liquidity, activity, profitability, or leverage); debt levels or reductions; sales-related goals; financing and other capital raising transactions; cash on hand; acquisition activity; investment sourcing activity; and marketing initiatives, any of which may be measured in absolute terms or as compared to any incremental increase or decrease. Such performance goals also may be based solely by reference to our performance or the performance of a subsidiary, division, business segment, or business unit, or based upon performance relative to performance of other companies or upon comparisons of any of the indicators of performance relative to performance of other companies.

Director Compensation. The 2026 Plan provides that the plan administrator may establish compensation for non-employee directors from time to time subject to the 2026 Plan's limitations. In connection with this offering, we intend to adopt and ask our stockholders to approve the initial terms of our non-employee director compensation program, which is described in the subsection titled "Non-Employee Director Compensation" below. Our board of directors or its authorized committee may modify the non-employee director compensation program from time to time in its discretion and pursuant to the exercise of its business judgment, taking into account such factors, circumstances and considerations as it deems relevant from time to time, provided that the sum of any cash compensation or other compensation and the grant date fair value (as determined in accordance with FASB ASC 718, or any successor thereto) of any equity awards granted as compensation for services as a non-employee director during any calendar year may not exceed $1,000,000 (which limit will not apply to the compensation for any non-employee director who serves in any capacity in addition to that of a non-employee director for which he or she receives additional compensation or any compensation paid to any non-employee director prior to the calendar year following the calendar year in which this offering occurs). The plan administrator may make exceptions to this limit for individual non-employee directors in such circumstances as the plan administrator may determine in its discretion.

Certain Transactions. In connection with certain transactions and events affecting our common stock, including a change in control (as defined below), or change in any applicable laws or accounting principles, the plan administrator has broad discretion to act under the 2026 Plan to prevent the dilution or enlargement of intended benefits, facilitate such transaction or event, or give effect to such change in applicable laws or accounting principles. This includes canceling awards in exchange for either an amount in cash or other property with a value equal to the amount that would have been obtained upon exercise or settlement of the vested portion of such award or realization of the participant's rights under the vested portion of such award, accelerating the vesting of awards,

providing for the assumption or substitution of awards by a successor entity, adjusting the number and type of shares available, replacing awards with other rights or property or terminating awards under the 2026 Plan.

For purposes of the 2026 Plan, a "change in control" means and includes each of the following:

- a transaction or series of transactions whereby any "person" or related "group" of "persons" (as such terms are used in Sections 13(d) and 14(d)(2) of the Exchange Act) (other than our company or our subsidiaries or any employee benefit plan maintained by us or any of our subsidiaries or a "person" that, prior to such transaction, directly or indirectly controls, is controlled by, or is under common control with, us) directly or indirectly acquires beneficial ownership (within the meaning of Rule 13d-3 under the Exchange Act) of our securities possessing more than 50% of the total combined voting power of our securities outstanding immediately after such acquisition; or
- during any period of two consecutive years, individuals who, at the beginning of such period, constitute two-thirds of our board of directors together with any new directors (other than a director designated by a person who has entered into an agreement with us to effect a change in control transaction) whose election by our board of directors or nomination for election by our stockholders was approved by a vote of at least two-thirds of the directors then still in office who either were directors at the beginning of the two-year period or whose election or nomination for election was previously so approved, cease for any reason to constitute a majority thereof; or
- the consummation by us (whether directly or indirectly) of (i) a merger, consolidation, reorganization, or business combination or (ii) a sale or other disposition of all or substantially all of our assets in any single transaction or series of related transactions or (iii) the acquisition of assets or stock of another entity, in each case other than a transaction:
    - which results in our voting securities outstanding immediately before the transaction continuing to represent either by remaining outstanding or by being converted into voting securities of the Company or the person that, as a result of the transaction, controls, directly or indirectly, the Company or owns, directly or indirectly, all or substantially all of our assets or otherwise succeeds to our business, directly or indirectly, at least a majority of the combined voting power of the successor entity's outstanding voting securities immediately after the transaction, and
    - after which no person or group beneficially owns voting securities representing 50% or more of the combined voting power of the successor entity; provided, however, that no person or group will be treated as beneficially owning 50% or more of the combined voting power of the successor entity solely as a result of the voting power held in our company prior to the consummation of the transaction.

Foreign Participants, Clawback Provisions, Transferability, and Participant Payments. With respect to foreign participants, the plan administrator may modify award terms, establish subplans and/or adjust other terms and conditions of awards, subject to the share limits described above. All awards will be subject to the provisions of any clawback policy implemented by us and to the extent set forth in such clawback policy or in the applicable award agreement. With limited exceptions for estate planning, domestic relations orders, certain beneficiary designations, and the laws of descent and distribution, awards under the 2026 Plan are generally nontransferable prior to vesting and are exercisable only by the participant. With regard to tax withholding obligations arising in connection with awards under the 2026 Plan and exercise price obligations arising in connection with the exercise of stock options under the 2026 Plan, the plan administrator may, in its discretion, accept cash, wire transfer, or check, shares of our common stock that meet specified conditions (a market sell order) or such other consideration as it deems suitable or any combination of the foregoing.

Plan Amendment and Termination. Our board of directors may amend, suspend, or terminate the 2026 Plan at any time; however, except in connection with certain changes in our capital structure, stockholder approval will be required for any amendment that increases the number of shares available under the 2026 Plan. The plan administrator will have the authority, without the approval of our stockholders, to amend any outstanding stock option or SAR to reduce its exercise price per share or cancel outstanding stock options or SARs that have an

exercise price in excess of fair market value in exchange for cash, other award or stock option or SARs with an exercise price per share that is less than the exercise price per share of the original stock option or SARs. No incentive stock option may be granted pursuant to the 2026 Plan after the tenth anniversary of the date on which our board of directors adopts the 2026 Plan.

2026 Employee Stock Purchase Plan

Prior to this offering, our board of directors adopted and will ask our stockholders to approve the Mobia Medical, Inc. 2026 Employee Stock Purchase Plan (the ESPP), which will become effective in connection with this offering. The material terms of the ESPP, as it is currently contemplated, are summarized below.

The ESPP is comprised of two distinct components in order to provide increased flexibility to grant options to purchase shares under the ESPP to U.S. and to non-U.S. employees. Specifically, the ESPP authorizes (i) the grant of options to U.S. employees that are intended to qualify for favorable U.S. federal tax treatment under Section 423 of the Code, (the Section 423 Component), and (ii) the grant of options that are not intended to be tax-qualified under Section 423 of the Code to facilitate participation for employees located outside of the U.S. who do not benefit from favorable U.S. federal tax treatment and to provide flexibility to comply with non-U.S. law and other considerations (the Non-Section 423 Component). Where permitted under local law and custom, we expect that the Non-Section 423 Component will generally be operated and administered on terms and conditions similar to the Section 423 Component.

Shares Available for Awards; Administration. The number of shares initially available for issuance pursuant to the ESPP will be equal to a number of shares equal to 1% of the number of pricing date fully-diluted shares (which term has the same meaning as under the 2026 Plan, as described above). In addition, the number of shares available for issuance under the ESPP will be annually increased on January 1 of each calendar year beginning in 2027 and ending in and including 2036, by an amount equal to the lesser of (A) 1% of the shares outstanding on the final day of the immediately preceding calendar year and (B) such smaller number of shares as is determined by the plan administrator, provided that no more than 250,000,000 shares of our common stock may be issued under the ESPP (which number gives effect to the reverse stock split expected to be implemented in connection with this offering). Our board of directors or a committee of our board of directors will administer and will have authority to interpret the terms of the ESPP and determine eligibility of participants. We expect that the compensation committee will be the initial administrator of the ESPP (referred to as the plan administrator below).

Eligibility. We expect that all of our employees will be eligible to participate in the ESPP. However, an employee may not be granted rights to purchase stock under the ESPP if the employee, immediately after the grant, would own (directly or through attribution) stock possessing 5% or more of the total combined voting power or value of all classes of our stock.

Grant of Rights; Transferability. Stock will be offered under the ESPP during offering periods. The length of the offering periods under the ESPP will be determined by the plan administrator and may be up to twenty-seven months long and may consist of one or more purchase periods. Employee payroll deductions will be used to purchase shares on each purchase date during an offering period. The purchase dates for each offering period will be the final trading day in each purchase period under an offering period. Offering periods under the ESPP will commence when determined by the plan administrator. The plan administrator may, in its discretion, modify the terms of future offering periods. In non-U.S. jurisdictions where participation in the ESPP through payroll deductions is prohibited, the plan administrator may provide that an eligible employee may elect to participate through contributions to the participant's account under the ESPP in a form acceptable to the plan administrator in lieu of or in addition to payroll deductions.

The ESPP permits participants to purchase common stock through payroll deductions of up to a specified percentage of their eligible compensation. The plan administrator will establish a maximum number of shares that may be purchased by a participant during any purchase period or offering period. In addition, no employee will be permitted to accrue the right to purchase stock under the Section 423 Component at a rate in excess of $25,000 worth of shares during any calendar year during which such a purchase right is outstanding (based on the fair market value per share of our common stock as of the first day of the offering period).

On the first trading day of each offering period, each participant will automatically be granted an option to purchase shares of our common stock. The option will expire at the end of the applicable offering period and will be exercised on each applicable purchase date during an offering period to the extent of the payroll deductions accumulated during the applicable purchase period. The purchase price of the shares, in the absence of a contrary designation, will be 85% of the lower of the fair market value of our common stock on the first trading day of the offering period or on the purchase date. Participants may voluntarily end their participation in the ESPP at any time during a specified period prior to the end of the applicable offering period and will be paid their accrued payroll deductions that have not yet been used to purchase shares of common stock. Participation ends automatically upon a participant's termination of employment.

A participant may not transfer rights granted under the ESPP other than by will or the laws of descent and distribution, and such rights are generally exercisable only by the participant.

Certain Transactions. In the event of certain non-reciprocal transactions or events affecting our common stock, the plan administrator will make equitable adjustments to the ESPP and outstanding rights. In the event of certain unusual or non-recurring events or transactions, including a change in control, the plan administrator may provide for (i) either the replacement of outstanding rights with other rights or property or termination of outstanding rights in exchange for cash, (ii) the assumption or substitution of outstanding rights by the successor or survivor corporation or parent or subsidiary thereof, if any, (iii) the adjustment in the number and type of shares of stock subject to outstanding rights, (iv) the use of participants' accumulated payroll deductions to purchase stock on a new purchase date prior to the next scheduled purchase date and termination of any rights under ongoing offering periods, or (v) the termination of all outstanding rights.

Plan Amendment and Termination. The plan administrator may amend, suspend, or terminate the ESPP at any time. However, stockholder approval will be obtained for any amendment that increases the aggregate number or changes the type of shares that may be sold pursuant to rights under the ESPP or changes the corporations or classes of corporations whose employees are eligible to participate in the ESPP.

2022 Plan

Eligibility and Administration. Our employees, consultants, and directors are eligible to receive awards under the 2022 Plan. The 2022 plan is generally administered by our board of directors, which may delegate its duties and responsibilities to committees of our directors and/or officers (referred to collectively as the plan administrator below), subject to certain limitations that may be imposed under the 2022 Plan, Section 16 of the Exchange Act and/or stock exchange rules, as applicable. The plan administrator has the authority to make all determinations and interpretations under, prescribe all forms for use with, and adopt rules for the administration of, the 2022 Plan, subject to its express terms and conditions. The plan administrator also sets the terms and conditions of all awards under the 2022 Plan, including any vesting and vesting acceleration conditions.

Limitation on Awards and Shares Available. The number of shares available for issuance under awards granted pursuant to the 2022 Plan is 5,112,485. Shares issued under the 2022 Plan may be authorized but unissued shares, shares purchased on the open market or treasury shares. If an award under the 2022 Plan expires, lapses, or is terminated, surrendered or cancelled without having been fully exercised or forfeited, in any case, in a manner that results in us acquiring shares covered by the award at a price not greater than the price paid by the participant for such shares or not issuing any shares covered by the award, any shares subject to such award will, as applicable, become or again be available for new grants under the 2022 Plan. Further, shares delivered (either by actual delivery or attestation) to us by a participant to satisfy the applicable exercise or purchase price of an award and/or to satisfy any applicable tax withholding obligation (including shares retained by us from the award being exercised or purchased and/or creating the tax obligation) shall be added to the number of shares available for the grant of awards under the 2022 Plan.

Awards. The 2022 Plan provides for the grant of stock options, including incentive stock options, or ISOs within the meaning of Section 422 of the Code, and nonqualified stock options, or NSOs; restricted stock; dividend equivalents; restricted stock units, or RSUs; and other stock-based awards. Certain awards under the 2022 Plan may constitute or provide for a deferral of compensation, subject to Section 409A of the Code, which may impose

additional requirements on the terms and conditions of such awards. All awards under the 2022 Plan are set forth in award agreements, which detail the terms and conditions of the awards, including any applicable vesting and payment terms and post-termination exercise limitations. Awards generally will be settled in shares of our common stock, but the plan administrator may provide for cash settlement of any award. A brief description of each award type follows.

- *Stock Options*. Stock options provide for the purchase of shares of our common stock in the future at an exercise price set on the grant date. ISOs, by contrast to NSOs, may provide tax deferral beyond exercise and favorable capital gains tax treatment to their holders if certain holding period and other requirements of the Code are satisfied. The exercise price of a stock option will not be less than 100% of the fair market value of the underlying share on the date of grant (or 110% in the case of ISOs granted to certain significant stockholders), except with respect to certain substitute options granted in connection with a corporate transaction. The term of a stock option may not be longer than ten years (or five years in the case of ISOs granted to certain significant stockholders). Vesting conditions determined by the plan administrator may apply to stock options and may include continued service, performance, and/or other conditions. ISOs generally may be granted only to our employees and employees of our parent or subsidiary corporations, if any.

- *Restricted Stock and RSUs*. Restricted stock is an award of nontransferable shares of our common stock that remain forfeitable unless and until specified conditions are met, and which may be subject to a purchase price. RSUs are contractual promises to deliver shares of our common stock in the future, which may also remain forfeitable unless and until specified conditions are met. Delivery of the shares underlying RSUs may be deferred under the terms of the award or at the election of the participant, if the plan administrator permits such a deferral. Conditions applicable to restricted stock and RSUs may be based on continuing service, the attainment of performance goals and/or such other conditions as the plan administrator may determine.

- *Other Stock-Based Awards*. Other stock-based awards are awards of fully vested shares of our common stock and other awards valued wholly or partially by referring to, or otherwise based on, shares of our common stock. Other stock-based awards may be granted to participants and may also be available as a payment form in the settlement of other awards, as standalone payments and as payment in lieu of compensation otherwise payable to any individual who is eligible to receive awards. The plan administrator will determine the terms and conditions of other stock-based awards, which may include vesting conditions based on continued service, performance and/or other conditions.

- *Dividend Equivalents*. RSUs may be accompanied by the right to receive the equivalent value of dividends paid on shares of our common stock prior to the delivery of the underlying shares. Such dividend equivalents will be paid out only to the extent that any vesting conditions are subsequently satisfied, unless otherwise determined by the plan administrator. No dividend equivalents will be payable on stock options or other stock-based awards.

Certain Transactions. In connection with certain transactions and events affecting our common stock, including a change in control (as defined below), or change in any applicable laws or accounting principles, the plan administrator has broad discretion to act under the 2022 Plan to prevent the dilution or enlargement of intended benefits, facilitate such transaction or event, or give effect to such change in applicable laws or accounting principles. This includes canceling awards in exchange for either an amount in cash or other property with a value equal to the amount that would have been obtained upon exercise or settlement of the vested portion of such award or realization of the participant's rights under the vested portion of such award, accelerating the vesting of awards, providing for the assumption or substitution of awards by a successor entity, adjusting the number and type of shares available, replacing awards with other rights or property, to cancel or arrange for cancellation of eligibility for "early exercise" of an award (if applicable) or terminating awards under the 2022 Plan. In addition, in the event of certain non-reciprocal transactions with our stockholders (an equity restructuring), the plan administrator will make equitable adjustments to the 2022 Plan and outstanding awards as it deems appropriate to reflect the equity restructuring.

For purposes of the 2022 Plan, a "change in control" means and includes each of the following: (i) a merger or consolidation of us with or into any other corporation or other entity or person, (ii) a sale, lease, exchange or other transfer in one transaction or a series of related transactions of all or substantially all of our assets, or (iii) any other transaction, including the sale by us of new shares of its capital stock or a transfer of existing shares of capital stock, the result of which is that a third party that is not an affiliate of ours or its stockholders (or a group of third parties not affiliated with us or our stockholders) immediately prior to such transaction acquires or holds capital stock representing a majority of our outstanding voting power immediately following such transaction; provided that the following events shall not constitute a "change in control": (A) a transaction (other than a sale of all or substantially all of our assets) in which the holders of the voting securities immediately prior to the merger or consolidation hold, directly or indirectly, at least a majority of the voting securities in the successor corporation or its parent immediately after the merger or consolidation; (B) a sale, lease, exchange or other transaction in one transaction or a series of related transactions of all or substantially all of our assets to an affiliate of ours; (C) an initial public offering of any of our securities; (D) a reincorporation solely to change our jurisdiction; or (E) a transaction undertaken for the primary purpose of creating a holding company that will be owned in substantially the same proportion by the persons who held our securities immediately before such transaction. Notwithstanding the foregoing, if a change in control would give rise to a payment or settlement event with respect to any award that constitutes "nonqualified deferred compensation," the transaction or event constituting the change in control must also constitute a "change in control event" (as defined in Treasury Regulation §1.409A-3(i)(5)) in order to give rise to the payment or settlement event for such Award, to the extent required by Section 409A.

Foreign Participants, Claw-Back Provisions, Transferability, and Participant Payments. With respect to foreign participants, the plan administrator may modify award terms, establish subplans and/or adjust other terms and conditions of awards, subject to the share limits described above. All awards will be subject to the provisions of any clawback policy implemented by us and to the extent set forth in such clawback policy or in the applicable award agreement. With limited exceptions for estate planning, domestic relations orders, certain beneficiary designations, and the laws of descent and distribution, awards under the 2022 Plan are generally nontransferable prior to vesting and are exercisable only by the participant. With regard to tax withholding obligations arising in connection with awards under the 2022 Plan and exercise price obligations arising in connection with the exercise of stock options under the 2022 Plan, the plan administrator may, in its discretion, accept cash or certified check, delivery of shares, including shares retained from the award creating the tax obligation, valued at fair market value; or such other consideration as it deems suitable or any combination of the foregoing.

Plan Amendment and Termination. Our board of directors may amend, suspend, or terminate the 2022 Plan or any portion thereof at any time. Stockholder approval of any amendment will be obtained to the extent required by applicable law. The plan administrator will have the authority, without the approval of our stockholders, to amend any outstanding stock option to reduce its exercise price per share or cancel outstanding stock options that have an exercise price in excess of fair market value in exchange for cash, other award or stock option with an exercise price per share that is less than the exercise price per share of the original stock option. No incentive stock option may be granted pursuant to the 2022 Plan after the tenth anniversary of the date on which our board of directors adopted the 2022 Plan.

2007 Plan

Eligibility and Administration. Our key employees, nonemployee directors and advisors were eligible to receive awards of stock options under the 2007 Plan. The 2007 plan was generally administered by our board of directors, which could delegate its duties and responsibilities to committees of our directors and/or officers (referred to collectively as the plan administrator below), subject to certain limitations that may be imposed under the 2007 Plan, Section 16 of the Exchange Act and/or stock exchange rules, as applicable. The plan administrator had the authority to make all determinations and interpretations under, prescribe all forms for use with, and adopt rules for the administration of, the 2007 Plan, subject to its express terms and conditions. The plan administrator also set the terms and conditions of all awards under the 2007 Plan, including any vesting and vesting acceleration conditions.

Limitation on Awards and Shares Available. The number of shares available for issuance under awards granted pursuant to the 2007 Plan was 2,174,872. Shares issued under the 2007 Plan could have been authorized but unissued shares or shares issued and thereafter acquired by us. If an award under the 2007 Plan terminated without

having been fully exercised any shares subject to such award would have, as applicable, become or again been available for new grants under the 2007 Plan.

Awards. The 2007 Plan provided for the grant of nonqualified stock options, or NSOs. All awards under the 2007 Plan were set forth in award agreements, which detailed the terms and conditions of the awards, including any applicable vesting and payment terms and post-termination exercise limitations. A brief description of such stock options follows.

- *Stock Options*. Stock options provide for the purchase of shares of our common stock in the future at an exercise price set on the grant date. The exercise price of a stock option will not be less than 100% of the fair market value of the underlying share on the date of grant, except with respect to certain substitute options granted in connection with a corporate transaction. The term of a stock option may not be longer than ten years. Vesting conditions determined by the plan administrator may apply to stock options and may include continued service, performance, and/or other conditions.

Certain Transactions. In the event of any "corporate transaction" (as defined below), each outstanding stock option would have automatically accelerated so that each such stock option would, immediately prior to the effective date of the corporate transaction, become fully exercisable for all of the shares of common stock at the time subject to such stock option and could have been exercised for any or all of those shares as fully-vested shares of common stock. However, an outstanding stock option would not have so accelerated if and to the extent: (i) such stock option was, in connection with the corporate transaction, either assumed by the successor corporation (or parent thereof) or was replaced with a comparable stock option to purchase shares of the capital stock of the successor corporation (or parent thereof), (ii) such stock option was replaced with a cash incentive program of the successor corporation which preserves the spread that existed on the unvested stock option shares at the time of the corporate transaction and provided for subsequent payout in accordance with the same vesting schedule applicable to such stock option or (iii) the acceleration of such stock option was subject to other limitations imposed by the plan administrator at the time of the stock option grant. The plan administrator had the discretion, exercisable at the time the stock option was granted or at any time while the stock option remained outstanding, to provide that any stock options which were assumed or replaced in a corporate transaction and did not otherwise accelerate at that time would have automatically accelerated (and any of our outstanding repurchase rights under an applicable shareholders agreement which did not otherwise terminate at the time of the corporate transaction automatically terminated) in the event the participant's service should subsequently terminate by reason of an involuntary termination within 18 months following the effective date of such corporate transaction. Any stock options so accelerated remained exercisable for fully-vested shares until the earlier of (a) the expiration of the option term or (b) the expiration of the 1-year period measured from the effective date of the involuntary termination.

For purposes of the 2007 Plan, a "corporate transaction" meant and included each of the following: (i) a merger or consolidation, or series of related transactions to effect such merger of consolidation, which resulted in the voting securities outstanding immediately prior thereto failing to continue to represent (either by remaining outstanding or by being converted into voting securities of the surviving or another entity) at least 50% of the combined voting power of our voting securities or such surviving or other entity outstanding immediately after such merger or consolidation, (ii) the sale, transfer or other disposition of all or substantially all of our assets (including our subsidiaries) taken as a whole to a party that was not a subsidiary of ours or (iii) the transfer or exchange of all or substantially all of our outstanding stock existing immediately prior thereto in a single transaction or series of related transactions for shares of another entity or other property in which, after such transaction, our prior shareholders owned 50% or less of the shares outstanding of the continuing or surviving entity.

Transferability, and Participant Payments. With limited exceptions for estate planning, domestic relations orders and the laws of descent and distribution, awards under the 2007 Plan were generally nontransferable prior to vesting and are exercisable only by the participant. With regard to tax withholding obligations arising in connection with awards under the 2007 Plan and exercise price obligations arising in connection with the exercise of stock options under the 2007 Plan, the plan administrator could have, in its discretion, accepted cash or check, or any other form of valid consideration as permitted by the plan administrator in its discretion.

Plan Amendment and Termination. The 2007 Plan shall terminate with respect to NSOs on the date that is twenty years after the adoption of the Plan. Subject to the limitations contained in the 2007 Plan, the plan administrator could have at any time amended or revised the terms of the 2007 Plan, including the form and substance of the stock option agreements used in connection therewith. No amendment, suspension, or termination of the 2007 Plan could have, without the consent of the participant who received a stock option under the 2007 Plan, alter or impair any of that participant's rights or obligations under any stock option granted under the 2007 Plan prior to such amendment, suspension, or termination.

Director Compensation

During 2025, we paid certain of our non-employee directors an annual cash retainer of $50,000. From time to time, we have granted stock-based compensation to the non-employee members of our board of directors for their services as directors. In March 2025, we granted each of Mr. Mead and Ms. Lucchese stock options to purchase 25,140 shares of our common stock, with an exercise price of $3.73 per share, which was the fair market value on the date of grant as determined by our board of directors based on an independent third-party valuation. In October 2025, we granted each of Mr. Mead and Ms. Lucchese stock options to purchase 17,728 shares of our common stock, with an exercise price of $3.94 per share, which was the fair market value on the date of grant as determined by our board of directors based on an independent third-party valuation. These stock options vest over a period of four years, with 25% vesting on the first anniversary of the date of grant and the remainder vesting in substantially equal monthly installments over the three years thereafter.

We have reimbursed, and will continue to reimburse, our non-employee directors for their actual out-of-pocket costs and expenses incurred in connection with attending board meetings. Richard Foust, our President and Chief Executive Officer, Nelson Bunker Curnes, our Chief Financial Officer, and Thomas Jordan Curnes II, our Co-Founder, are employees and are also members of our board of directors, but do not receive any additional compensation for their service as directors in addition to their employment compensation. Mr. Foust's compensation arrangements are described above under the section titled ""—Narrative to Summary Compensation Table." The employment arrangements with Mr. Jordan Curnes II and Mr. Bunker Curnes are described below.

Director Compensation Table

The following table sets forth information regarding compensation earned with respect to the fiscal year ended December 31, 2025 by each individual who served as a non-employee director during such fiscal year.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)[1]	Total ($)
Maxwell Bikoff	—	—	—
Edward Hanlon	—	—	—
William (Bill) Harrington	—	—	—
Cindy Lucchese	$ 50,000	$ 88,314	$ 138,314
Dana G. Mead, Jr.	$ 50,000	$ 88,314	$ 138,314
Casey Tansey	—	—	—

(1) Amounts reflect the full grant-date fair value of stock options granted during 2025 computed in accordance with ASC Topic 718. We provide information regarding the assumptions used to calculate the value of all option awards made to our directors in Note 11 to the consolidated financial statements included in this prospectus. The amounts reported in this column reflect the accounting cost for the stock options and do not reflect the actual economic value that will be realized by our non-employee directors upon the vesting or exercise of such awards or the sale of the common stock underlying such awards.

The table below shows the aggregate numbers of stock options (exercisable and unexercisable) held as of December 31, 2025 by each non-employee director who was serving as of December 31, 2025.

Name	Options Outstanding at December 31, 2025
Cindy Lucchese	118,370
Dana G. Mead, Jr.	118,370

Director Compensation Program

In connection with this offering, our board of directors adopted and will ask our stockholders to approve the terms of a non-employee director compensation program. Pursuant to this non-employee director compensation program, each non-employee director will receive a mixture of cash and equity compensation.

Pursuant to this program, each eligible non-employee director will receive an annual cash retainer of $45,000 that will be paid quarterly in arrears. In addition, an eligible director serving as chair of our board of directors will receive an additional cash retainer of $40,000; the chairperson of the audit committee will receive an additional cash retainer of $20,000 and each other member of the audit committee will receive an additional cash retainer of $10,000; the chairperson of the compensation committee will receive an additional cash retainer of $17,500 and each other member of the compensation committee will receive an additional cash retainer of $10,000; and the chairperson of the nominating and corporate governance committee will receive an additional cash retainer of $12,500 and each other member of the nominating and corporate governance committee will receive an additional cash retainer of $7,500.

In connection with this offering, each of our non-employee directors will receive an award of stock options on the date on which this registration statement becomes effective with a grant value of $260,000 at an exercise price equal to the initial public offering price in this offering. The number of options granted to each non-employee director will be the quotient obtained by dividing (a) $260,000 by (b) 55% of the initial public offering price in this offering, with the resulting number of options rounded up to the nearest 10 shares. These stock options will generally vest in three substantially equal installments on the first three anniversaries of the grant date, subject to the non-employee director continuing service through each such date.

Also, pursuant to this program, on the date of each annual meeting of our stockholders following this offering, we intend to grant each eligible non-employee director an annual equity award of stock options with a grant date fair value of $130,000 (as computed in accordance with ASC Topic 718) (an Annual Award), which will generally vest in full on the earlier of (i) the day immediately prior to the date of our annual stockholder meeting immediately following the date of grant and (ii) the first anniversary of the grant date, subject to the non-employee director continuing service through such date. Following this offering, an individual who is appointed or elected to our board of directors will receive (a) an initial equity award on the date of such election or appointment of stock options with a grant date fair value of $130,000 (as computed in accordance with ASC Topic 718) (an Initial Award), which will generally vest in three substantially equal installments on the first three anniversaries of the grant date and (b) a prorated Annual Award based on the number of months remaining in the 12-month period measured from the annual meeting of the Company's stockholders preceding the date of such election or appointment, in each case of the Initial Award and prorated Annual Award, subject to the non-employee director continuing service through each such vesting date. In the event of a change in control (as defined in the 2026 Plan), or a director's termination of service due to death or disability, all outstanding equity awards granted to our non-employee directors pursuant to this program will accelerate and vest in full.

Employment Arrangements with Thomas Jordan Curnes II and Nelson Bunker Curnes

We expect to enter into Restated Employment Agreements with each of Mr. Jordan Curnes II and Mr. Bunker Curnes effective upon the effectiveness of the registration statement relating to this offering. The terms of these Restated Employment Agreements are generally consistent with the terms of each of the employment agreements described below, other than the Restated Employment Agreements do not include severance provisions and instead provide that each of Mr. Jordan Curnes II and Mr. Bunker Curnes are eligible to participate in our Severance Plan. Upon the effectiveness of the Restated Employment Agreements, Mr. Jordan Curnes II and Mr. Bunker Curnes will be eligible for an annual base salary of $255,000 and $430,000, respectively, and a target annual bonus equal to 40% and 60% of his annual base salary, respectively. The Restated Employment Agreement with Mr. Jordan Curnes II

will also provide that (i) in the event of a change in control, or Mr. Jordan Curnes' termination of employment without Cause, any then unvested stock options held by him that were granted prior to the consummation of this offering will immediately become fully vested immediately prior to such termination or the consummation of such change in control and (ii) in the event of a change in control, such stock options will be assumed by the successor entity (or one of its affiliates) or Mr. Jordan Curnes shall be granted an equivalent option or right by such successor entity (or one of its affiliates).

Mr. Jordan Curnes II and Mr. Bunker Curnes have been designated as Tier 2 Covered Employees under the Severance Plan.

Thomas Jordan Curnes II

We have entered into an employment agreement with Mr. Jordan Curnes II (the Curnes II Employment Agreement). Mr. Jordan Curnes II's employment with us is at-will. The Curnes II Employment Agreement provides that Mr. Jordan Curnes II will be entitled to an annual base salary, which was $240,000, $247,200 and $254,616, respectively, in each of 2023, 2024 and 2025. Mr. Jordan Curnes II also received an annual bonus payment in each of 2023, 2024 and 2025 equal to $68,400, $85,520 and $93,571, respectively.

The Curnes II Employment Agreement provides that upon termination of Mr. Jordan Curnes II's employment by us without Cause (as defined below), he will be entitled to receive, in addition to any accrued amounts, a lump sum payment equal to 12 months of his base salary (based on the highest 12-month total he had or would have received if he had remained employed for the full term of the Curnes II Employment Agreement). Additionally, in the event of a change in control, or Mr. Jordan Curnes' termination of employment without Cause, any then unvested stock options held by him will immediately become fully vested immediately prior to such termination or the consummation of such change in control.

As defined in the Curnes II Employment Agreement, "Cause" generally means any of the following: (i) Mr. Jordan Curnes II's repeated failure to perform his assigned duties (other than as a result of a cause or event outside of his control), or to perform and observe his employment obligations under the Curnes II Agreement, in either case if such failure is intentional or continues for 30 or more days after our board of directors gives written notice thereof to Mr. Jordan Curnes II; (ii) any material breach of the Curnes II Employment Agreement by Mr. Jordan Curnes II and such breach continues for 30 or more days after we give written notice thereof to the him; or (iii) his conviction of or a plea of guilty or *nolo contendre* to a charge of felony, or for a misdemeanor involving fraud, embezzlement, theft, dishonesty or breach of fiduciary duty, or other criminal conduct, or the violation of any state or federal law (other than traffic violations or other insignificant infractions of law that do not affect the performance of duties hereunder); or (iv) any material violation of our written policies and such violation continues for 30 or more days after we give written notice thereof to Mr. Jordan Curnes II.

Mr. Jordan Curnes II also entered into a PIIA which includes confidentiality and assignment of intellectual property provisions.

On each of March 27, 2025 and October 17, 2025, we granted Mr. Jordan Curnes II options to purchase 18,343 and 51,057 shares of our common stock, with exercise prices of $4.11 and $3.94, respectively, which was the fair market value per share on the applicable date of grant as determined by an independent third party valuation. The options vest as to 25% of the options on the first anniversary of the vesting commencement date and as to 1/48th of the options on each monthly anniversary of the vesting commencement date thereafter for 36 months, subject to Mr. Jordan Curnes II's continuous service with us as of each such vesting date. We did not grant any equity awards to Mr. Jordan Curnes II in 2023 or 2024.

Nelson Bunker Curnes

We have entered into an employment agreement with Mr. Bunker Curnes (the Curnes Employment Agreement). Mr. Bunker Curnes' employment with us is at-will. The Curnes Employment Agreement provides that Mr. Bunker Curnes will be entitled to an annual base salary, which was $247,200, $340,000 and $380,000, respectively, in each of 2023, 2024 and 2025, and that Mr. Bunker Curnes is eligible to participate in our 401(k) plan. Mr. Bunker Curnes

also received an annual bonus payment in each of 2023, 2024 and 2025 equal to $68,400, $85,520 and $124,950, respectively.

The Curnes Employment Agreement includes certain confidentiality provisions and certain restrictive covenants, including one-year post employment non-interference and non-competition provisions.

On each of March 27, 2025 and October 17, 2025, we granted Mr. Bunker Curnes options to purchase 81,261 and 34,037 shares of our common stock, with exercise prices of $4.11 and $3.94, respectively, which was the fair market value per share on the applicable date of grant as determined by an independent third party valuation. The options vest as to 25% of the options on the first anniversary of the vesting commencement date and as to 1/48th of the options on each monthly anniversary of the vesting commencement date thereafter for 36 months, subject to Mr. Bunker Curnes' continuous service with us as of each such vesting date. We did not grant any equity awards to Mr. Bunker Curnes in 2023 or 2024.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Other than compensation arrangements, including employment, termination of employment, and change in control arrangements, with our directors and executive officers, including those discussed in the sections titled "Management" and "Executive and Director Compensation," and the registration rights described in the section titled "Description of Capital Stock—Registration Rights," the following is a description of each transaction since January 1, 2023 and each currently proposed transaction in which:

- the amount involved exceeded or exceeds $120,000 or one percent of the average of our total assets at year-end for the last two completed fiscal years; and
- any of our directors, executive officers, or holders of more than 5% of our common stock, or any member of the immediate family of the foregoing persons, had or will have a direct or indirect material interest.

Series E Redeemable Convertible Preferred Stock Financing

In December 2023 and October 2024, we issued and sold 5,895,531 shares and 5,895,531 shares, respectively, of our Series E-2 redeemable convertible preferred stock at a purchase price of $2.5443 per share for an aggregate purchase price of approximately $15.0 million for each tranche. Each share of our Series E-2 convertible preferred stock will convert into 0.287108814 shares of common stock immediately prior to the completion of this offering.

The table below sets forth the number of shares of Series E-2 redeemable convertible preferred stock sold to our directors, executive officers, and holders of more than 5% of our capital stock:

	Tranche 2 Closing		Second Tranche 2 Closing	
Participants[1]	Shares of Series E-2 Redeemable Convertible Preferred Stock	Aggregate Purchase Price	Shares of Series E-2 Redeemable Convertible Preferred Stock	Aggregate Purchase Price
Entities affiliated with U.S. Venture Partners [1]	1,473,882	3,749,998	1,473,883	3,750,001
Entities affiliated with GPG Healthcare Opportunities Fund, LLC[2]	705,495	$ 1,794,991	705,499	$ 1,795,001
Osage University Partners III, LP	982,588	$ 2,499,999	982,588	$ 2,499,999
Lyda Hunt – Bunker Trust – Elizabeth H Curnes	786,070	$ 1,999,998	786,071	$ 2,000,000
Action Potential Venture Capital, Limited[3]	978,658	$ 2,490,000	978,658	$ 2,490,000
Exceller Hunt Microtransponder 2017, LP	594,431	$ 1,512,411	594,431	$ 1,512,411

(1) Entities affiliated with U.S. Venture Partners holding shares of our Series E-2 redeemable convertible preferred stock which are aggregated for purposes of reporting share ownership information include U.S. Venture Partners XII, L.P. and U.S. Venture Partners XII-A, L.P.

(2) Entities affiliated with GPG Healthcare Opportunities Fund, LLC holding shares of our Series E-2 redeemable convertible preferred stock which are aggregated for purposes of reporting share ownership information include GPG MTI 22, LLC, GPG GR, LLC, GPG Healthcare Opportunities Fund II, LLC, GPG SC, LLC and GPG JCT, LLC.

(3) In November 2025, Action Potential Venture Capital, Limited assigned all of its shares of Series E-2 Redeemable Convertible Preferred Stock and Series F Redeemable Convertible Preferred Stock to Synapse Investment, LP.

Some of our directors and executive officers are associated with the principal stockholders listed in the table above:

Director / Officer	Principal Stockholder
Casey Tansey	Entities affiliated with U.S. Venture Partners
Nelson Bunker Curnes	Exceller Hunt Microtransponder 2017, LP and Lyda Hunt – Bunker Trust – Elizabeth H Curnes
Jordan Curnes	Exceller Hunt Microtransponder 2017, LP
William (Bill) Harrington	Entities affiliated with Osage University Partners

Series F Redeemable Convertible Preferred Stock Financing

In March 2025, we issued and sold an aggregate of 12,349,423 shares of our Series F redeemable convertible preferred stock at a purchase price of $2.6317 per share for an aggregate purchase price of approximately $32.5 million in the first closing. In October 2025, we issued and sold an aggregate of 12,349,423 shares of our Series F redeemable convertible preferred stock at a purchase price of $2.6317 per share for an aggregate purchase price of approximately $32.5 million in a second closing. Each share of our Series F convertible preferred stock will convert into 0.287108814 shares of common stock immediately prior to the completion of this offering.

The table below sets forth the number of shares of Series F redeemable convertible preferred stock sold to our directors, executive officers, and holders of more than 5% of our capital stock:

	Initial Tranche		Second Tranche	
Participants	Shares of Series F Redeemable Convertible Preferred Stock	Aggregate Purchase Price	Shares of Series F Redeemable Convertible Preferred Stock	Aggregate Purchase Price
Entities affiliated with U.S. Venture Partners [(1)]	2,821,369	$ 7,424,996.82	2,821,369	$ 7,424,996.82
Entities affiliated with GPG Healthcare Opportunities Fund, LLC[(2)]	844,509	$ 2,222,494.36	844,509	$ 2,222,494.36
Entities affiliated with Osage University Partners[(3)]	2,089,903	$ 5,499,997.74	2,089,903	$ 5,499,997.74
Lyda Hunt – Bunker Trust – Elizabeth H Curnes	569,973	$ 1,499,997.95	569,973	$ 1,499,997.95
Action Potential Venture Capital, Limited[(4)]	949,956	$ 2,499,999.21	949,956	$ 2,499,999.21
Exceller Hunt Microtransponder 2017, LP	569,973	$ 1,499,997.95	569,973	$ 1,499,997.95
Curnes Fund 2001	427,480	$ 1,124,999.12	427,480	$ 1,124,999.12

(1) Entities affiliated with U.S. Venture Partners holding shares of our Series F redeemable convertible preferred stock which are aggregated for purposes of reporting share ownership information include U.S. Venture Partners Select Fund I, L.P. on its own behalf and as a nominee for U.S. Venture Partners Select Fund I-A, L.P., U.S. Venture Partners XII, L.P. and U.S. Venture Partners XII-A, L.P.

(2) Entities affiliated with GPG Healthcare Opportunities Fund, LLC holding shares of our Series F redeemable convertible preferred stock which are aggregated for purposes of reporting share ownership information include GPG Charles & Potomac, LLC, GPG Dais, LLC, GPG Healthcare Opportunities Fund II, LLC, GPG MTI 22, LLC, GPG MTI 25, LLC and GPG SC, LLC.

(3) Entities affiliated with Osage University Partners holding shares of our Series F redeemable convertible preferred stock which are aggregated for purposes of reporting share ownership information include Osage University Partners III, LP and Osage University Partners IV, L.P.

(4) In November 2025, Action Potential Venture Capital, Limited assigned all of its shares of Series F Redeemable Convertible Preferred Stock and Series E-2 Redeemable Convertible Preferred Stock to Synapse Investment, LP.

Some of our directors and executive officers are associated with the principal stockholders listed in the table above:

Director / Officer	Principal Stockholder
Casey Tansey	Entities affiliated with U.S. Venture Partners
Nelson Bunker Curnes	Exceller Hunt Microtransponder 2017, LP, Lyda Hunt – Bunker Trust – Elizabeth H Curnes, and Curnes Fund 2001
Jordan Curnes	Exceller Hunt Microtransponder 2017, LP and Curnes Fund 2001
William (Bill) Harrington	Entities affiliated with Osage University Partners

2026 Convertible Note Financing

From January 30, 2026 through February 11, 2026, we issued the 2026 Convertible Notes to certain investors in an aggregate principal amount of $40.0 million. Immediately prior to the closing of this offering, the 2026 Convertible Notes and any accrued interest will automatically convert into shares of our common stock at the

applicable conversion price. Based on an assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and without giving effect to accrued interest (if any), the 2026 Convertible Notes will automatically convert into an aggregate of 3,333,324 shares of our common stock immediately prior to the closing of this offering. The table below sets forth the principal amount of the 2026 Convertible Notes issued to our directors, executive officers, and holders of more than 5% of our capital stock:

Participants	Principal Amount of 2026 Convertible Note
Entities affiliated with U.S. Venture Partners[1]	$ 3,769,090.08
Entities affiliated with GPG Healthcare Opportunities Fund, LLC[2]	$ 7,438,878.52
Entities affiliated with Osage University Partners[3]	$ 6,588,847.28
Exceller Hunt Microtransponder 2017, LP	$ 4,000,000.00
Synapse Investment, LP	$ 3,000,000.00
Coöperatieve Gilde Healthcare VG VI U.A.	$ 3,971,192.75
Longitude Venture Partners V, L.P.	$ 3,971,192.75
Casey Tansey	$ 2,000,000.00
Curnes Fund 2001	$ 2,100,937.62

(1) Entities affiliated with U.S. Venture Partners holding the 2026 Convertible Notes include U.S. Venture Partners Select Fund I, L.P. on its own behalf and as a nominee for U.S. Venture Partners Select Fund I-A, L.P.
(2) Entities affiliated with GPG Healthcare Opportunities Fund, LLC holding the 2026 Convertible Notes which are aggregated for purposes of reporting share ownership information include GPG MTI 22, LLC, GPG MTIF, LLC, GPG Charles & Potomac, LLC, GPG JCT, LLC, GPG Dais, LLC, GPG SC, LLC, GPG WG, LLC and GPG Healthcare Opportunities Fund II, LLC.
(3) Entities affiliated with Osage University Partners holding shares of our Series F redeemable convertible preferred stock which are aggregated for purposes of reporting share ownership information include Osage University Partners III, LP and Osage University Partners IV, L.P.

Some of our directors and executive officers are associated with the principal stockholders listed in the table above:

Director / Officer	Principal Stockholder
Casey Tansey	Entities affiliated with U.S. Venture Partners
Nelson Bunker Curnes	Exceller Hunt Microtransponder 2017, LP and Curnes Fund 2001
Jordan Curnes	Exceller Hunt Microtransponder 2017, LP and Curnes Fund 2001
William (Bill) Harrington	Entities affiliated with Osage University Partners
Edward Hanlon	Coöperatieve Gilde Healthcare VG VI U.A.
Maxwell Bikoff	Longitude Venture Partners V, L.P.

Employment Matter

Kimberly Tansey has served as one of our territory managers since January 2025. Ms. Tansey is the daughter of Casey Tansey, who currently serves as a member of our board of directors. Ms. Tansey's annual compensation for the year ended December 31, 2025 was comparable to the compensation of other of our territory managers with similar experience and responsibilities and exceeded $120,000.

Consultant Matter

Dana Mead III has served as our director of strategic programs since March 2026. Mr. Mead III is the son of Dana G. Mead, Jr., who currently serves as a member of our board of directors. Mr. Mead III previously served as a consultant. As a consultant, compensation was determined based on time and materials utilized in connection with

the provision of consulting services to us. For the year ended December 31, 2025, we paid an aggregate amount of approximately $250,000 for such consulting services.

Agreements with Stockholders

Amended and Restated Registration Rights Agreement

We are party to an amended and restated registration rights agreement with certain holders of our capital stock, including entities with which certain of our directors are affiliated. Under our amended and restated registration rights agreement, certain holders of our capital stock have the right to demand that we file a registration statement or request that their shares of our capital stock be covered by a registration statement that we are otherwise filing. See the section titled "Description of Capital Stock—Registration Rights" for additional information regarding these registration rights.

Amended and Restated Shareholders' Agreement

We are party to an amended and restated shareholders' agreement under which certain holders of our capital stock, including the holders of more than 1% of our outstanding capital stock, have agreed as to the manner in which they will vote their shares of our capital stock on certain matters, including with respect to the election of directors. Upon the completion of this offering, the amended and restated shareholders' agreement will terminate, and none of our stockholders will have any special rights regarding the election or designation of members of our board of directors.

Right of First Refusal

Pursuant to certain of our equity compensation plans and certain agreements with our stockholders, including the amended and restated shareholders' agreement dated March 5, 2025, we have a right to purchase shares of our capital stock that stockholders propose to sell to other parties. Our right of first refusal will terminate upon the completion of this offering.

Director and Officer Indemnification Agreements

We have entered, and intend to continue to enter, into separate indemnification agreements with each of our directors and executive officers, in addition to the indemnification provided for in our amended and restated certificate of incorporation and amended and restated bylaws. The indemnification agreements and our amended restated certificate of incorporation and amended and restated bylaws that will be in effect upon the completion of this offering require us to indemnify our directors, executive officers, and certain controlling persons to the fullest extent permitted by Delaware law. See the section titled "*Limitations on Liability and Indemnification Matters*" for additional information.

Policies and Procedures for Related Person Transactions

Our board of directors will adopt a written related person transaction policy, to be effective upon the completion of this offering, setting forth the policies and procedures for the review and approval or ratification of related person transactions. This policy will cover, with certain exceptions set forth in Item 404 of Regulation S-K under the Securities Act, any transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we were or are to be a participant, where the amount involved exceeds $120,000 in any fiscal year, or, for so long as we qualify as a smaller reporting company, the lesser of $120,000 or one percent of the average of our total assets at year-end for the last two completed fiscal years, and a related person had, has or will have a direct or indirect material interest, including without limitation, purchases of goods or services by or from the related person or entities in which the related person has a material interest, indebtedness, guarantees of indebtedness and employment by us of a related person. In reviewing and approving any such transactions, our audit committee will be tasked to consider all relevant facts and circumstances, including, but not limited to, whether the transaction is on terms comparable to those that could be obtained in an arm's length transaction and the extent of the related person's interest in the transaction. All of the transactions described in this section will have occurred prior to the adoption of this policy.

Reserved Share Program

At our request, the underwriters have reserved for sale, at the initial public offering price, up to 5% of the shares offered by this prospectus for sale to some of our directors, officers, employees, distributors, dealers, business associates and related persons. See “Underwriting—Reserved Shares.”

PRINCIPAL STOCKHOLDERS

The following table sets forth the beneficial ownership of our common stock as of April 27, 2026 by:

- each person, or group of affiliated persons, who is known by us to beneficially own more than 5% of our common stock;
- each of the named executive officers;
- each of our directors; and
- all of our current executive officers and directors as a group.

The number of shares beneficially owned by each stockholder is determined under rules issued by the SEC. Under these rules, beneficial ownership includes any shares as to which the individual or entity has sole or shared voting power or investment power. Applicable percentage ownership is based on 23,218,012 shares of common stock outstanding as of April 27, 2026, assuming (i) the Preferred Stock Conversion, (ii) the Warrant Exercises, (iii) the Warrant Conversion, and (iv) the issuance of the 2026 Convertible Notes and the related Notes Conversion. In computing the number of shares beneficially owned by an individual or entity and the percentage ownership of that person, shares of common stock subject to options, warrants or other rights held by such person that are currently exercisable or will become exercisable within 60 days of April 27, 2026 are considered outstanding, although these shares are not considered outstanding for purposes of computing the percentage ownership of any other person. The percentage ownership information under the column titled "Shares beneficially owned after this offering" assumes the foregoing and the issuance of 10,000,000 shares of common stock in this offering, and assumes no exercise of the underwriters' option to purchase additional shares. The table below excludes any shares of our common stock that may be purchased in this offering pursuant to the reserved share program. See "Underwriting—Reserved Shares." Unless otherwise indicated, the persons or entities identified in this table have sole voting and investment power with respect to all shares shown as beneficially owned by them, subject to applicable community property laws.

Unless otherwise indicated, the address of each beneficial owner listed in the table below is c/o Mobia Medical, Inc., 2802 Flintrock Trace, Suite 226, Austin, TX 78738. We believe, based on information provided to us, that each of the stockholders listed below has sole voting and investment power with respect to the shares beneficially owned by the stockholder unless noted otherwise, subject to community property laws where applicable.

	Shares beneficially owned prior to this offering		Shares beneficially owned after this offering	
Name of beneficial owner	**Shares**	**Percentage**	**Shares**	**Percentage**
5% Stockholders:				
Entities affiliated with U.S. Venture Partners[1]	3,626,826	15.6 %	3,626,826	10.9 %
Entities affiliated with GPG Healthcare Opportunities Fund, LLC[2]	3,480,102	15.0 %	3,480,102	10.5 %
Entities affiliated with Osage University Partners[3]	2,877,566	12.4 %	2,877,566	8.7 %
Lyda Hunt – Bunker Trust – Elizabeth H Curnes[4]	1,230,039	5.3 %	1,230,039	3.7 %
Synapse Investment, LP[5]	1,919,406	8.3 %	1,919,406	5.8 %
Coöperatieve Gilde Healthcare VG VI U.A.[6]	1,421,894	6.1 %	1,421,894	4.3 %
Longitude Venture Partners V, L.P.[7]	1,421,894	6.1 %	1,421,894	4.3 %
Named executive officers and directors:				
Richard John Foust[8]	704,207	2.9 %	704,207	2.1 %
Nelson Bunker Curnes[9]	1,427,043	6.1 %	1,427,043	4.3 %
Douglas (Doug) Ellison[10]	188,151	*	188,151	*
Prashant Rawat[11]	239,659	1.0 %	239,659	*

Name of beneficial owner	Shares beneficially owned prior to this offering		Shares beneficially owned after this offering	
	Shares	Percentage	Shares	Percentage
Dana G. Mead, Jr.[12]	66,055	*	66,055	*
Maxwell Bikoff	—	—	—	—
Thomas Jordan Curnes II[13]	843,268	3.6 %	843,268	2.5 %
Edward Hanlon	—	—	—	—
William (Bill) Harrington[3]	2,877,566	12.4 %	2,877,566	8.7 %
Cynthia Lucchese[14]	48,752	*	48,752	*
Casey Tansey[1][15]	3,793,492	16.3 %	3,793,492	11.4 %
All executive officers and directors as a group (12 persons)[16]	10,013,116	40.4 %	10,013,116	28.8 %

* Represents ownership of less than 1%

(1) Consists of (i) 1,309,155 shares of our common stock issuable upon the conversion of Series F redeemable convertible preferred stock held by U.S. Venture Partners Select Fund I, L.P. ("USVP SFI") on its own behalf and as a nominee for U.S. Venture Partners Select Fund I-A, L.P. ("USVP SFI-A" and, together with USVP SFI, the "USVP Select Funds"), (ii) 314,090 shares of our common stock issuable upon the conversion of the 2026 Convertible Notes held by USVP SFI, (iii) 1,610,903 shares of our common stock issuable upon the conversion of Series E-2 redeemable convertible preferred stock held by U.S. Venture Partners XII, L.P. ("USVP XII"), (iv) 295,906 shares of our common stock issuable upon the conversion of Series F redeemable convertible preferred stock held by USVP XII, (v) 81,755 shares of our common stock issuable upon the conversion of Series E-2 redeemable convertible preferred stock held by U.S. Venture Partners XII-A, L.P. ("USVP XII-A" and, together with USVP XII, the "USVP XII Funds"), and (vi) 15,017 shares of our common stock issuable upon the conversion of Series F redeemable convertible preferred stock held by USVP XII-A. Presidio Management Group XII, L.L.C. ("PMG XII") is the general partner of USVP XII and USVP XII-A and may be deemed to have sole voting and dispositive power with respect to the shares held by USVP XII and USVP XII-A. Steven M. Krausz, Richard W. Lewis, Jonathan D. Root, and Dafina Toncheva are managing members of PMG XII, and may be deemed to share voting and dispositive power with respect to the shares held by USVP XII and USVP XII-A. Presidio Management Group Select Fund I, L.L.C. ("PMG Select") is the general partner of USVP SFI and USVP SFI-A and may be deemed to have sole voting and dispositive power with respect to the shares held by USVP SFI and USVP SFI-A. Richard W. Lewis, Jonathan D. Root, and Dafina Toncheva are the managing members of PMG Select, and may be deemed to share voting and dispositive power with respect to the shares held by USVP SFI and USVP SFI-A. In addition, Casey M. Tansey (a member of our board of directors) is the managing partner and a managing member of PMG XII and PMG Select, respectively, and may be deemed to share voting and dispositive power over the reported securities held by the USVP XII Funds and the USVP Select Funds. Each of the managing members of PMG XII and PMG Select disclaims beneficial ownership of such holdings, except to the extent of their pecuniary interest in the shares. The address for each of these entities is 1460 El Camino Real, Suite 100, Menlo Park, CA 94025.

(2) Consists of (i) 11,139 shares of our common stock issuable upon the conversion of Series E-1 redeemable convertible preferred stock held by GPG BFH, LLC ("BFH"), (ii) 29,704 shares of our common stock issuable upon the conversion of Series E-1 redeemable convertible preferred stock held by GPG Charles & Potomac, LLC ("C&P"), (iii) 21,819 shares of our common stock issuable upon the conversion of Series F redeemable convertible preferred stock held by C&P, (iv) 10,000 shares of our common stock issuable upon the conversion of the 2026 Convertible Notes held by C&P, (v) 22,278 shares of our common stock issuable upon the conversion of Series E-1 redeemable convertible preferred stock held by GPG Dais, LLC ("Dais"), (vi) 10,909 shares of our common stock issuable upon the conversion of Series F redeemable convertible preferred stock held by Dais, (vii) 8,500 shares of our common stock issuable upon the conversion of the 2026 Convertible Notes held by Dais, (viii) 141,054 shares of our common stock issuable upon the conversion of Series E-2 redeemable convertible preferred stock held by GPG GR, LLC ("GR"), (ix) 96,540 shares of our common stock issuable upon the conversion of Series E-1 redeemable convertible preferred stock held by GPG Healthcare Opportunities Fund II, LLC ("HOF II"), (x) 112,843 shares of our common stock issuable upon the conversion of Series E-2 redeemable convertible preferred stock held by HOF II, (xi) 108,005 shares of our common stock issuable upon the conversion of Series F redeemable convertible preferred stock held by HOF II, (xii) 33,333 shares of our common stock issuable upon the conversion of the 2026 Convertible Notes held by HOF II, (xiii) 68,044 shares of our common stock issuable upon the conversion of Series D redeemable convertible preferred stock held by GPG Healthcare Opportunities Fund, LLC ("HOF"), (xiv) 200,202 shares of our common stock issuable upon the conversion of Series E-1 redeemable convertible preferred stock held by HOF, (xv) 18,374 shares of our common stock issuable upon the conversion of Series D redeemable convertible preferred stock held by GPG JCT, LLC ("JCT"), (xvi) 116,940 shares of our common stock issuable upon the conversion of Series E-1 redeemable convertible preferred stock held by JCT, (xvii) 56,421 shares of our common stock issuable upon the conversion of Series E-2 redeemable convertible preferred stock held by JCT, (xviii) 41,666 shares of our common stock issuable upon the conversion of the 2026 Convertible Notes held by JCT, (xix) 477,329 shares of our common stock issuable upon the conversion of Series E-2 redeemable convertible preferred stock held by GPG MTI 22, LLC ("MTI 22"), (xx) 45,711 shares of our common stock issuable upon the conversion of Series F redeemable convertible preferred stock held by MTI 22, (xxi) 32,750 shares of our common stock issuable upon the conversion of the 2026 Convertible Notes held by MTI 22, (xxii) 282,122 shares of our common stock issuable upon the conversion of Series F redeemable convertible preferred stock held by GPG MTI 25, LLC ("MTI 25"), (xxiii) 60,579 shares of our common stock issuable upon the conversion of Series D redeemable convertible preferred stock held by GPG MTI 3-17 Investment, LLC ("MTI 3-17"), (xxiv) 219 shares of our common stock issuable upon the net exercise of warrant to purchase our Series D redeemable convertible preferred stock held by MTI 3-17 (based upon an assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover of this prospectus), (xxv) 24,506 shares of our common stock issuable upon the conversion of Series E-1 redeemable convertible preferred stock held by GPG PHL,

LLC (“PHL”), (xxvi) 43,640 shares of our common stock issuable upon the conversion of Series D redeemable convertible preferred stock held by GPG RM Investment, LLC (“RM”), (xxvii) 159 shares of our common stock issuable upon the net exercise of warrant to purchase our Series D redeemable convertible preferred stock held by RM (based upon an assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover of this prospectus), (xxviii) 22,568 shares of our common stock issuable upon the conversion of Series E-2 redeemable convertible preferred stock held by GPG SC, LLC (“SC”), (xxix) 16,364 shares of our common stock issuable upon the conversion of Series F redeemable convertible preferred stock held by SC, (xxx) 8,333 shares of our common stock issuable upon the conversion of the 2026 Convertible Notes held by SC, (xxxi) 25,991 shares of our common stock issuable upon the conversion of Series E-1 redeemable convertible preferred stock held by GPG WG, LLC (“WG”), (xxxii) 20,833 shares of our common stock issuable upon the conversion of the 2026 Convertible Notes held by WG, (xxxiii) 464,489 shares of our common stock issuable upon the conversion of the 2026 Convertible Notes held by GPG MTIF, LLC (“MTIF”), (xxxiv) 23,255 shares of our common stock issuable upon the conversion of Series B redeemable convertible preferred stock held by Micro TI Investment 2, LLC (“Micro TI 2”), (xxxv) 3,073 shares of our common stock issuable upon the net exercise of warrant to purchase our Series B redeemable convertible preferred stock held by Micro TI 2 (based upon an assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover of this prospectus), (xxxvi) 26,988 shares of our common stock issuable upon the conversion of Series B redeemable convertible preferred stock held by Micro TI Investment, LLC (“Micro TI”), (xxxvii) 24,416 shares of our common stock issuable upon the conversion of the 2026 Convertible Notes held by Micro TI, (xxxviii) 311,112 shares of our common stock issuable upon the conversion of Series E-1 redeemable convertible preferred stock held by MTI 20 Investment, LLC (“MTI 20”), (xxxix) 71,202 shares of our common stock issuable upon the conversion of Series C redeemable convertible preferred stock held by MTI 2015 Investment, LLC (“MTI 2015”), (xl) 38,875 shares of our common stock issuable upon the conversion of Series E-1 redeemable convertible preferred stock held by HTX MCT1 0320 Investment, LLC (“HTX MCT1”), (xli) 83,579 shares of our common stock issuable upon the conversion of Series E-1 redeemable convertible preferred stock held by HTX MCT2 0221 Investment, LLC (“HTX MCT2”), (xlii) 138,233 shares of our common stock issuable upon the conversion of Series E-2 redeemable convertible preferred stock held by HTX MCT3 0322 Investment, LLC (“HTX MCT3”), and (xliii) 126,005 shares of our common stock issuable upon the conversion of Series F redeemable convertible preferred stock held by HTX MCT3. Green Park & Golf Ventures II, LLC (“GPG Ventures II”) is the managing member of each of BFH, C&P, Dais, GR, HOF, HOF II, JCT, MTI 22, MTI 25, MTI 3-17, MTIF, PHL, RM, SC, WG, Micro TI, Micro TI 2, MTI 20 and MTI 2015. Clay M. Heighten, MD, Carl D. Soderstrom and Gilbert G. Garcia II are managers of GPG Ventures II and share voting and dispositive power with respect to the shares held by each of BFH, C&P, Dais, GR, HOF, HOF II, JCT, MTI 22, MTI 25, MTI 3-17, MTIF, PHL, RM, SC, WG, Micro TI, Micro TI 2, MTI 20 and MTI 2015, and as a result may be deemed to beneficially own such securities. Green Park & Golf Ventures - Houston, LLC (“GPG Ventures Houston”) is the managing member of each of HTX MCT1, HTX MCT2 and HTX MCT3. Clay M. Heighten, MD, Carl D. Soderstrom and Gilbert G. Garcia II are managers of GPG Ventures Houston and share voting and dispositive power with respect to the shares held by each of HTX MCT1, HTX MCT2 and HTX MCT3, and as a result may be deemed to beneficially own such securities. The address for each of these entities is 5910 N. Central Expressway, Suite 1400, Dallas, TX 75206.

(3) Consists of (i) 1,128,438 shares of our common stock issuable upon the conversion of Series E-2 redeemable convertible preferred stock held by Osage University Partners III, LP (“OUP III”), (ii) 327,288 shares of our common stock issuable upon the conversion of Series F redeemable convertible preferred stock held by OUP III, (iii) 284,324 shares of our common stock issuable upon the conversion of the 2026 Convertible Notes held by OUP III, (iv) 872,770 shares of our common stock issuable upon the conversion of Series F redeemable convertible preferred stock held by Osage University Partners IV, LP (“OUP IV”), and (v) 264,746 shares of our common stock issuable upon the conversion of the 2026 Convertible Notes held by OUP IV. Osage University GP III, LLC (“OUP GP III”) is the general partner of OUP III and Osage University GP IV, LLC (“OUP GP IV”) is the general partner of OUP IV. William Harrington (a member of our board of directors) is one of the managers (the “OUP Managers”) of both OUP GP III and OUP GP IV. OUP GP III and OUP GP IV and the OUP Managers may be deemed to share voting, investment and dispositive power over the shares held by OUP III and OUP IV and as a result may be deemed to have beneficial ownership over such securities. Each of OUP GP III and OUP GP IV and the OUP Managers disclaims beneficial ownership over the securities held by OUP III and OUP IV, except to the extent of their respective pecuniary interests therein. The address for each of these entities is 50 Monument Road, Suite 201, Bala Cynwyd, PA 19004.

(4) Consists of (i) 902,751 shares of our common stock issuable upon the conversion of Series E-2 redeemable convertible preferred stock and (ii) 327,288 shares of our common stock issuable upon the conversion of Series F redeemable convertible preferred stock. Houston B. Hunt, Charles B. Middlekauf, Jr., and Ellen H. Flowers are trustees for Lyda Hunt – Bunker Trust – Elizabeth H Curnes. The address for Lyda Hunt – Bunker Trust – Elizabeth H Curnes is 3811 Turtle Creek #1825, Dallas, TX 75219.

(5) Consists of (i) 1,123,925 shares of our common stock issuable upon the conversion of Series E-2 redeemable convertible preferred stock, (ii) 545,481 shares of our common stock issuable upon the conversion of Series F redeemable convertible preferred stock, and (iii) 250,000 shares of our common stock issuable upon the conversion of the 2026 Convertible Notes. Synapse Investment Partners I, LP (“Partners I”) is the general partner of Synapse Investment, LP (“Synapse”). Synapse Investment Partners, LLC (“Partners”) is the sole general partner of Partners I. Simeon George, MD is the managing member of Partners. Partners I, Partners, and Simeon George share voting and dispositive power with respect to the securities directly held by Synapse. Each of Partners I, Partners, and Simeon George disclaims beneficial ownership of such securities except to the extent of their pecuniary interests therein. The address for Synapse is 929 Main Street, Suite 200, Redwood City, CA 94063.

(6) Consists of (i) 1,090,962 shares of our common stock issuable upon the conversion of Series F redeemable convertible preferred stock and (ii) 330,932 shares of our common stock issuable upon the conversion of the 2026 Convertible Notes. Gilde Healthcare VI Management B.V. (“Gilde Healthcare Management”) is the managing director of Coöperatieve Gilde Healthcare VG VI U.A. (“Gilde”) and has sole voting and dispositive power with respect to the shares held by Gilde. Gilde Healthcare Management is owned by Gilde Healthcare Holding B.V. and managed by Edwin de Graaf and Pieter Van der Meer, who may be deemed to share voting and dispositive power with respect to the shares held of record by Gilde. Each of Mr. De Graaf, and Mr. Van der Meer disclaims beneficial ownership of such holdings, except to the extent of their pecuniary interest in the shares. The address of Gilde is Stadsplateau 36, 3521 AZ Utrecht, The Netherlands, c/o Gilde Healthcare Partners.

(7) Consists of (i) 1,090,962 shares of our common stock issuable upon the conversion of Series F redeemable convertible preferred stock and (ii) 330,932 shares of our common stock issuable upon the conversion of the 2026 Convertible Notes. Longitude Capital Partners V, LLC (“LCPV”) is the general partner of Longitude Venture Partners V, L.P. (“LVPV”) and may be deemed to have voting, investment and

dispositive power with respect to these securities. Patrick G. Enright and Juliet Tammenoms Bakker are the managing members of LCPV, and may each be deemed to share voting, investment and dispositive power with respect to these securities. Each of LCPV, Mr. Enright and Ms. Tammenoms Bakker disclaims beneficial ownership of such securities except to the extent of their respective pecuniary interests therein. The address for these individuals and entities is 2740 Sand Hill Road, 2nd Floor, Menlo Park, CA 94025.

(8) Consists of 704,207 shares of our common stock issuable pursuant to an option held directly and exercisable within 60 days of April 27, 2026.

(9) Consists of (i) 19,427 shares of our common stock, (ii) 54,932 shares of our common stock issuable upon the conversion of Series A redeemable convertible preferred stock, (iii) 28,710 shares of our common stock issuable upon the conversion of Series C redeemable convertible preferred stock, (iv) 110,058 shares of our common stock issuable upon the conversion of Series D redeemable convertible preferred stock, (v) 8,374 shares of our common stock issuable upon the conversion of Series E-1 redeemable convertible preferred stock, (vi) 81,821 shares of our common stock issuable upon the conversion of Series F redeemable convertible preferred stock, (vii) 132,768 shares of our common stock issuable pursuant to an option held directly and exercisable within 60 days of April 27, 2026, (viii) 316 shares of our common stock issuable upon the net exercise of warrant to purchase our Series D redeemable convertible preferred stock, (ix) 5,742 shares of our common stock issuable upon the conversion of Series C redeemable convertible preferred stock held by family trusts for the benefit of Mr. Curnes' minor children (x) 145,067 shares of our common stock issuable upon the conversion of Series D redeemable convertible preferred stock held by Exceller Hunt Microtransponder 2017, LP ("Exceller"), (xi) 78,171 shares of our common stock issuable upon the conversion of Series E-1 redeemable convertible preferred stock held by Exceller, (xii) 171,179 shares of our common stock issuable upon the conversion of Series E-2 redeemable convertible preferred stock held by Exceller, (xiii) 82,068 shares of our common stock issuable upon the conversion of Series F redeemable convertible preferred stock held by Exceller, (xiv) 333,333 shares of our common stock issuable upon the conversion of the 2026 Convertible Notes held by Exceller, and (xv) 175,077 shares of our common stock issuable upon the conversion of the 2026 Convertible Notes held by Curnes Fund 2001. Nelson Bunker Curnes is the trustee of each of the family trusts for the benefit of Mr. Curnes' minor children, the manager of Exceller and a partner of Curnes Fund 2001, and has voting and dispositive power with respect to the shares held by each of the family trusts for the benefit of Mr. Curnes' minor children, Exceller and Curnes Fund 2001. As a result, Nelson Bunker Curnes may be deemed to beneficially own such securities.

(10) Consists of 188,151 shares of our common stock issuable pursuant to an option held directly and exercisable within 60 days of April 27, 2026.

(11) Consists of 239,659 shares of our common stock issuable pursuant to an option held directly and exercisable within 60 days of April 27, 2026.

(12) Consists of 66,055 shares of our common stock issuable pursuant to an option held directly and exercisable within 60 days of April 27, 2026.

(13) Consists of (i) 70,054 shares of our common stock, (ii) 75,222 shares of our common stock issuable upon the conversion of Series A redeemable convertible preferred stock, (iii) 62,589 shares of our common stock issuable upon the conversion of Series B redeemable convertible preferred stock, (iv) 34,165 shares of our common stock issuable upon the conversion of Series D redeemable convertible preferred stock, (v) 208,281 shares of our common stock issuable pursuant to an option held directly and exercisable within 60 days of April 27, 2026, (vi) 2,542 shares of our common stock issuable upon the net exercise of warrant to purchase our Series B redeemable convertible preferred stock (based upon an assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover of this prospectus), (vii) 157 shares of our common stock issuable upon the net exercise of warrant to purchase our Series D redeemable convertible preferred stock (based upon an assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover of this prospectus), (viii) 3,636 shares of our common stock held by Vivian Ventures LLC ("VV"), (ix) 54,933 shares of our common stock issuable upon the conversion of Series A redeemable convertible preferred stock held by VV, (x) 66,417 shares of our common stock issuable upon the conversion of Series D redeemable convertible preferred stock held by VV, (xi) 8,374 shares of our common stock issuable upon the conversion of Series E-1 redeemable convertible preferred stock held by VV, (xii) 81,821 shares of our common stock issuable upon the conversion of Series F redeemable convertible preferred stock held by VV, and (xiii) 175,077 shares of our common stock issuable upon the conversion of the 2026 Convertible Notes held by Curnes Fund 2001. Thomas Jordan Curnes II is a managing member of VV and a partner of Curnes Fund 2001, and has voting and dispositive power with respect to the shares held by each of VV and Curnes Fund 2001, and as a result may be deemed to beneficially own such securities.

(14) Consists of 48,752 shares of our common stock issuable pursuant to an option held directly and exercisable within 60 days of April 27, 2026.

(15) Consists of 166,666 shares of our common stock issuable upon the conversion of the 2026 Convertible Notes.

(16) Consists of (i) 6,883,992 shares of our common stock beneficially owned by our current directors and executive officers assuming the Preferred Stock Conversion, (ii) 1,587,873 shares of our common stock issuable pursuant to stock options held by such directors and executive officers and exercisable within 60 days of April 27, 2026 , (iii) 3,015 shares of our common stock issuable upon the net exercise of warrant to purchase our Series D redeemable convertible preferred stock and (iv) 1,713,313 shares of our common stock issuable upon the conversion of the 2026 Convertible Notes.

DESCRIPTION OF CAPITAL STOCK

The following descriptions of our capital stock and certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws are summaries and are qualified by reference to the amended and restated certificate of incorporation and the amended and restated bylaws that will be in effect upon completion of this offering. Copies of these documents will be filed with the SEC as exhibits to our registration statement, of which this prospectus forms a part. The descriptions of the common stock and preferred stock reflect changes to our capital structure that will occur upon the completion of this offering.

Upon the completion of this offering and the filing of our amended and restated certificate of incorporation to be effective upon completion of this offering, our authorized capital stock will consist of 950,000,000 shares of common stock, par value $0.01 per share, and 50,000,000 shares of preferred stock, par value $0.01 per share.

Upon the completion of this offering, all of the outstanding shares of our redeemable convertible preferred stock will convert into an aggregate of 18,831,868 shares of our common stock.

Based on 23,085,391 shares of common stock outstanding as of December 31, 2025, which reflects (i) the Preferred Stock Conversion, (ii) the Notes Conversion and (iii) the Warrant Exercises, there will be 33,085,391 shares of common stock outstanding upon the completion of this offering. As of December 31, 2025, we had 136 stockholders of record.

Common Stock

Voting Rights

Each holder of common stock is entitled to one vote for each share on all matters submitted to a vote of the stockholders, including the election of directors. Our stockholders do not have cumulative voting rights in the election of directors. Accordingly, holders of a majority of the voting shares are able to elect all of the directors. In addition, the affirmative vote of holders of 66-2/3% of the voting power of all of the then outstanding voting stock will be required to take certain actions, including amending certain provisions of our amended and restated certificate of incorporation, including the provisions relating to amending our amended and restated bylaws, the classified board and director liability.

Dividends

Subject to preferences that may be applicable to any then outstanding preferred stock, holders of our common stock are entitled to receive ratably any dividends that our board of directors may declare out of funds legally available.

Liquidation

In the event of our liquidation, dissolution, or winding up, holders of our common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any then outstanding shares of preferred stock.

Rights, Preferences and Privileges

Holders of our common stock have no preemptive, conversion, or subscription rights, and there are no redemption or sinking-fund provisions applicable to our common stock. The rights, preferences, and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that we may designate and issue in the future.

Preferred Stock

Immediately prior to the completion of this offering, all of our currently outstanding shares of redeemable convertible preferred stock will convert into common stock, and we will not have any preferred shares outstanding.

Immediately prior to the completion of this offering, our certificate of incorporation will be amended and restated to delete all references to such shares of redeemable convertible preferred stock. Under the amended and restated certificate of incorporation, our board of directors will have the authority, without further action by the stockholders, to issue up to 50,000,000 shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the rights, preferences, and privileges of the shares of each wholly unissued series and any qualifications, limitations, or restrictions thereon, and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of common stock. The issuance of preferred stock, while providing flexibility in connection with possible acquisitions and other corporate purposes, could, among other things, have the effect of delaying, deferring, or preventing a change in control of our company that may otherwise benefit holders of our common stock and may adversely affect the market price of the common stock and the voting and other rights of the holders of common stock. We have no current plans to issue any shares of preferred stock.

Common Stock Options

As of December 31, 2025, 4,046,266 shares of common stock were issuable upon the exercise of outstanding stock options, at a weighted-average exercise price of $3.51 per share. For additional information regarding terms of our equity incentive plans, see the section titled “Executive and Director Compensation—Equity Incentive Plans.”

Preferred Stock Warrants

Series B Redeemable Convertible Preferred Stock Warrant

As of December 31, 2025, warrants to purchase an aggregate of up to 908,000 shares of our Series B redeemable convertible preferred stock were outstanding, with an exercise price of $3.73744 per share. Unless exercised earlier, the warrants will expire in December 2032 or February 2033. The warrants contain provisions for the adjustment of the exercise price and the number of shares issuable upon the exercise of the warrants in the event of certain stock dividends, stock splits, reorganizations, reclassifications and consolidations. The warrants have a net exercise provision under which the respective holder may, in lieu of payment of the exercise price in cash, surrender the warrants and receive a net amount of shares based on the fair market value of the shares at the time of exercise of the warrants after deduction of the aggregate exercise price. In connection with an initial public offering, the warrants will either be exercised or will expire immediately prior to the consummation of such initial public offering. Based upon an assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover of this prospectus, we will issue 34,455 shares of our common stock assuming the net exercise of the warrants immediately prior to the completion of this offering.

Series D Redeemable Convertible Preferred Stock Warrant

As of December 31, 2025, warrants to purchase an aggregate of up to 258,000 shares of our Series D redeemable convertible preferred stock were outstanding, with an exercise price of $4.207 per share. Unless exercised earlier, the warrants will expire in April 2033, May 2033, or June 2033. The warrants contain provisions for the adjustment of the exercise price and the number of shares issuable upon the exercise of the warrants in the event of certain stock dividends, stock splits, reorganizations, reclassifications and consolidations. The warrants have a net exercise provision under which the respective holder may, in lieu of payment of the exercise price in cash, surrender the warrants and receive a net amount of shares based on the fair market value of the shares at the time of exercise of the warrants after deduction of the aggregate exercise price. In connection with an initial public offering, the warrants will either be exercised or will expire immediately prior to the consummation of such initial public offering. Based upon an assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover of this prospectus, we will issue 1,714 shares of our common stock assuming the net exercise of the warrants immediately prior to the completion of this offering.

Redeemable Convertible Preferred Stock Warrant

As of December 31, 2025, warrants to purchase up to $262,500 of shares of our (i) shares of Series E-2 redeemable convertible preferred stock at an exercise price of $2.5443 per share or (ii) shares of Series F redeemable convertible preferred stock at an exercise price of $2.6317 per share, were outstanding. Unless exercised earlier, the warrants will expire in December 2033. The warrant contains provisions for the adjustment of the exercise price and the number of shares issuable upon the exercise of the warrant in the event of certain stock dividends, stock splits, reorganizations, reclassifications and consolidations. The warrant has a net exercise provision under which the respective holder may, in lieu of payment of the exercise price in cash, surrender the warrant and receive a net amount of shares based on the fair market value of the shares at the time of exercise of the warrant after deduction of the aggregate exercise price. Immediately prior to the completion of this offering, the warrant will automatically convert into a warrant to purchase 29,622 shares of our common stock with an average exercise price of $8.8618 per share.

2026 Convertible Notes

From January 30, 2026 through February 11, 2026, we issued the 2026 Convertible Notes to certain investors in an aggregate principal amount of $40.0 million. The Maturity Date for the 2026 Convertible Notes is January 30, 2028. The 2026 Convertible Notes bear no interest for the first six months following the date of issuance. Following such period, the 2026 Convertible Notes accrue interest at a rate of 7.0% per annum through the Maturity Date, which interest payments shall be paid in kind. Immediately prior to the closing of this offering, the 2026 Convertible Notes and any accrued interest will automatically convert into shares of our common stock at the applicable conversion price. The conversion price is the lower of (a) 80% of the initial public offering price per share in this offering and (b) the valuation of the Company immediately prior to the closing of this offering divided by the Fully Diluted Capitalization, provided, that in no event shall such conversion price be less than the quotient obtained by dividing $226.0 million by the Fully Diluted Capitalization or greater than the quotient obtained by dividing $750.0 million by the Fully Diluted Capitalization. Based on an assumed initial public offering price of $15.00 per share, which is the midpoint of the price range set forth on the cover page of this prospectus, and without giving effect to accrued interest (if any), the 2026 Convertible Notes will automatically convert into an aggregate of 3,333,324 shares of our common stock immediately prior to the closing of this offering.

Registration Rights

After the completion of this offering, under our amended and restated investor rights agreement, the holders of up to 21,904,521 shares of common stock or their transferees, have the right to require us to register the offer and sale of their shares, or to include their shares in any registration statement we file, in each case as described below.

Demand registration rights

After the completion of this offering, the holders of up to 21,904,521 shares of our common stock will be entitled to certain demand registration rights. At any time beginning after 180 days following the effective date of the registration statement of which this prospectus forms a part, the holders of at least 40% of the shares having registration rights then outstanding can request that we file a registration statement to register the offer and sale of their shares. These demand registration rights are subject to specified conditions and limitations, including the right of the underwriters to limit the number of shares included in any such registration under certain circumstances. If we determine that it would be materially detrimental to us and our stockholders to effect such a demand registration, we have the right to defer or withdraw such registration, not more than twice in any twelve-month period.

Form S-3 registration rights

After the completion of this offering, the holders of up to 21,904,521 shares of our common stock will be entitled to certain Form S-3 registration rights. When we are eligible to file a registration statement on Form S-3, the holders of the shares having these rights then outstanding can request that we register the offer and sale of their shares of our common stock on a registration statement on Form S-3. These stockholders may make an unlimited number of requests for registration on a registration statement on Form S-3. These Form S-3 registration rights are subject to specified conditions and limitations, including the right of the underwriters to limit the number of shares

included in any such registration under certain circumstances. Additionally, if we determine that it would be seriously detrimental to us and our stockholders to effect such a demand registration, we have the right to defer or withdraw such registration, not more than twice in any twelve-month period.

Piggyback registration rights

After the completion of this offering, the holders of up to 21,904,521 shares of our common stock will be entitled to certain "piggyback" registration rights. If we propose to register the offer and sale of shares of our common stock under the Securities Act, all holders of these shares then outstanding can request that we include their shares in such registration, subject to certain marketing and other limitations, including the right of the underwriters to limit the number of shares included in any such registration statement under certain circumstances. As a result, whenever we propose to file a registration statement under the Securities Act, other than with respect to (1) a registration related to any employee benefit plan or a corporate reorganization or other transaction covered by Rule 145 promulgated under the Securities Act, (2) a registration relating to the offer and sale of debt securities or (3) a registration on any registration form that does not permit secondary sales, the holders of these shares are entitled to notice of the registration and have the right, subject to certain limitations, to include their shares in the registration.

Expenses of registration

We will pay all expenses relating to any demand registrations, Form S-3 registrations, and piggyback registrations, subject to specified exceptions.

Termination

The registration rights terminate upon the earliest of (1) the date that is five years after the completion of this offering, (2) immediately prior to the completion of certain liquidation events and (3) as to a given holder of registration rights, the date after the completion of this offering when such holder of registration rights can sell all of such holder's registrable securities during any ninety day period pursuant to Rule 144 promulgated under the Securities Act.

Anti-Takeover Provisions of Delaware Law and Our Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws

Some provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws could make the following transactions more difficult: an acquisition of us by means of a tender offer; an acquisition of us by means of a proxy contest or otherwise; or the removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interests, including transactions which provide for payment of a premium over the market price for our shares.

These provisions, summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of the increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Undesignated Preferred Stock

The ability of our board of directors, without action by the stockholders, to issue up to 50,000,000 shares of undesignated preferred stock with voting or other rights or preferences as designated by our board of directors could impede the success of any attempt to change control of us. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of our company.

Stockholder Meetings

Our amended and restated bylaws provide that a special meeting of stockholders may be called only by our chair of the board, chief executive officer or president (in the absence of a chief executive officer), or by a resolution adopted by a majority of our board of directors.

Requirements for Advance Notification of Stockholder Nominations and Proposals

Our amended and restated bylaws establish advance notice procedures with respect to stockholder proposals to be brought before a stockholder meeting and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

Elimination of Stockholder Action by Written Consent

Our amended and restated certificate of incorporation eliminates the right of stockholders to act by written consent without a meeting.

Staggered Board

Our board of directors is divided into three classes. The directors in each class will serve for a three-year term, one class being elected each year by our stockholders. For more information on the classified board, see the section titled "Management—Board Composition." This system of electing and removing directors may tend to discourage a third-party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Removal of Directors

Our amended and restated certificate of incorporation provides that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of the holders of at least two-thirds in voting power of the outstanding shares of stock entitled to vote in the election of directors.

Stockholders Not Entitled to Cumulative Voting

Our amended and restated certificate of incorporation does not permit stockholders to cumulate their votes in the election of directors. Accordingly, the holders of a majority of the outstanding shares of our common stock entitled to vote in any election of directors can elect all of the directors standing for election, if they choose, other than any directors that holders of our preferred stock may be entitled to elect.

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the Delaware General Corporation Law, which prohibits persons deemed to be "interested stockholders" from engaging in a "business combination" with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. Generally, an "interested stockholder" is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation's voting stock. Generally, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors.

Choice of Forum

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative form, the Court of Chancery of the State of Delaware will be the sole and exclusive forum for: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty or other wrongdoing by any of our directors, officers, or stockholders to us or our stockholders; (iii)

any action asserting a claim against us arising pursuant to any provision of the Delaware General Corporation Law or our certificate of incorporation or bylaws; (iv) any action to interpret, apply, enforce or determine the validity of our certificate of incorporation or bylaws; or (v) any action asserting a claim governed by the internal affairs doctrine; provided that the exclusive forum provision will not apply to suits brought to enforce any liability or duty created by the Securities Act or the Exchange Act, or to any claim for which the federal courts have exclusive jurisdiction. For instance, the provision would not apply to actions arising under federal securities laws, including suits brought to enforce any liability or duty created by the Securities Act, Exchange Act, or the rules and regulations thereunder. Our amended and restated certificate of incorporation further provides that, unless we consent in writing to the selection of an alternative forum, the federal district courts of the United States shall, to the fullest extent permitted by law, be the sole and exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Our amended and restated certificate of incorporation also provides that any person or entity purchasing or otherwise acquiring any interest in shares of our capital stock will be deemed to have notice of and to have consented to this choice of forum provision. It is possible that a court of law could rule that the choice of forum provision contained in our amended and restated certificate of incorporation is inapplicable or unenforceable if it is challenged in a proceeding or otherwise.

Amendment of Charter Provisions

The amendment of any of the above provisions, except for the provision making it possible for our board of directors to issue preferred stock and the provision prohibiting cumulative voting, would require approval by holders of at least two-thirds in voting power of the outstanding shares of stock entitled to vote thereon.

The provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the composition of our board and management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

Limitations on Liability and Indemnification Matters

Our amended and restated certificate of incorporation provides that no director or officer will be personally liable to us or our stockholders for monetary damages for breaches of certain fiduciary duties as a director or officer, except as required by applicable law. The Delaware General Corporation Law permits a corporation to provide in its certificate of incorporation that a director or officer of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for certain breaches of fiduciary duties as a director or officer, except for liability for:

- any breach of the director's or officer's duty of loyalty to our company or our stockholders;
- any act or omission not in good faith or which involved intentional misconduct or a knowing violation of law;
- in the case of directors, for unlawful payments of dividends or unlawful stock repurchases, redemptions, or other distributions;
- any transaction from which the director or officer derived an improper personal benefit; and
- an officer in any action by or in the right of the Company.

As a result, neither we nor our stockholders have the right, through stockholders' derivative suits on our behalf, to recover monetary damages for breaches of fiduciary duties, including breaches resulting from grossly negligent behavior, except in the situations described above.

Our amended and restated certificate of incorporation also provides that, to the fullest extent permitted by law, we will indemnify any officer or director of our company against all damages, claims and liabilities arising out of the fact that the person is or was our director or officer, or served any other enterprise at our request as a director or

officer. Amending this provision will not reduce our indemnification obligations relating to actions taken before an amendment.

Listing

We have applied to list our common stock on the Nasdaq Global Select Market under the trading symbol "MOBI," and this offering is contingent upon obtaining approval of such listing.

Transfer Agent and Registrar

Upon completion of this offering, the transfer agent and registrar for our common stock will be Equiniti Trust Company, LLC. The transfer agent and registrar's address is 6201 15th Avenue, Brooklyn, NY 11219.

SHARES ELIGIBLE FOR FUTURE SALE

Prior to this offering, there has been no public market for our common stock, and although we expect that our common stock will be approved for listing on the Nasdaq Global Select Market, we cannot assure investors that there will be an active public market for our common stock following this offering. We cannot predict what effect, if any, sales of our shares in the public market or the availability of shares for sale will have on the market price of our common stock. Future sales of substantial amounts of common stock in the public market, including shares issued upon exercise of outstanding options, or the perception that such sales may occur, however, could adversely affect the market price of our common stock and also could adversely affect our future ability to raise capital through the sale of our common stock or other equity-related securities of ours at times and prices we believe appropriate.

Upon completion of this offering, based on our shares outstanding as of December 31, 2025 and after giving effect to the Preferred Stock Conversion, issuance of the 2026 Convertible Notes and related Notes Conversion, and Warrant Exercise, 33,085,391 shares of our common stock will be outstanding, or 34,585,391 shares of common stock if the underwriters exercise their option to purchase additional shares in full, assuming no exercise of outstanding options or warrants. All of the shares of common stock expected to be sold in this offering will be freely tradable without restriction or further registration under the Securities Act unless held by our "affiliates," as that term is defined in Rule 144 under the Securities Act. The remaining outstanding shares of our common stock will be deemed "restricted securities" as that term is defined under Rule 144. Restricted securities may be sold in the public market only if their offer and sale is registered under the Securities Act or if the offer and sale of those securities qualify for an exemption from registration, including exemptions provided by Rules 144 and 701 under the Securities Act, which are summarized below.

As a result of the lock-up agreements and market stand-off provisions described below and the provisions of Rules 144 or 701 and assuming no exercise of the underwriters' option to purchase additional shares, the shares of our common stock that will be deemed "restricted securities" will be available for sale in the public market following the completion of this offering as follows:

- 10,000,000 shares will be eligible for sale on the date of this prospectus; and
- additional 23,085,391 shares will be eligible for sale upon expiration of the lock-up agreements and market stand-off provisions described below, beginning 181 days after the date of this prospectus.

Lock-Up Agreements and Market Stand-Off Agreements

Our officers, directors, and the holders of substantially all of our capital stock, options, and warrants have entered into market stand-off agreements with us and have entered into or will enter into lock-up agreements with the underwriters, whereby they have agreed, for a period of 180 days after the date of this prospectus, subject to certain exceptions, not to offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right, or warrant to purchase, lend, or otherwise dispose of or transfer any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock; exercise any right with respect to the registration of any of these securities; file, cause to be filed or cause to be confidentially submitted a registration statement related to these securities; or enter into any hedging, swap, loan or any other agreement or any transaction that transfers to another, in whole or in part, directly or indirectly, the economic consequence of ownership of the common stock. BofA Securities, Inc., J.P. Morgan Securities LLC and Goldman Sachs & Co. LLC, may, in their sole discretion and at any time or from time to time before the termination of the lock-up period, in certain cases without public notice, release all or any portion of the securities subject to lock-up agreements. There are no existing agreements between the underwriters and any of our stockholders who will execute a lock-up agreement providing consent to the sale of shares prior to the expiration of the lock-up period. Upon the expiration of the lock-up period, substantially all of the shares subject to such lock-up restrictions will become eligible for sale, subject to the limitations discussed above. See the section titled "Underwriting" for additional information.

Rule 144

Rule 144, as currently in effect, generally provides that, once we have been subject to the public company reporting requirements of Section 13 or Section 15(d) of the Exchange Act for at least 90 days, a stockholder who is not deemed to have been one of our affiliates at any time during the preceding 90 days and who has beneficially owned the shares of our capital stock proposed to be sold for at least six months is entitled to sell such shares in reliance upon Rule 144 without complying with the volume limitation, manner of sale or notice conditions of Rule 144 (subject to the lock-up agreement referred to above, if applicable). If such stockholder has beneficially owned the shares of our capital stock proposed to be sold for at least one year, then such person is entitled to sell such shares in reliance upon Rule 144 without complying with any of the conditions of Rule 144 (subject to the lock-up agreement referred to above, if applicable).

Rule 144 also provides that a stockholder who is deemed to have been one of our affiliates at any time during the preceding 90 days and who has beneficially owned the shares of our common stock proposed to be sold for at least six months is entitled to sell such shares in reliance upon Rule 144, upon expiration of any applicable lock-up agreements and within any three month period beginning 90 days after the date of this prospectus a number of shares that does not exceed the greater of the following:

- 1% of the number of shares of our capital stock then outstanding, which will equal 330,854 shares immediately after the completion of this offering, assuming no exercise by the underwriters of their option to purchase additional shares; or
- the average weekly trading volume of our common stock during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Sales of our capital stock made in reliance upon Rule 144 by a stockholder who is deemed to have been one of our affiliates at any time during the preceding 90 days are also subject to the current public information, manner of sale and notice conditions of Rule 144. Notwithstanding the availability of Rule 144, the holders of substantially all of our restricted securities have entered into lock-up agreements as referenced above and their restricted securities will become eligible for sale (subject to the above limitations under Rule 144) upon the expiration of the restrictions set forth in those agreements.

Rule 701

Rule 701 generally provides that, once we have been subject to the public company reporting requirements of Section 13 or Section 15(d) of the Exchange Act for at least 90 days, a stockholder who purchased shares of our common stock pursuant to a written compensatory benefit plan or contract and who is not deemed to have been one of our affiliates at any time during the preceding 90 days may sell such shares in reliance upon Rule 144 without complying with the current public information or holding period conditions of Rule 144. Rule 701 also provides that a stockholder who purchased shares of our common stock pursuant to a written compensatory benefit plan or contract and who is deemed to have been one of our affiliates during the preceding 90 days may sell such shares under Rule 144 without complying with the holding period condition of Rule 144. However, all stockholders who purchased shares of our common stock pursuant to a written compensatory benefit plan or contract are required to wait until 90 days after the date of this prospectus before selling such shares pursuant to Rule 701.

Registration Rights

After the completion of this offering, the holders of up to 21,904,521 shares of our common stock will, subject to the lock-up agreements referred to above, be entitled to certain rights with respect to the registration of such shares under the Securities Act. The registration of these shares of our common stock under the Securities Act would result in these shares becoming eligible for sale in the public market without restriction under the Securities Act immediately upon the effectiveness of such registration, subject to the Rule 144 limitations applicable to affiliates. See the section titled “Description of Capital Stock—Registration Rights” for a description of these registration rights.

Registration Statement

After the completion of this offering, we intend to file a registration statement on Form S-8 under the Securities Act to register all of the shares of our common stock subject to equity awards outstanding or reserved for issuance under our equity compensation plans. The shares of our common stock covered by such registration statement will be eligible for sale in the public market without restriction under the Securities Act immediately upon the effectiveness of such registration statement, subject to vesting restrictions, the conditions of Rule 144 applicable to affiliates, and any applicable market stand-off agreements and lock-up agreements. See the section titled "Executive and Director Compensation—Equity Incentive Plans" for a description of our equity compensation plans.

MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS FOR NON-U.S. HOLDERS OF OUR COMMON STOCK

The following discussion is a summary of the material U.S. federal income tax consequences to Non-U.S. Holders (as defined below) of the purchase, ownership, and disposition of our common stock issued pursuant to this offering, but does not purport to be a complete analysis of all potential tax effects. The effects of other U.S. federal tax laws, such as estate and gift tax laws, and any applicable state, local, or non-U.S. tax laws are not discussed. This discussion is based on the Code, Treasury Regulations promulgated thereunder, judicial decisions, and published rulings and administrative pronouncements of the U.S. Internal Revenue Service (the IRS), in each case in effect as of the date hereof. These authorities may change or be subject to differing interpretations. Any such change or differing interpretation may be applied retroactively in a manner that could adversely affect a Non-U.S. Holder. We have not sought and will not seek any rulings from the IRS regarding the matters discussed below. There can be no assurance the IRS or a court will not take a contrary position to that discussed below regarding the tax consequences of the purchase, ownership, and disposition of our common stock.

This discussion is limited to Non-U.S. Holders that hold our common stock as a "capital asset" within the meaning of Section 1221 of the Code (generally, property held for investment). This discussion does not address all U.S. federal income tax consequences relevant to a Non-U.S. Holder's particular circumstances, including the impact of the Medicare contribution tax on net investment income and the alternative minimum tax. In addition, it does not address consequences relevant to Non-U.S. Holders subject to special rules, including, without limitation:

- U.S. expatriates and former citizens or long-term residents of the United States;
- persons holding our common stock as part of a hedge, straddle, or other risk reduction strategy or as part of a conversion transaction or other integrated investment;
- banks, insurance companies, and other financial institutions;
- brokers, dealers, or traders in securities;
- "controlled foreign corporations," "foreign controlled foreign corporations," "passive foreign investment companies," and corporations that accumulate earnings to avoid U.S. federal income tax;
- partnerships or other entities or arrangements treated as partnerships for U.S. federal income tax purposes (and investors therein);
- tax-exempt organizations or governmental organizations;
- persons deemed to sell our common stock under the constructive sale provisions of the Code;
- persons who hold or receive our common stock pursuant to the exercise of any employee stock option or otherwise as compensation;
- tax-qualified retirement plans;
- "qualified foreign pension funds" as defined in Section 897(l)(2) of the Code and entities all of the interests of which are held by qualified foreign pension funds; and
- persons subject to special tax accounting rules as a result of any item of gross income with respect to the stock being taken into account in an applicable financial statement.

If an entity treated as a partnership for U.S. federal income tax purposes holds our common stock, the tax treatment of a partner in the partnership will depend on the status of the partner, the activities of the partnership, and certain determinations made at the partner level. Accordingly, partnerships holding our common stock and the partners in such partnerships should consult their tax advisors regarding the U.S. federal income tax consequences to them.

THIS DISCUSSION IS FOR INFORMATIONAL PURPOSES ONLY AND IS NOT TAX ADVICE. INVESTORS SHOULD CONSULT THEIR TAX ADVISORS WITH RESPECT TO THE APPLICATION OF THE U.S. FEDERAL INCOME TAX LAWS TO THEIR PARTICULAR SITUATIONS AS WELL AS ANY TAX CONSEQUENCES OF THE PURCHASE, OWNERSHIP, AND DISPOSITION OF OUR COMMON STOCK ARISING UNDER THE U.S. FEDERAL ESTATE OR GIFT TAX LAWS OR UNDER THE LAWS OF ANY STATE, LOCAL, OR NON-U.S. TAXING JURISDICTION OR UNDER ANY APPLICABLE INCOME TAX TREATY.

Definition of a Non-U.S. Holder

For purposes of this discussion, a "Non-U.S. Holder" is any beneficial owner of our common stock that is neither a "U.S. person" nor an entity treated as a partnership for U.S. federal income tax purposes. For purposes of this discussion, a "U.S. person" is any person that, for U.S. federal income tax purposes, is or is treated as any of the following:

- an individual who is a citizen or resident of the United States;
- a corporation created or organized under the laws of the United States, any state thereof, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income tax regardless of its source; or
- a trust that (1) is subject to the primary supervision of a U.S. court and the control of one or more "United States persons" (within the meaning of Section 7701(a)(30) of the Code), or (2) has a valid election in effect to be treated as a United States person for U.S. federal income tax purposes.

Distributions

As described in the section titled "Dividend Policy" above, we do not anticipate paying any cash dividends to holders of our common stock in the foreseeable future. However, if we do make distributions of cash or property on our common stock, such distributions will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. Amounts not treated as dividends for U.S. federal income tax purposes will constitute a return of capital and first be applied against and reduce a Non-U.S. Holder's adjusted tax basis in its common stock, but not below zero. Any excess will be treated as capital gain and will be treated as described below under "—Sale or Other Taxable Disposition."

Subject to the discussion below on effectively connected income, dividends paid to a Non-U.S. Holder will be subject to U.S. federal withholding tax at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty, provided the Non-U.S. Holder furnishes a valid IRS Form W-8BEN or W-8BEN-E (or other applicable documentation) certifying qualification for the lower treaty rate). A Non-U.S. Holder that does not timely furnish the required documentation, but that qualifies for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. Holders should consult their tax advisors regarding their entitlement to benefits under any applicable income tax treaty.

If dividends paid to a Non-U.S. Holder are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such dividends are attributable), the Non-U.S. Holder will be exempt from the U.S. federal withholding tax described above. To claim the exemption, the Non-U.S. Holder must furnish to the applicable withholding agent a valid IRS Form W-8ECI, certifying that the dividends are effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States.

Any such effectively connected dividends will be subject to U.S. federal income tax on a net income basis at the regular rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30%

(or such lower rate specified by an applicable income tax treaty) on such effectively connected dividends, as adjusted for certain items. Non-U.S. Holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

Sale or Other Taxable Disposition

A Non-U.S. Holder will not be subject to U.S. federal income tax on any gain realized upon the sale or other taxable disposition of our common stock unless:

- the gain is effectively connected with the Non-U.S. Holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, the Non-U.S. Holder maintains a permanent establishment in the United States to which such gain is attributable);
- the Non-U.S. Holder is a nonresident alien individual present in the United States for 183 days or more during the taxable year of the disposition and certain other requirements are met; or
- our common stock constitutes a U.S. real property interest (USRPI), by reason of our status as a U.S. real property holding corporation (USRPHC), for U.S. federal income tax purposes.

Gain described in the first bullet point above generally will be subject to U.S. federal income tax on a net income basis at the regular rates. A Non-U.S. Holder that is a corporation also may be subject to a branch profits tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on such effectively connected gain, as adjusted for certain items.

A Non-U.S. Holder described in the second bullet point above will be subject to U.S. federal income tax at a rate of 30% (or such lower rate specified by an applicable income tax treaty) on gain realized upon the sale or other taxable disposition of our common stock, which may be offset by U.S. source capital losses of the Non-U.S. Holder (even though the individual is not considered a resident of the United States), provided the Non-U.S. Holder has timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third bullet point above, we believe we currently are not, and do not anticipate becoming, a USRPHC. Because the determination of whether we are a USRPHC depends, however, on the fair market value of our USRPIs relative to the fair market value of our non-U.S. real property interests and our other business assets, there can be no assurance we currently are not a USRPHC or will not become one in the future. Even if we are or were to become a USRPHC, gain arising from the sale or other taxable disposition of our common stock by a Non-U.S. Holder will not be subject to U.S. federal income tax if our common stock is "regularly traded," as defined by applicable Treasury Regulations, on an established securities market and such Non-U.S. Holder owned, actually and constructively, 5% or less of our common stock throughout the shorter of the five-year period ending on the date of the sale or other taxable disposition or the Non-U.S. Holder's holding period.

Non-U.S. Holders should consult their tax advisors regarding potentially applicable income tax treaties that may provide for different rules.

Information Reporting and Backup Withholding

Payments of dividends on our common stock will not be subject to backup withholding, provided the applicable withholding agent does not have actual knowledge or reason to know the holder is a United States person and the holder either certifies its non-U.S. status, such as by furnishing a valid IRS Form W-8BEN, W-8BEN-E or W-8ECI, or otherwise establishes an exemption. However, information returns are required to be filed with the IRS in connection with any distributions on our common stock paid to the Non-U.S. Holder, regardless of whether such distributions constitute dividends or whether any tax was actually withheld. In addition, proceeds of the sale or other taxable disposition of our common stock within the United States or conducted through certain U.S.-related brokers generally will not be subject to backup withholding or information reporting if the applicable withholding agent receives the certification described above and does not have actual knowledge or reason to know that such holder is a United States person or the holder otherwise establishes an exemption. Proceeds of a disposition of our

common stock conducted through a non-U.S. office of a non-U.S. broker generally will not be subject to backup withholding or information reporting.

Copies of information returns that are filed with the IRS may also be made available under the provisions of an applicable treaty or agreement to the tax authorities of the country in which the Non-U.S. Holder resides or is established.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a Non-U.S. Holder's U.S. federal income tax liability, provided the required information is timely furnished to the IRS.

Additional Withholding Tax on Payments Made to Foreign Accounts

Withholding taxes may be imposed under Sections 1471 to 1474 of the Code (such Sections commonly referred to as the Foreign Account Tax Compliance Act (FATCA)) on certain types of payments made to non-U.S. financial institutions and certain other non-U.S. entities. Specifically, a 30% withholding tax may be imposed on dividends on, or (subject to the proposed Treasury Regulations discussed below) gross proceeds from the sale or other disposition of, our common stock paid to a "foreign financial institution" or a "non-financial foreign entity" (each as defined in the Code), unless (1) the foreign financial institution undertakes certain diligence and reporting obligations, (2) the non-financial foreign entity either certifies it does not have any "substantial United States owners" (as defined in the Code) or furnishes identifying information regarding each substantial United States owner, or (3) the foreign financial institution or non-financial foreign entity otherwise qualifies for an exemption from these rules. If the payee is a foreign financial institution and is subject to the diligence and reporting requirements in clause (1) above, it must enter into an agreement with the U.S. Department of the Treasury requiring, among other things, that it undertake to identify accounts held by certain "specified United States persons" or "United States owned foreign entities" (each as defined in the Code), annually report certain information about such accounts, and withhold 30% on certain payments to non-compliant foreign financial institutions and certain other account holders. Foreign financial institutions located in jurisdictions that have an intergovernmental agreement with the United States governing FATCA may be subject to different rules.

Under the applicable Treasury Regulations and administrative guidance, withholding under FATCA generally applies to payments of dividends on our common stock. While withholding under FATCA would have applied also to payments of gross proceeds from the sale or other disposition of stock, proposed Treasury Regulations eliminate FATCA withholding on payments of gross proceeds entirely. Taxpayers generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued.

Prospective investors should consult their tax advisors regarding the potential application of withholding under FATCA to their investment in our common stock.

UNDERWRITING

BofA Securities, Inc., J.P. Morgan Securities LLC and Goldman Sachs & Co. LLC are acting as representatives of each of the underwriters named below. Subject to the terms and conditions set forth in an underwriting agreement among us and the underwriters, we have agreed to sell to the underwriters, and each of the underwriters has agreed, severally and not jointly, to purchase from us, the number of shares of common stock set forth opposite its name below.

Underwriter	Number of Shares
BofA Securities, Inc.	
J.P. Morgan Securities LLC	
Goldman Sachs & Co. LLC	
BTIG, LLC	
Nomura Securities International, Inc.	
WR Securities, LLC	
Total	10,000,000

"Wolfe | Nomura Alliance" is the marketing name used by Wolfe Research Securities and Nomura Securities International, Inc. in connection with certain equity capital markets activities conducted jointly by the firms. Both Nomura Securities International, Inc. and WR Securities, LLC are serving as underwriters in the offering described herein. In addition, WR Securities, LLC and certain of its affiliates may provide sales support services, investor feedback, investor education, and/or other independent equity research services in connection with this offering.

Subject to the terms and conditions set forth in the underwriting agreement, the underwriters have agreed, severally and not jointly, to purchase all of the shares sold under the underwriting agreement if any of these shares are purchased. If an underwriter defaults, the underwriting agreement provides that the purchase commitments of the nondefaulting underwriters may be increased or the underwriting agreement may be terminated.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, or to contribute to payments the underwriters may be required to make in respect of those liabilities.

The underwriters are offering the shares, subject to prior sale, when, as and if issued to and accepted by them, subject to approval of legal matters by their counsel, including the validity of the shares, and other conditions contained in the underwriting agreement, such as the receipt by the underwriters of officer's certificates and legal opinions. The underwriters reserve the right to withdraw, cancel or modify offers to the public and to reject orders in whole or in part.

Commissions and Discounts

The representatives have advised us that the underwriters propose initially to offer the shares to the public at the public offering price set forth on the cover page of this prospectus and to dealers at that price less a concession not in excess of $ per share. After the initial offering, the public offering price, concession or any other term of the offering may be changed. Sales of any shares made outside of the United States may be made by affiliates of the underwriters.

The following table shows the initial public offering price, underwriting discounts and commissions and proceeds before expenses to us. The information assumes either no exercise or full exercise by the underwriters of their option to purchase additional shares.

	Per Share	Without Option	With Option
Initial public offering price			
Underwriting discounts and commissions			
Proceeds, before expenses, to us			

The expenses of the offering, not including the underwriting discounts and commissions, are estimated at $5,000,000 and are payable by us. We have also agreed to reimburse the underwriters for expenses relating to clearance of this offering with the Financial Industry Regulatory Authority in an amount up to $50,000.

We have engaged WR Securities, LLC to provide certain financial advisory services in connection with the offering for a fee of $100,000.

Option to Purchase Additional Shares

We have granted an option to the underwriters, exercisable for 30 days after the date of this prospectus, to purchase up to 1,500,000 additional shares at the public offering price, less the underwriting discounts and commissions. If the underwriters exercise this option, each will be obligated, subject to conditions contained in the underwriting agreement, to purchase a number of additional shares proportionate to that underwriter's initial amount reflected in the above table.

Reserved Shares

At our request, an affiliate of BofA Securities, Inc., a participating underwriter has reserved for sale, at the initial public offering price, up to 5% of the shares offered by this prospectus for sale to some of our directors, officers, employees, distributors, dealers, business associates and related persons. The sales will be made at our discretion to parties identified by management through a reserved share program. Management will provide the list of potential participants to Merrill Lynch, Pierce, Fenner & Smith Incorporated, which will administer the program. Pursuant to this program, once a preliminary prospectus has been filed, an invitation package will be made available or sent to each party identified by management, which will include the preliminary prospectus and other reserved share program documentation. An invitation to participate in the program does not guarantee that the participant will receive an allocation of shares. Accordingly, we cannot provide any assurance that any director, officer, employee, distributor, dealer, business associate, related person, or participant will receive an invitation or an allocation in the program. If a potential participant is interested in participating, that participant will be required to complete the required documentation and will be required to return such documentation to the program administrator. The program administrator will not accept funds from any participant until after the registration statement for this offering is declared effective, this offering is priced, and the participants are notified of their final allocation and given an opportunity to confirm that they wish to purchase the shares allocated to them. After the registration statement has been declared effective and this offering is priced, we and the program administrator will prepare a final approved list of allocations. The program administrator will notify each participant who has been allocated shares of the number of shares that have been allocated and the total purchase price due upon confirmation of their participation. Thereafter, participants will be required to wire or transfer their funds to the program administrator. The shares under the reserved share program will be allocated following pricing and settle in the same manner as the shares sold to the general public. Any shares purchased in the program by our directors or officers will be subject to the 180-day lock-up restrictions described below. If participants purchase reserved shares, this will reduce the number of shares available for sale to the general public. Any reserved shares that are not so purchased will be offered by the underwriters to the general public on the same terms as the other shares offered by this prospectus. We have agreed to reimburse the underwriters for certain fees and expenses in connection with this reserved share program, including the fees and disbursements of counsel to the underwriters, which we estimate to be approximately $25,000.

No Sales of Similar Securities

We, our executive officers and directors and our other existing security holders have agreed not to sell or transfer any common stock or securities convertible into or exercisable or exchangeable for common stock (collectively, the Lock-Up Securities) for 180 days after the date of this prospectus (the Lock-Up Period) without first obtaining the written consent of BofA Securities, Inc., J.P. Morgan Securities LLC and Goldman Sachs & Co. LLC. Specifically, we and these other persons have agreed (and with respect to those other persons, to also cause any direct or indirect affiliates), with certain limited exceptions, not to directly or indirectly

- offer, pledge, sell or contract to sell any Lock-Up Securities,

- sell any option or contract to purchase any Lock-Up Securities,
- purchase any option or contract to sell any Lock-Up Securities,
- grant any option, right or warrant for the sale of any Lock-Up Securities,
- lend or otherwise dispose of or transfer any Lock-Up Securities,
- request or demand that we file or make a confidential submission of a registration statement related to the Lock-Up Securities,
- enter into any swap or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, the economic consequence of ownership of Lock-Up Securities whether any such swap or transaction is to be settled by delivery of shares or other securities, in cash or otherwise, or
- publicly disclose the intention to do any of the foregoing.

This lock-up provision applies to any Lock-Up Securities whether now owned or acquired later by the person executing the agreement or for which the person executing the agreement has or later acquires the power of disposition. BofA Securities, Inc., J.P. Morgan Securities LLC and Goldman Sachs & Co. LLC, in their sole discretion, may release the Lock-Up Securities subject to the lock-up agreements described above in whole or in part at any time with or without notice.

Listing

We have applied to list our common stock on the Nasdaq Global Select Market under the symbol “MOBI”.

Before this offering, there has been no public market for our common stock. The initial public offering price will be determined through negotiations between us and the representatives. In addition to prevailing market conditions, the factors to be considered in determining the initial public offering price are

- the valuation multiples of publicly traded companies that the representatives believe to be comparable to us,
- our financial information,
- the history of, and the prospects for, our company and the industry in which we compete,
- an assessment of our management, its past and present operations, and the prospects for, and timing of, our future revenues,
- the present state of our development, and
- the above factors in relation to market values and various valuation measures of other companies engaged in activities similar to ours.

An active trading market for the shares may not develop. It is also possible that after the offering the shares will not trade in the public market at or above the initial public offering price.

The underwriters do not expect to sell more than 5% of the shares in the aggregate to accounts over which they exercise discretionary authority.

Price Stabilization, Short Positions and Penalty Bids

Until the distribution of the shares is completed, SEC rules may limit underwriters and selling group members from bidding for and purchasing our common stock. However, the representatives may engage in transactions that stabilize the price of the common stock, such as bids or purchases to peg, fix or maintain that price.

In connection with the offering, the underwriters may purchase and sell our common stock in the open market. These transactions may include short sales, purchases on the open market to cover positions created by short sales

and stabilizing transactions. Short sales involve the sale by the underwriters of a greater number of shares than they are required to purchase in the offering. "Covered" short sales are sales made in an amount not greater than the underwriters' option to purchase additional shares described above. The underwriters may close out any covered short position by either exercising their option to purchase additional shares or purchasing shares in the open market. In determining the source of shares to close out the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the option granted to them. "Naked" short sales are sales in excess of such option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of our common stock in the open market after pricing that could adversely affect investors who purchase in the offering. Stabilizing transactions consist of various bids for or purchases of shares of common stock made by the underwriters in the open market prior to the completion of the offering.

The underwriters may also impose a penalty bid. This occurs when a particular underwriter repays to the underwriters a portion of the underwriting discount received by it because the representatives have repurchased shares sold by or for the account of such underwriter in stabilizing or short covering transactions.

Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales may have the effect of raising or maintaining the market price of our common stock or preventing or retarding a decline in the market price of our common stock. As a result, the price of our common stock may be higher than the price that might otherwise exist in the open market. The underwriters may conduct these transactions on Nasdaq, in the over-the-counter market or otherwise.

Neither we nor any of the underwriters make any representation or prediction as to the direction or magnitude of any effect that the transactions described above may have on the price of our common stock. In addition, neither we nor any of the underwriters make any representation that the representatives will engage in these transactions or that these transactions, once commenced, will not be discontinued without notice.

Electronic Distribution

In connection with the offering, certain of the underwriters or securities dealers may distribute prospectuses by electronic means, such as e-mail.

Other Relationships

The underwriters and their respective affiliates are full service financial institutions engaged in various activities, which may include sales and trading, commercial and investment banking, advisory, investment management, investment research, principal investment, hedging, market making, brokerage, and other financial and non-financial activities and services. Some of the underwriters and their affiliates have engaged in, and may in the future engage in, investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. They have received, or may in the future receive, customary fees and commissions for these transactions.

In addition, in the ordinary course of their business activities, the underwriters and their affiliates may make or hold a broad array of investments and actively trade debt and equity securities (or related derivative securities) and financial instruments (including bank loans) for their own account and for the accounts of their customers. Such investments and securities activities may involve securities and/or instruments of ours or our affiliates. The underwriters and their affiliates may also make investment recommendations and/or publish or express independent research views in respect of such securities or financial instruments and may hold, or recommend to clients that they acquire, long and/or short positions in such securities and instruments.

Notice to Prospective Investors in the European Economic Area

In relation to each member state of the European Economic Area (each a Relevant State), no shares have been offered or will be offered pursuant to this offering to the public in that Relevant State prior to the publication of a prospectus in relation to the shares which has been approved by the competent authority in that Relevant State or,

where appropriate, approved in another Relevant State and notified to the competent authority in that Relevant State, all in accordance with the Prospectus Regulation, except that offers of shares may be made to the public in that Relevant State at any time under the following exemptions under the Prospectus Regulation:

a. to any legal entity which is a qualified investor as defined under the Prospectus Regulation;

b. to fewer than 150 natural or legal persons (other than qualified investors as defined under the Prospectus Regulation), subject to obtaining the prior consent of the representatives of the underwriters for any such offer; or

c. in any other circumstances falling within Article 1(4) of the Prospectus Regulation,

provided that no such offer of shares shall require us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the Prospectus Regulation.

Each person in a Relevant State who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with the Company and the underwriters that it is a qualified investor within the meaning of the Prospectus Regulation.

In the case of any shares being offered to a financial intermediary as that term is used in Article 5(1) of the Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer to the public other than their offer or resale in a Relevant State to qualified investors, in circumstances in which the prior consent of the representatives of the underwriters has been obtained to each such proposed offer or resale.

The Company, the underwriters and their respective affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgements and agreements.

For the purposes of this provision, the expression an “offer to the public” in relation to any shares in any Relevant State means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, and the expression “Prospectus Regulation” means Regulation (EU) 2017/1129.

The above selling restriction is in addition to any other selling restrictions set out below.

Notice to Prospective Investors in the United Kingdom

In relation to the United Kingdom (UK), no shares have been offered or will be offered pursuant to this offering to the public in the UK prior to the publication of a prospectus in relation to the shares which has been approved by the Financial Conduct Authority in the UK in accordance with the UK Prospectus Regulation and the FSMA, except that offers of shares may be made to the public in the UK at any time under the following exemptions under the UK Prospectus Regulation and the FSMA:

a. to any legal entity which is a qualified investor as defined under the UK Prospectus Regulation;

b. to fewer than 150 natural or legal persons (other than qualified investors as defined under the UK Prospectus Regulation), subject to obtaining the prior consent of the representatives of the underwriters for any such offer; or

c. at any time in other circumstances falling within section 86 of the FSMA,

provided that no such offer of shares shall require the Company or any underwriter to publish a prospectus pursuant to Section 85 of the FSMA or Article 3 of the UK Prospectus Regulation or supplement a prospectus pursuant to Article 23 of the UK Prospectus Regulation.

Each person in the UK who initially acquires any shares or to whom any offer is made will be deemed to have represented, acknowledged and agreed to and with the Company and the underwriters that it is a qualified investor within the meaning of the UK Prospectus Regulation.

In the case of any shares being offered to a financial intermediary as that term is used in Article 5(1) of the UK Prospectus Regulation, each such financial intermediary will be deemed to have represented, acknowledged and agreed that the shares acquired by it in the offer have not been acquired on a non-discretionary basis on behalf of, nor have they been acquired with a view to their offer or resale to, persons in circumstances which may give rise to an offer to the public other than their offer or resale in the UK to qualified investors, in circumstances in which the prior consent of the representatives of the underwriters has been obtained to each such proposed offer or resale.

The Company, the underwriters, and their respective affiliates will rely upon the truth and accuracy of the foregoing representations, acknowledgements, and agreements.

For the purposes of this provision, the expression an "offer to the public" in relation to any shares in the UK means the communication in any form and by any means of sufficient information on the terms of the offer and any shares to be offered so as to enable an investor to decide to purchase or subscribe for any shares, the expression "UK Prospectus Regulation" means Regulation (EU) 2017/1129 as it forms part of domestic law by virtue of the European Union (Withdrawal) Act 2018, and the expression "FSMA" means the Financial Services and Markets Act 2000, as amended.

This document is for distribution only to persons who (i) have professional experience in matters relating to investments and who qualify as investment professionals within the meaning of Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (as amended, the Financial Promotion Order), (ii) are persons falling within Article 49(2)(a) to (d) (high net worth companies, unincorporated associations, etc.) of the Financial Promotion Order, (iii) are outside the UK, or (iv) are persons to whom an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the FSMA) in connection with the issue or sale of any securities may otherwise lawfully be communicated or caused to be communicated (all such persons together being referred to as relevant persons). This document is directed only at relevant persons and must not be acted on or relied on by persons who are not relevant persons. Any investment or investment activity to which this document relates is available only to relevant persons and will be engaged in only with relevant persons.

Notice to Prospective Investors in Switzerland

The shares may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange (SIX) or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the shares or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, the Company or the shares have been or will be filed with or approved by any Swiss regulatory authority. In particular, this document will not be filed with, and the offer of shares will not be supervised by, the Swiss Financial Market Supervisory Authority, and the offer of shares has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes (CISA). The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of shares.

Notice to Prospective Investors in the Dubai International Financial Centre

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority (DFSA). This prospectus is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents in connection with Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility

for the prospectus. The shares to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the shares offered should conduct their own due diligence on the shares. If you do not understand the contents of this prospectus you should consult an authorized financial advisor.

Notice to Prospective Investors in Australia

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission, in relation to the offering. This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001 (the Corporations Act), and does not purport to include the information required for a prospectus, product disclosure statement, or other disclosure document under the Corporations Act.

Any offer in Australia of the shares may only be made to persons (the Exempt Investors) who are "sophisticated investors" (within the meaning of section 708(8) of the Corporations Act), "professional investors" (within the meaning of section 708(11) of the Corporations Act), or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the shares without disclosure to investors under Chapter 6D of the Corporations Act.

The shares applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring shares must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation, or particular needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances, and, if necessary, seek expert advice on those matters.

Notice to Prospective Investors in Hong Kong

The shares have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance; or (b) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation or document relating to the shares has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to shares which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the Securities and Futures Ordinance and any rules made under that Ordinance.

Notice to Prospective Investors in Japan

The shares have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) and, accordingly, will not be offered or sold, directly or indirectly, in Japan, or for the benefit of any Japanese Person or to others for re-offering or resale, directly or indirectly, in Japan or to any Japanese Person, except in compliance with all applicable laws, regulations and ministerial guidelines promulgated by relevant Japanese governmental or regulatory authorities in effect at the relevant time. For the purposes of this paragraph, "Japanese Person" shall mean any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

Notice to Prospective Investors in Singapore

This prospectus has not been registered as a prospectus with the Monetary Authority of Singapore. Accordingly, the shares were not offered or sold or caused to be made the subject of an invitation for subscription or purchase and will not be offered or sold or caused to be made the subject of an invitation for subscription or purchase, and this prospectus or any other document or material in connection with the offer or sale, or invitation for subscription or purchase, of the shares, has not been circulated or distributed, nor will it be circulated or distributed, whether directly or indirectly, to any person in Singapore other than (i) to an institutional investor (as defined in Section 4A of the Securities and Futures Act (Chapter 289) of Singapore, as modified or amended from time to time (the SFA)) pursuant to Section 274 of the SFA, (ii) to a relevant person (as defined in Section 275(2) of the SFA) pursuant to Section 275(1) of the SFA, or any person pursuant to Section 275(1A) of the SFA, and in accordance with the conditions specified in Section 275 of the SFA, or (iii) otherwise pursuant to, and in accordance with the conditions of, any other applicable provision of the SFA.

Where the shares are subscribed or purchased under Section 275 of the SFA by a relevant person which is:

a. a corporation (which is not an accredited investor (as defined in Section 4A of the SFA)) the sole business of which is to hold investments and the entire share capital of which is owned by one or more individuals, each of whom is an accredited investor; or

b. a trust (where the trustee is not an accredited investor) whose sole purpose is to hold investments and each beneficiary of the trust is an individual who is an accredited investor,

securities or securities-based derivatives contracts (each term as defined in Section 2(1) of the SFA) of that corporation or the beneficiaries' rights and interest (howsoever described) in that trust shall not be transferred within six months after that corporation or that trust has acquired the shares pursuant to an offer made under Section 275 of the SFA except:

a. to an institutional investor or to a relevant person, or to any person arising from an offer referred to in Section 275(1A) or Section 276(4)(i)(B) of the SFA;

b. where no consideration is or will be given for the transfer;

c. where the transfer is by operation of law; or

d. as specified in Section 276(7) of the SFA.

Notice to Prospective Investors in Canada

The shares may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 *Prospectus Exemptions* or subsection 73.3(1) of the *Securities Act* (Ontario), and are permitted clients, as defined in National Instrument 31-103 *Registration Requirements, Exemptions, and Ongoing Registrant Obligations*. Any resale of the shares must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 (or, in the case of securities issued or guaranteed by the government of a non-Canadian jurisdiction, section 3A.4) of National Instrument 33-105 *Underwriting Conflicts* (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Notice to Prospective Investors in Brazil

The offer and sale of the securities have not been and will not be registered with the Brazilian Securities Commission (Comissão de Valores Mobiliários, or CVM) and, therefore, will not be carried out by any means that would constitute a public offering in Brazil under CVM Resolution No. 160, dated 13 July 2022, as amended (CVM Resolution 160) or unauthorized distribution under Brazilian laws and regulations. The securities may only be offered to Brazilian professional investors (as defined by applicable CVM regulation), who may only acquire the securities through a non-Brazilian account, with settlement outside Brazil in non-Brazilian currency. The trading of these securities on regulated securities markets in Brazil is prohibited.

LEGAL MATTERS

The validity of the issuance of our common stock offered in this prospectus will be passed upon for us by Latham & Watkins LLP. Cleary Gottlieb Steen & Hamilton LLP, New York, New York is acting as counsel for the underwriters.

EXPERTS

The financial statements as of December 31, 2025 and 2024 and for the years then ended included in this prospectus have been so included 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 2 to the financial statements) of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of our common stock offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement, as permitted by the rules and regulations of the SEC. For further information with respect to us and our common stock, we refer you to the registration statement, including the exhibits filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any contract or any other document is not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. The SEC maintains an Internet website that contains the registration statement of which this prospectus forms a part, as well as the exhibits thereto. These documents, along with future reports, proxy statements, and other information about us, are available at the SEC's website, www.sec.gov.

As a result of this offering, we will become subject to the information and reporting requirements of the Securities Exchange Act of 1934, as amended, and, in accordance with this law, will file periodic reports, proxy statements, and other information with the SEC. We also maintain a website at www.mobia.com where these materials are available. Upon the completion of this offering, you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on, or that can be accessible through, our website is not a part of this prospectus and the inclusion of our website address in this prospectus is an inactive textual reference only.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Mobia Medical, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Mobia Medical, Inc. (the "Company") as of December 31, 2025 and 2024, and the related statements of operations, of redeemable convertible preferred stock and stockholders' deficit, and of cash flows for the years then ended, including the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for the years then ended in conformity with accounting principles generally accepted in the United States of America.

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

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has incurred operating losses and negative cash flows from operations since its inception and an accumulated deficit as of December 31, 2025 that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits of these financial statements in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

Los Angeles, California

March 11, 2026, except for the effects of the revision discussed in Note 3 to the financial statements, as to which the date is April 27, 2026, and except for the effects of the reverse stock split discussed in Note 3 to the financial statements, as to which the date is May 4, 2026

We have served as the Company's auditor since 2024.

Mobia Medical, Inc.
Balance Sheets

	December 31, 2025	December 31, 2024
Assets		
Current assets		
Cash and cash equivalents	$ 33,587,308	$ 14,620,320
Accounts receivable	4,435,223	2,826,236
Inventory	5,456,757	3,429,162
Deferred offering costs	934,996	—
Other current assets	1,942,958	299,023
Total current assets	**46,357,242**	**21,174,741**
Property and equipment, net	669,130	456,376
Right-of-use-assets – operating leases	1,068,452	438,588
Other Assets	53,875	21,332
Total assets	**$ 48,148,699**	**$ 22,091,037**
Liabilities, redeemable convertible preferred stock, and stockholders' deficit		
Current liabilities		
Accounts payable	$ 2,222,970	$ 1,139,326
Operating lease liabilities, current	357,522	23,646
Product warranty liability	843,671	437,219
Accrued payroll, commissions, and bonuses	4,853,892	2,738,377
Accrued offering costs	934,995	—
Accrued and other current liabilities	993,157	258,238
Total current liabilities	**10,206,207**	**4,596,806**
Warrant liabilities	865,390	1,007,342
Notes payable, net of discount and deferred financing costs	7,129,928	7,094,070
Operating lease liability – long term	947,886	603,050
Total liabilities	**19,149,411**	**13,301,268**
Commitments and contingencies (Note 15)		
Redeemable convertible preferred stock issuable in series, $0.01 par value; 67,174,403 and 42,475,557 shares authorized as of December 31, 2025 and December 31, 2024, respectively; 65,591,701 and 40,892,855 shares issued and outstanding as of December 31, 2025 and December 31, 2024, respectively; aggregate liquidation value of $182,255,492 and $117,255,538 as of December 31, 2025 and December 31, 2024, respectively	179,772,875	114,825,572
Stockholders' deficit		
Common stock, $0.01 par value, 86,600,000 and 54,062,688 shares authorized as of December 31, 2025 and 2024, respectively; 884,030 and 776,701 outstanding shares as of December 31, 2025 and 2024, respectively	8,840	7,767
Additional paid-in capital	7,006,706	5,247,375
Accumulated deficit	(157,789,133)	(111,290,945)
Total stockholders' deficit	**(150,773,587)**	**(106,035,803)**
Total liabilities, redeemable convertible preferred stock, and stockholders' deficit	**$ 48,148,699**	**$ 22,091,037**

The accompanying notes are an integral part of these financial statements.

Mobia Medical, Inc.
Statements of Operations

	Years Ended December 31,	
	2025	**2024**
Revenue	$ 32,040,978	$ 15,644,398
Cost of goods sold	6,065,955	3,193,173
Gross profit	**25,975,023**	**12,451,225**
Operating Expenses		
Research and development costs	6,515,249	4,243,399
Selling, general and administrative expenses	65,827,675	32,444,116
Total operating expenses	**72,342,924**	**36,687,515**
Loss from operations	**(46,367,901)**	**(24,236,290)**
Other income (expense)		
Interest expense	(967,368)	(969,920)
Other income, net	842,531	617,109
Total other expense, net	**(124,837)**	**(352,811)**
Loss before provision for income tax	**(46,492,738)**	**(24,589,101)**
Provision for income tax	(5,450)	(13,913)
Net loss attributable to common stockholders	**$ (46,498,188)**	**$ (24,603,014)**
Net loss per share attributable to common stockholders		
Basic	**$ (54.78)**	**$ (42.82)**
Diluted	**$ (54.78)**	**$ (42.82)**
Weighted-average shares used to compute net loss per share attributable to common stockholders		
Basic	**848,812**	**574,632**
Diluted	**848,812**	**574,632**

The accompanying notes are an integral part of these financial statements.

Mobia Medical, Inc.
Statements of Redeemable Convertible Preferred Stock and Stockholders' Deficit

	Redeemable Convertible Preferred Stock		Common Stock		Paid-In Capital	Accumulated Deficit	Total Stockholders' Deficit
	Shares	Amount	Shares	Amount			
Balance, January 1, 2024	**34,997,324**	**$ 99,527,210**	**485,116**	**$ 4,851**	**$ 3,820,537**	**$ (86,687,931)**	**$ (82,862,543)**
Net loss	—	—	—	—	—	(24,603,014)	(24,603,014)
Issuance of Series E-2 redeemable convertible preferred stock in connection with the settlement of tranche liability, net of issuance costs of $12,011	5,301,100	13,787,299	—	—	—	—	—
Related party issuance of Series E-2 redeemable convertible preferred stock in connection with settlement of tranche liability, net of issuance costs of $1,347	594,431	1,511,063	—	—	—	—	—
Exercise of common stock options	—	—	291,585	2,916	668,711	—	671,627
Share-based compensation	—	—	—	—	758,127	—	758,127
Balance, December 31, 2024	**40,892,855**	**$ 114,825,572**	**776,701**	**$ 7,767**	**$ 5,247,375**	**$ (111,290,945)**	**$ (106,035,803)**
Net loss	—	—	—	—	—	(46,498,188)	(46,498,188)
Issuance of Series F redeemable convertible preferred stock and settlement of tranche liability, net of issuance costs of $264,065	22,703,940	59,701,561	—	—	—	—	—
Related party issuance of Series F redeemable convertible preferred stock and settlement of tranche liability, net of issuance costs of $23,202	1,994,906	5,245,742	—	—	—	—	—
Exercise of common stock options			107,329	1,073	312,629	—	313,702
Share-based compensation	—	—	—	—	1,446,702	—	1,446,702
Balance, December 31, 2025	**65,591,701**	**$ 179,772,875**	**884,030**	**$ 8,840**	**$ 7,006,706**	**$ (157,789,133)**	**$ (150,773,587)**

The accompanying notes are an integral part of these financial statements.

Mobia Medical, Inc.
Statements of Cash Flows

	Years Ended December 31,	
	2025	2024
Cash flows from operating activities		
Net loss	$ (46,498,188)	$ (24,603,014)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	151,657	116,010
Share-based compensation	1,446,702	758,127
Change in fair value of warrant liability	(141,952)	-
Fair value adjustment of redeemable convertible preferred stock tranche liability	234,616	12,440
Amortization of debt issuance costs	35,858	35,857
Changes in assets and liabilities		
Accounts receivable	(1,608,987)	(1,386,950)
Inventory	(2,027,595)	(245,409)
Other assets	(2,611,473)	(288,570)
Accounts payable	1,083,644	(108,594)
Accrued liabilities and other	4,240,728	1,394,802
Net cash used in operating activities	(45,694,990)	(24,315,301)
Cash flows from investing activities		
Purchase of fixed assets	(364,411)	(40,848)
Net cash used in investing activities	(364,411)	(40,848)
Cash flows from financing activities		
Exercise of common stock options	313,702	671,627
Proceeds from issuance of Series E-2 redeemable convertible preferred stock, net of issuance costs	—	13,475,579
Proceeds from the related party issuance of Series E-2 redeemable convertible preferred stock, net of issuance costs	—	1,511,063
Proceeds from issuance of Series F redeemable convertible preferred stock, net of issuance costs	59,485,894	—
Proceeds from the related party issuance of Series F redeemable convertible preferred stock, net of issuance costs	5,226,793	—
Net cash provided by financing activities	65,026,389	15,658,269
Net change in cash and cash equivalents	18,966,988	(8,697,880)
Cash and cash equivalents, beginning of year	14,620,320	23,318,200
Cash and cash equivalents, end of year	$ 33,587,308	$ 14,620,320
Supplemental disclosures of cash flows information		
Cash paid for interest	$ 931,510	$ 969,920
Cash paid for income taxes	$ 2,725	$ 13,913
Non-cash investing and financing activities		
Settlement of redeemable convertible preferred stock tranche liability	$ 915,216	$ 311,800

The accompanying notes are an integral part of these financial statements.

Note 1 – Description of Business

Mobia Medical, Inc. (the "Company") was incorporated in Delaware in March 2007. Effective February 23, 2026, the Company amended its articles of incorporation to change its name from MicroTransponder, Inc. to Mobia Medical, Inc. The change was solely a corporate name change and had no impact on the Company's financial statements.

The Company develops, markets and sells devices for the treatment of medical conditions. The first device brought to market, the Vivistim Paired VNS System (Vivistim System), received U.S. Food and Drug Administration premarket approval in 2021 and is intended to be used by chronic ischemic stroke survivors with moderate to severe upper extremity impairments to reduce upper extremity motor deficits and improve motor function. The Vivistim System was first brought to market in 2022, with the first commercial implant in May 2022, and commenced full commercial launch in 2023.

Risks and Uncertainties – The Company's activities are subject to significant risks and uncertainties, including, but not limited to, failure to manage growth effectively, reliance on the success of the Vivistim System, new technological innovations, dependence upon third-party payers to provide adequate coverage and reimbursement to our customers, the absence of a national coverage determination or local coverage determinations applicable to its device administrated by the Centers for Medicare and Medicaid Services (CMS), dependence on key personnel, dependence on key suppliers, protection of proprietary technology, product liability, and compliance with government regulations. The Company is also subject to risks relating to cybersecurity and the protection of confidential information and personal information, as well as risks relating to evolving regulatory requirements (including potential additional clinical evidence requirements) that could affect commercialization of existing or future products. These risks and uncertainties, as well as failure to secure additional funding, if needed, can adversely affect the Company's future financial results, financial position, and cash flow.

In addition, economic conditions in the United States, including any economic disruptions, inflationary, or supply chain pressures, may adversely impact the Company's future financial results. The Company uses contract manufacturers in Uruguay to supply key products. Political instability or the deterioration of trade relations, including implementation of new tariffs, could adversely impact the Company's business.

Concentration of credit risk – The Company maintains its cash deposits with high credit quality financial institutions. At times, such deposits may be in excess of the Federal Deposit Insurance Corporation insured limits; however, management does not believe it is exposed to any significant credit risk. All such accounts are monitored by management to mitigate risk and cash equivalents are invested in highly rated money market funds.

Supplier concentration risk – The Company depends on a small number of third-party contract manufacturers and suppliers, some of which are single source, to produce and package all elements comprising our Vivistim System as well as certain implantation tools, and if these suppliers and manufacturers fail to supply the Vivistim System or its components or subcomponents in sufficient quantities or at all, it will have a material adverse effect on our business, financial condition, and results of operations.

Note 2 – Liquidity and Going Concern

These financial statements were prepared on a going concern basis. The going concern basis assumes that the Company will continue in operation for the foreseeable future and will be able to realize its assets and discharge its liabilities and commitments in the normal course of business.

The Company has incurred operating losses and negative cash flows from operations since its inception. For the year ended December 31, 2025, the Company had a net loss of $46,498,188 and had an accumulated deficit of $157,789,133 as of December 31, 2025. Additionally, the Company has generated negative cash flows from operations for the year ended December 31, 2025.

Since inception, the Company has financed its activities principally from the issuance of preferred stock, debt financing arrangements and revenue from sales of the Vivistim System. The Vivistim System was first brought to market in 2022, with the first commercial implant in May 2022, and commenced full commercial launch in 2023.

The Company believes that its operating losses and negative operating cash flows will continue into the foreseeable future. There can be no assurance that the Company's products will generate sufficient revenue for the Company to achieve profitable operations.

Based on its current operating plan, which was updated in January 2026, the Company plans significant increases in marketing expenditures to facilitate further awareness and adoption of the Vivistim System, spending on research and development, including regulatory affairs and clinical studies, and costs related to scaling the Company's commercial operations and infrastructure. In addition, general and administrative expenses are expected to increase following the Company's planned initial public offering (IPO) due to the additional costs associated with being a public company. As a result, the Company's existing cash and cash equivalents are not expected to be sufficient for the Company to continue as a going concern for at least one year from the date these financial statements are issued. These conditions raise substantial doubt upon the Company's ability to continue as a going concern. As a result, the Company will be required to raise additional capital.

The Company is seeking to complete an IPO of its common stock. In the event the Company does not complete an IPO, the Company would expect to obtain additional funding through the issuance of additional redeemable convertible preferred stock or debt; however, such funding is not guaranteed.

If future revenue is not sufficient or if sufficient funds on acceptable terms are not available when needed, the Company may be required to curtail planned activities to significantly reduce its operating expenses. Failure to manage discretionary spending or raise additional financing, as needed, may have a material adverse effect on the Company's future viability and results of operations.

Note 3 – Summary of Significant Accounting and Reporting Policies and Basis of Presentation

Basis of presentation – The accompanying financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America (U.S. GAAP).

Reverse Stock Split – On May 1, 2026 the Company effected a 1-for-3.483 reverse stock split of its issued and outstanding common stock. All references to common stock issued and outstanding, stock options, loss per share and per share amounts presented in the accompanying financial statements and notes thereto have been retroactively adjusted for all periods presented to reflect the reverse stock split. The per share par value, authorized numbers of shares of the Company's common stock and redeemable convertible preferred stock, issued and outstanding number of shares of redeemable convertible preferred stock, and redeemable convertible preferred stock warrants were not adjusted as a result of the reverse stock split. Instead, the conversion ratio was updated whereby each share of each series of Preferred Stock was convertible into shares of common stock on a 1:3.483 basis.

Revision of previously issued financial statements and recast to reflect the reverse stock split – Subsequent to the issuance of the Company's financial statements as of December 31, 2025 and 2024 and for the years then ended included in its Registration Statement on Form S-1, the Company's management identified an error in the calculation of weighted-average shares used to compute basic and diluted net loss per share attributable to common stockholders for the year ended December 31, 2025. Specifically, the Company concluded that the weighted-average share amount as previously reported was incorrectly calculated resulting in basic and diluted net loss per share attributable to common stockholders being overstated for the year ended December 31, 2025.

The Company evaluated the error in accordance with Staff Accounting Bulletin ("SAB") No. 99, *Materiality*, and SAB No. 108, *Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements,* and concluded that the error was not material to the previously issued financial statements. However, the Company has determined to correct the error by revising its financial statements as of and for the year ended December 31, 2025 in this amended Registration Statement on Form S-1.

The error had no impact on the balance sheet, the statement of redeemable convertible preferred stock and stockholders' deficit, or the statement of cash flows.

The following table summarizes the impact of the correction for the year ended December 31, 2025, and has been further adjusted to reflect the reverse stock split:

	Year ended December 31, 2025			
	As reported (prior to reverse stock split)	Adjustment (prior to reverse stock split)	As revised (prior to reverse stock split)	As recasted [1]
Net loss per share attributable to common stockholders:				
Basic and diluted	$ (20.64)	$ (4.91)	$ (15.73)	$ (54.78)
Weighted-average shares used to compute net loss per share attributable to common stockholders:				
Basic and diluted	2,252,494	703,921	2,956,415	848,812

(1) Amounts have been recasted to reflect the 1:3.483 reverse stock split

In addition, Note 14 - Net Loss Per Share has been updated to reflect the revised amounts for the correction and the effects of the reverse stock split.

Use of estimates – The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Significant estimates and assumptions include, but are not limited to, stock compensation, valuation of common and preferred stock, valuation of warrant liability, product warranty liability, and redeemable convertible preferred stock tranche liability. Actual results could differ from those estimates.

Emerging Growth Company Status - The Company is an emerging growth company ("EGC"), as defined in the Jumpstart Our Business Startups Act (the "JOBS Act"), enacted in 2012. Under the JOBS Act, EGCs can delay adopting new or revised accounting standards issued after the enactment of the JOBS Act until those standards apply to private companies. The Company has elected to use this extended transition period for complying with new or revised accounting standards that have different effective dates for public and private companies until the earlier of the date that it (i) is no longer an EGC or (ii) affirmatively and irrevocably opts out of the extended transition period provided in the JOBS Act. As a result, these financial statements may not be comparable to companies that comply with the new or revised accounting pronouncements as of public company effective dates.

Segment reporting – The Company operates and manages its business as a single reportable and operating segment. Operating segments are defined as components of an enterprise where separate financial information is evaluated regularly by the chief operating decision maker (CODM) in deciding how to allocate resources and assess performance. The Company's CODM is the Chief Executive Officer, who reviews financial information on a company-wide basis for purposes of allocating resources and assessing financial performance and does not regularly review expenses or financial results on a more granular level. For the year ended December 31, 2025, the Company updated the presentation of certain significant segment expenses as a result of changes in the financial information regularly provided to and reviewed by the CODM. For additional segment reporting information, refer to Note 16.

Cash and cash equivalents – The Company considers all highly liquid debt instruments purchased with an original maturity of three months or less to be cash equivalents.

Research and development – Research and development costs are expensed when incurred and are included in operating expenses.

Accounts receivable and allowance for credit losses – The Company records accounts receivables at the invoiced amount and accounts for credit losses in accordance with ASC 326, *Financial Instruments—Credit Losses*. The Company maintains an allowance for credit losses for any receivables the Company may be unable to collect. The Company estimates expected credit losses on an individual basis, as appropriate, based on the receivables' age, customers' expected ability to pay and collection history, current economic conditions, and reasonable and supportable forecasts, among other factors that may affect customers' ability to pay. The Company uses its

judgment, based on the best available facts and circumstances, and records an allowance against amounts due to reduce the receivable to the amount that is expected to be collected. The Company began selling its products in 2022 and has not experienced material bad debt write-offs since inception, and as of December 31, 2025 and 2024, a significant majority of outstanding receivables were current. Based on its evaluation of historical loss experience, aging of receivables, customer creditworthiness, current economic conditions, and whether reasonably foreseeable future conditions could affect collectability as required under ASC 326, the Company determined that no allowance for expected credit losses was required for the periods presented. Accordingly, no allowance for credit losses was recorded as of December 31, 2025 and 2024.

Inventory – Inventory costs are comprised primarily of finished goods and raw materials and include the acquisition costs of raw materials and components, in addition to direct labor and overhead. All inventory is stated at the lower of cost or net realizable value and is accounted for on a first in, first out (FIFO) basis. The balance of finished goods and raw materials as of December 31, 2025 and 2024 are as follows:

	2025	2024
Raw materials	$ 1,191,550	$ 1,518,000
Finished goods	4,265,207	1,911,162
Total inventory	$ 5,456,757	$ 3,429,162

The Company performs an assessment of the recoverability of inventory during each reporting period, and, if applicable, writes down any excess and obsolete inventories to their estimated net realizable value in the period in which the impairment is first identified. The determination of whether inventory costs will be realizable requires estimates by management. If actual market conditions are less favorable than projected by management, additional write-downs of inventory may be required. There were no expenses recorded for excess inventory or other impairments during the years ending December 31, 2025 and 2024.

Deferred Offering Costs - Deferred offering costs include certain legal, accounting, consulting and other fees incurred directly related to Company's planned IPO. The Company defers offering costs until the effective date of the IPO, upon which, these costs will be recorded as a reduction of the offering proceeds included within additional paid-in capital. Should the IPO no longer be considered probable of being consummated, all deferred offering costs will be charged to operating expenses in the statement of operations at such time.

Property and equipment, net – Property and equipment are recorded at cost and depreciated using the straight-line method over the estimated useful lives of the respective assets, and leasehold improvements are amortized on a straight-line basis over the shorter of the term of the lease or the estimated useful life of the asset as follows:

	Estimated Life
Furniture and fixtures	5-7 years
Machinery and equipment	5-7 years
Computers and software	3 years
Leasehold Improvements	5 years

Income taxes – Income taxes are provided for the tax effects of transactions reported in the financial statements and consist of taxes currently due plus deferred taxes related primarily to differences between the basis of assets and liabilities for financial and income tax reporting. Deferred tax assets and liabilities represent future tax return consequences of those differences, which will either be taxable or deductible when the assets and liabilities are recovered or settled. Deferred taxes are also recognized for operating losses that are available to offset future taxable income. Management assesses the available positive and negative evidence to estimate whether sufficient future taxable income will be generated to permit use of the existing deferred tax assets. On the basis of this evaluation, as of December 31, 2025 and 2024, valuation allowances were recorded such that no net deferred tax assets were recognized.

Tax benefits associated with uncertain tax positions are recognized in the period in which one of the following conditions are satisfied: (1) the more likely than not recognition threshold is satisfied; (2) the position is ultimately settled through negotiation or litigation; or (3) the statute of limitations for the taxing authority to examine and challenge the position has expired. Tax benefits associated with an uncertain tax position are derecognized in the period in which the more likely than not recognition threshold is no longer satisfied. Any potential interest and penalty associated with a tax contingency, should one arise, would be included as a component of income tax expense in the period in which the assessment arises.

Long-lived assets – The Company assesses the recoverability of long-lived assets using an assessment of the estimated undiscounted future cash flows related to such assets. In the event that assets are found to be carried at amounts which are in excess of estimated gross future cash flows, the assets will be adjusted for impairment to a level commensurate with a discounted cash flow analysis of the underlying assets. No impairments of long-lived assets have been recognized to date.

Intangible assets – Intangible assets are stated at cost and consist primarily of intellectual property rights granting exclusive rights to use patented technology, which are amortized using the straight-line method over 16 to 20 years. Intangible assets are immaterial.

Revenue Recognition – The Company is in the business of medical device sales. The Vivistim System consists of an Implantable Pulse Generator (IPG) and an implantable lead that, once implanted, stimulates the vagus nerve in the patients.

The Company sells the Vivistim System to customers, primarily stroke hospitals located in the United States. The Company applies the provisions of ASU 2014-09, *Revenue from Contracts with Customers*, and all subsequent amendments (collectively, ASC 606). Revenue is recognized upon transfer of control of promised products to customers in an amount that reflects the consideration the Company expects to receive in exchange for those products. Any taxes collected from customers are subsequently remitted to governmental authorities.

A contract with a customer exists when (i) the Company enters into a legally enforceable contract with a customer that defines each party's rights regarding the products to be transferred and identifies the related payment terms, (ii) the contract has commercial substance, and (iii) the Company determines that collection of substantially all consideration for the products transferred is probable based on the customer's intent and ability to pay the promised consideration. Master terms agreements between the Company and its customers govern customer relationships. However, the contract is not determined to have commercial substance until a purchase order is submitted by the customer under a master terms agreement and accepted by the Company.

A performance obligation is a promise in a contract to transfer a distinct good or service to the customer and is the unit of account for revenue recognition. A contract's transaction price is allocated to each distinct performance obligation and recognized as revenue when, or as, the performance obligation is satisfied. Payment terms and conditions vary by contract type, although terms generally include a requirement of payment within 30 days. The Company has determined that its contracts generally do not include a significant financing component. The primary purpose of the Company's invoicing terms is to provide customers with simplified and predictable ways of purchasing the Company's products, not to receive financing from its customers or to provide customers with financing.

The IPG and implantable lead components of the Vivistim System each represent distinct performance obligations to the customer based on the benefit provided to the customer for each patient implantation. The Company also provides customers with equipment (stroke application & programming software, wireless transmitter, remote control, and magnet) at the outset of each new master terms agreement, in addition to post-delivery technical support for the equipment. Both the equipment and technical support services are considered immaterial in the context of the contract.

Accordingly, the performance obligations of the Company's customer contract are determined by each individual purchase order and the respective product order for IPGs and implantable leads, with revenue being recognized at a point-in-time when the obligation under the terms of the agreement is satisfied and product control is transferred to the customer and not when implantation occurs. In general, a purchase order from a customer and the

Company's invoice identify the product, quantity, price, payment terms and final delivery terms. The Company does not serve as an agent for any other enterprise. For the majority of the Company's customer arrangements, control transfers to customers at a point-in-time when the Vivistim System has been delivered to the healthcare provider, as that is generally when the customer has the ability to direct the use of and obtain substantially all of the remaining benefits from the Vivistim System. Revenue for the years ended December 31, 2025 and 2024 was $32,040,978 and $15,644,398, respectively.

The transaction price is determined as the amount of consideration the Company expects to be entitled to in exchange for the products to be transferred to the customer under each purchase order, which is based on the stated price for the Vivistim System in each invoice. All pricing is fixed and there are no discounts, rebates or other price concessions.

The timing of satisfaction of the performance obligation is not subject to significant judgment due to the simplistic nature of satisfying the performance obligation. After the completion of the performance obligation, the Company has an unconditional right to payment from customers.

The Company warrants that each product received by the customer will meet the agreed upon technical and quality specifications and requirements. Only when the delivered products do not meet these requirements can the customer return the non-compliant units as a corrective action under the warranty. The remedy offered to the customer is repair of the returned products or replacement if repair is not viable. Accordingly, warranty activities are not considered to be a separate performance obligation. The Company offers an implicit warranty for product replacement for aged, damaged, or unusable items. See Note 7 for additional information.

The Company records amounts billed to customers for reimbursement of shipping and handling costs as revenue. Shipping and handling costs associated with outbound freight after control over a product has transferred to a customer are accounted for as fulfillment costs and are included in cost of sales. The Company does not evaluate whether the selling price includes a financing interest component for contracts that are less than a year. The Company expenses costs incurred to obtain a contract, primarily sales commissions, as the period of benefit is less than one year.

Leases – The Company recognizes and measures its leases in accordance with ASC 842, *Leases*. The Company determines if an arrangement is a lease, or contains a lease, at inception of a contract and when the terms of an existing contract are changed. The Company recognizes a lease liability and a right-of-use (ROU) asset at the commencement date of the lease. The lease liability is initially and subsequently recognized based on the present value of its future lease payments over the expected lease term. Variable payments are included in the future lease payments when those variable payments depend on an index or a rate. The discount rate is the implicit rate if it is readily determinable or otherwise the Company uses its incremental borrowing rate. The implicit rates of the Company's leases are not readily determinable and accordingly, management uses the incremental borrowing rate based on the information available at the commencement date for all leases. The Company's incremental borrowing rate for a lease is the rate of interest it would have to pay on a collateralized basis to borrow an amount equal to the lease payments under similar terms and in a similar economic environment. The ROU asset is subsequently calculated throughout the lease term at the amount of the remeasured lease liability (i.e., present value of the remaining lease payments), plus unamortized initial direct costs, plus (minus) any prepaid (accrued) lease payments, less the unamortized balance of lease incentives received, and any impairment recognized. As a practical expedient, the Company elected not to separate non-lease components from lease components.

Lease cost for lease payments is recognized on a straight-line basis over the lease term. Lease agreements with a non-cancelable term of less than 12 months are not recorded on the Company's balance sheet. The Company's ROU assets and lease liabilities as of December 31, 2025 and 2024 were attributable to operating leases. For the periods presented, the Company did not have any finance leases.

Cost of Goods Sold – Cost of goods sold consists primarily of costs directly attributable to the acquisition, assembly, and delivery of the Company's medical device products. These costs include amounts paid to third-party suppliers for finished goods and raw materials, assembly labor, assembly-related overhead, inbound freight and

logistics costs, customs and duties, inventory handling and storage costs, quality inspection and testing costs, and inventory write-downs for excess, obsolete, or slow-moving inventory.

Advertising costs – Advertising costs are expensed as incurred. The Company incurred $3,437,400 and $1,324,044 in advertising costs for the years ended December 31, 2025 and 2024, respectively, which are recorded within selling, general and administrative expenses.

Share-based compensation – The Company's share-based payments are accounted for in accordance with ASC 718, *Compensation – Stock Compensation*, using the fair value method at the grant date. The Company records share-based compensation expense on a straight-line basis over the requisite service period. Forfeitures are recognized as they occur.

Options awarded to employees are typically service-based and are amortized over the vesting term of the award, generally ranging from 36 to 48 months. Non-employee option expense is generally expensed at the date of grant unless there are service conditions in the award, in which case the options are amortized over the service period. Certain prior-period share-based compensation disclosures have been recast to conform to the current period presentation. Beginning in the current year, employee and non-employee share activity, which was presented separately in prior years, is presented on a combined basis. For additional information related to shared-based compensation, refer to Note 13.

Redeemable convertible preferred stock - The Company records redeemable convertible preferred stock at fair value on the dates of issuance, net of issuance costs and the initial fair value of any tranche obligation liability recognized. The redeemable convertible preferred stock is recorded outside of stockholders' deficit because the preferred shares are contingently redeemable upon the occurrence of an event that is outside of the Company's control. The carrying values of the redeemable convertible preferred stock are not adjusted to the liquidation preferences of such shares because it is uncertain whether or when an event would occur that would obligate the Company to pay the liquidation preferences to holders of shares of redeemable convertible preferred stock. Subsequent adjustments to the carrying values to the liquidation preferences will be made only when it becomes probable that such liquidation event will occur. Refer to Note 11 for additional information.

Redeemable convertible preferred stock warrants – The Company's redeemable convertible preferred stock warrants require liability classification and accounting as the underlying redeemable convertible preferred stock is considered contingently redeemable and may obligate the Company to transfer assets to the holders at a future date upon occurrence of a deemed liquidation event. The warrants are recorded at fair value upon issuance and are subject to remeasurement to fair value at each balance sheet date, with any changes in fair value recognized in other income, net in the statements of operations. The Company will continue to adjust the warrant liability for changes in fair value until the earlier of the exercise or expiration of the redeemable convertible preferred stock warrants, or the occurrence of a deemed liquidation event.

Net loss per share – The Company's earnings (loss) per share are accounted for in accordance with ASC 260, *Earnings Per Share*. Basic earnings (loss) per share is calculated by dividing net earnings (loss) attributable to common stockholders by the weighted average number of shares of common stock outstanding during the period. Diluted earnings (loss) per share is calculated similarly but includes potential dilution from the exercise of stock options and stock awards and conversion of redeemable convertible preferred stock and warrants, except when the effect would be anti-dilutive. In a period in which the Company has a net loss, all potentially dilutive securities are excluded from the computation of diluted shares outstanding as they would have an anti-dilutive impact. Earnings (loss) per share are computed using the treasury stock method.

For purposes of the diluted earnings (loss) per share calculation, the redeemable convertible preferred stock, redeemable convertible preferred stock warrants, common stock options and stock awards are considered to be potentially dilutive securities. Basic and diluted earnings (loss) attributable to common stockholders per share is presented in conformity with the two-class method required for participating securities as the redeemable convertible preferred stock and common stock subject to repurchase are considered participating securities. The Company's participating securities do not have a contractual obligation to share in the Company's losses. As such, the net loss is attributed entirely to common stockholders. Diluted net loss per share is the same as basic net loss per share because

the effects of potentially dilutive items were anti-dilutive given the Company's net loss position during the years ended December 31, 2025 and 2024.

Related Party Relationships - During the years ended December 31, 2025 and 2024, the Company's Chief Financial Officer held an indirect ownership interest in Exceller Hunt MicroTransponder 2017, LP (Exceller Hunt) and the Curnes Fund 2001 (Curnes Fund), both principal shareholders of the Company. Jordan Curnes, the Company's Co-founder and Board member, also held an indirect ownership interest in the Curnes Fund for the years ended December 31, 2025 and 2024. During the year ended December 31, 2025, Exceller Hunt and the Curnes Fund acquired 1,139,946 and 854,960 shares of Series F redeemable convertible preferred stock at a price of $2.631 per share, respectively. During the year ended December 31, 2024, Exceller Hunt acquired 594,431 shares of Series E-2 redeemable convertible preferred stock at a price of $2.5443 per share. Aside from the sale of Series F and E-2 redeemable convertible preferred stock, the Company did not engage in any other related party transactions with Exceller Hunt or the Curnes Fund during the years ended December 31, 2025 and 2024.

Recently adopted accounting standards - On November 27, 2023, the FASB issued ASU 2023-07, *Segment Reporting (Topic 280): Improvements to Reportable Segment Disclosures*, which sets forth improvements to the current segment disclosure requirements in accordance with ASC 280 *Segment Reporting*, including clarifying that entities with a single reportable segment are subject to both new and existing segment reporting requirements. The Company adopted this standard with an effective date of January 1, 2024, and the adoption did not have a significant impact on the financial statements.

Recently issued accounting standards not yet adopted – On December 14, 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*, which requires enhanced income tax disclosures, including specific categories and disaggregation of information in the effective tax rate reconciliation, disaggregated information related to income taxes paid, income or loss from continuing operations before income tax expense or benefit, and income tax expense or benefit from continuing operations. This guidance is effective for annual periods beginning after December 15, 2024; however, as an EGC, the Company has elected to use the extended transition period for adopting new or revised accounting standards, and therefore the guidance will be effective for the Company for the year ended December 31, 2026. The adoption of ASU 2023-09 is expected to have a disclosure-only impact on the Company's financial statements for the year ended December 31, 2026. The Company is currently evaluating the impact of this pronouncement on the disclosures in its financial statements.

On November 4, 2024, the FASB issued ASU 2024-03, *Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*, which requires more detailed disclosures about specified categories of expenses (including employee compensation, depreciation, and amortization) included in certain expense captions presented on the face of the income statement. This ASU is effective for fiscal years beginning after December 15, 2026, and for interim periods within fiscal years beginning after December 15, 2027, with early adoption permitted. The amendments may be applied either (i) prospectively to financial statements issued for reporting periods after the effective date of this ASU or (ii) retrospectively to all prior periods presented in the financial statements. The Company is currently evaluating the impact of this pronouncement on the disclosures in its financial statements.

On November 26, 2024, the FASB issued ASU 2024-04, *Debt – Debt with Conversion and Other Options (Subtopic 2024-04)*, which clarifies the requirements for determining whether certain settlements of convertible debt instruments should be accounted for as an induced conversion rather than as extinguishment of debt. The amendments may be applied on either a prospective or a retrospective basis. This ASU is effective for fiscal years beginning after December 15, 2025, and interim periods within those annual reporting periods. The Company is currently evaluating the impact of this pronouncement on its financial statements.

On December 8, 2025, the FASB issued ASU 2025-11, *Interim Reporting (Topic 270) Narrow-Scope Improvements*, which is intended to improve the navigability of interim disclosures, clarifies when Topic 270 applies, and provides additional interim disclosure guidance, including a principle to disclose material events since the most recent annual reporting period. The amendments do not change the underlying objectives of interim reporting but are designed to enhance clarity in application. This ASU is effective for interim reporting periods within annual reporting periods beginning after December 15, 2027; however, as an EGC, the Company has elected

to use the extended transition period for adopting new or revised accounting standards, and therefore the guidance will be effective for the Company for interim periods within the year ended December 31, 2029. The Company is currently evaluating the impact of this pronouncement on its financial statements.

Note 4 – Fair Value Measurements

ASC 820, *Fair Value Measurements and Disclosures*, defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. ASC 820 establishes a fair value hierarchy that distinguishes between (1) market participant assumptions developed based on market data obtained from independent sources (observable inputs) and (2) an entity's own assumptions about market participant assumptions developed based on the best information available in the circumstances (unobservable inputs). The fair value hierarchy consists of three levels, which gives the highest priority to unadjusted quoted prices in active markets for identical assets or liabilities (Level 1) and the lowest priority to unobservable inputs (Level 3). The three levels of the fair value hierarchy under ASC 820 are described below:

Level 1 – This level consists of quoted prices (unadjusted) in active markets that are accessible at the measurement date for identical assets or liabilities. The fair value hierarchy gives the highest priority to Level 1 inputs.

Level 2 – This level consists of directly or indirectly observable inputs as of the reporting date through correlation with market data, including quoted prices for similar assets and liabilities in active markets and quoted prices in markets that are not active. Level 2 also includes assets and liabilities that are valued using models or other pricing methodologies that do not require significant judgment since the input assumptions used in the models, such as interest rates and volatility factors, are corroborated by readily observable data from actively quoted markets for substantially the full term of the financial instrument.

Level 3 – This level consists of unobservable inputs that are supported by little or no market activity and reflect the use of significant management judgment. These values are generally determined using pricing models for which the assumptions utilize management's estimates of market participant assumptions.

In determining the fair value, the Company utilizes valuation techniques that maximize the use of observable inputs and minimize the unobservable inputs to the extent possible, as well as considers counterparty credit risk in its assessments of fair value.

Fair Value of Liabilities – The following tables represent the Company's financial liabilities according to the fair value hierarchy, measured at fair value:

	Level 1	Level 2	Level 3	Total
December 31, 2025				
Liabilities				
Warrant liability	$ —	$ —	$ 865,390	$ 865,390
Total liabilities, at fair value	$ —	$ —	$ 865,390	$ 865,390

	Level 1	Level 2	Level 3	Total
December 31, 2024				
Liabilities				
Warrant liability	$ —	$ —	$ 1,007,342	$ 1,007,342
Total liabilities, at fair value	$ —	$ —	$ 1,007,342	$ 1,007,342

The value of the warrants to purchase the Company's redeemable convertible preferred stock is dependent on inputs for which there is little or no market data, in particular the value of the Company's stock. As a result, the valuation of the warrants to purchase the Company's redeemable convertible preferred stock is categorized as Level 3. When a determination is made to classify a financial instrument within Level 3, the determination is based upon

the lowest level of significance of the unobservable inputs to the overall fair value measurement. However, Level 3 financial instruments typically include, in addition to the unobservable inputs, observable inputs (that is, components that are actively quoted and can be validated to external sources). The fair values could change significantly based on future market conditions.

The fair value of the warrant liability is estimated using the option-pricing model based on the Black-Scholes-Merton model with the following inputs:

December 31, 2025	Series B Preferred Warrants	Series D Preferred Warrants	Series E-2 and F Preferred Warrants
Strike Price	$ 3.73744	$ 4.207	$ 2.5443
Expected Dividend Yield	— %	— %	— %
Expected Term (years)	7	7.4	8
Volatility	80 %	80 %	80 %
Risk-free rate	3.445 %	3.445 %	3.445 %

December 31, 2024	Series B Preferred Warrants	Series D Preferred Warrants	Series E-2 and F Preferred Warrants
Strike Price	$ 3.73744	$ 4.207	$ 2.5443
Expected Dividend Yield	— %	— %	— %
Expected Term (years)	8	8.4	9
Volatility	85 %	85 %	85 %
Risk-free rate	4.289 %	4.289 %	4.289 %

The Company estimates volatility based upon analysis of the historical volatility of guideline public companies as well as factors specific to the Company, including, but not limited to, size, expected growth and relative risk. The expected life assumption is based on the remaining contractual terms of the warrants. The risk-free rate as of December 31, 2025 and 2024 is based on the 1.5 year and 2.5 year U.S. treasury bond yield, respectively. The expected dividend yield used is zero, because the Company has no present intention to pay cash dividends. The fair value of the warrant liability as of December 31, 2025 and 2024 was $865,390 and $1,007,342, respectively. The change in fair value of the warrant liability for the years ended December 31, 2025 and 2024 was immaterial and recorded within other income, net in the statements of operations.

Note 5 – Property and Equipment, net

Property and equipment, net consist of the following as of December 31, 2025 and 2024:

	2025	2024
Machinery and equipment	$ 56,298	$ 114,069
Leasehold improvements	848,302	568,276
Furniture & Fixtures	68,935	—
	973,535	682,345
Less accumulated depreciation	(304,405)	(225,969)
Property and equipment, net	$ 669,130	$ 456,376

Depreciation expense was $151,657 and $115,017 for the years ended December 31, 2025 and 2024, respectively.

Note 6 – Accrued and other current liabilities

Accrued expenses and other current liabilities consisted of the following as of December 31, 2025 and 2024:

	2025	2024
Employee expense reimbursements	$ 513,330	$ 195,923
Other	479,827	62,315
Total accrued and other current liabilities	$ 993,157	$ 258,238

Note 7 – Product Warranties

The Company provides an assurance-type warranty that its products will conform to agreed-upon technical and quality specifications. The warranty provides for repair or replacement of products that fail to meet specifications or become unusable during this period, which generally ranges from one to two years, depending on the product.

The Company maintains a warranty reserve for IPGs and leads and began recording a warranty liability in 2024 based on historical product replacement experience. A warranty liability is recorded at the time revenue is recognized for all periods presented and is separately presented as product warranty liability on the face of the balance sheets. The warranty reserve is estimated based on historical product replacement experience. The Company establishes product replacement rates separately for IPGs and leads using historical replacement data beginning with the first full period of commercial shipments. The replacement rate represents the average historical rate of product replacement and is applied to units sold during each reporting period to estimate expected warranty obligations.

In developing its replacement rate assumptions, the Company evaluates historical replacement patterns over the expected product life cycle. The warranty accrual is calculated quarterly. The Company evaluates and updates its replacement rate assumptions annually, or more frequently if actual experience or product performance trends indicate that revisions are necessary. A reconciliation of the changes in the product warranty liability is as follows:

	2025	2024
Beginning balance	$ 437,219	$ —
Accruals for warranties issued	720,555	529,379
Claims settled	(314,103)	(92,160)
Ending balance	$ 843,671	$ 437,219

Note 8 – Notes Payable

During December 2023, the Company entered into a Loan and Security Agreement (the Agreement) with a lender. The Agreement provides for loan commitments of up to an aggregate principal amount of $30,000,000, available in four equal tranches of $7,500,000. Each tranche comprises two equal loans of $3,750,000. The loan commitments are subject to various conditions and requirements set out in the Agreement, including capital raising requirements and revenue milestones. The Company's ability to draw additional loans under the Agreement expired on December 31, 2025.

Pursuant to the Agreement, the Company was required to issue warrants to purchase the Company's preferred or common stock securities in the event the Company draws down a tranche under the Agreement. The interest rate for each loan is an annual rate equal to the greater of (i) the Wall Street Journal (or any successor thereto) prime rate (subject to a floor of 8.50%) plus 3.75% and (ii) 12.25%. The Company is required to make monthly payments of interest only through January 1, 2028. Following such date, the Company is required to make monthly payments of principal and accrued interest through maturity. The unpaid balance of principal and accrued interest is due at maturity.

The Agreement matures on January 1, 2029. The loans are subject to prepayment penalties of 1% to 3% based upon the length of time that the Agreement has been in place. Collateral for the loans includes substantially all of the assets of the Company, excluding intellectual property.

The Company satisfied the conditions for the first tranche under the Loan Agreement and, on December 29, 2023, the Company drew down $7,500,000 under the Agreement. The amounts outstanding under the promissory notes issued pursuant to the Agreement (collectively, Notes) are classified as long-term liabilities on the Company's balance sheet.

The following represents the maturities of the Notes as of December 31, 2025:

Years Ending December 31,	
2026	$ —
2027	—
2028	6,875,000
2029	625,000
Total	7,500,000
Less: Unamortized debt discount and deferred financing costs	(370,072)
Total future minimum payments	$ 7,129,928

In connection with the Company's draw down of the first tranche under the Agreement, the Company issued warrants to purchase such number of securities representing an aggregate of $262,500 to the lender. The warrants are exercisable at the election of the holder for shares of (i) Series E-2 redeemable convertible preferred stock at an exercise price of $2.5443 per share or, (ii) shares of Series F redeemable convertible preferred stock at an exercise price of $2.6317 per share ("Series E-2 and F Preferred Warrants") and expire ten years from the date of issuance. The warrants allow for the settlement in shares and are transferable at the holders' discretion. The value of the warrants is capped at $2.5443 per share, a total of $262,500, but the number of shares is not limited.

Debt issuance costs of $179,287 that were proportionately allocated to the Notes, were recorded as a discount to the Notes to be amortized to interest expense over the term of the Notes. Total debt issuance costs incurred were $185,597. The amount of debt issuance costs that were allocated to the warrants were expensed as incurred.

Total interest expense was $967,368 and $969,920 for the years ended December 31, 2025 and 2024, respectively.

Note 9 – Leases

On March 7, 2023, the Company entered into a noncancellable operating lease for office space and warehouse space. The commencement date of this lease was July 1, 2023, with an end date of July 31, 2028. Leases for all prior years were month to month. The lease contains a renewal option to extend the term for a period of five years. Because the Company is reasonably certain to exercise its renewal option, the optional period is included in determining the lease term, and associated payments under these renewal options are included in lease payments. The Company's lease does not include termination options for either party to the lease or restrictive financial or other covenants. Payments due under the lease contract include fixed payments plus variable payments. The Company's office space lease requires it to make variable payments for the Company's proportionate share of the building's property taxes, and common area operating expenses. These variable lease payments are not included in lease payments used to determine lease liability and are recognized as variable costs when incurred.

On March 20, 2025 the Company entered into a modification of its existing operating lease. The modification extended the lease term to April 30, 2030, expanded the office space and revised the future lease payments. Although the modification grants the Company an additional right of use at a stand-alone price, the modification also changes the scope of the original lease by extending it two additional years while also removing the renewal option. As such, the modification has been accounted for as a single contract.

On August 8, 2025, the Company entered into an additional non-cancellable operating lease for office space. The commencement date of the lease was September 1, 2025, with an end date of August 31, 2028. Payments due under the lease contract include fixed payments plus variable payments. The Company's office space lease requires it to make variable payments for the Company's proportionate share of the building's property taxes, and common

area operating expenses. These variable lease payments are not included in lease payments used to determine lease liability and are recognized as variable costs when incurred in accordance with ASC 842.

	2025	2024
Operating lease cost	$ 191,148	$ 100,460
Short-term lease cost[1]	30,460	40,860
Variable lease cost	72,868	41,456
Total lease cost	$ 294,476	$ 182,776

(1) Beginning in 2025, the Company separately presents lease costs for operating leases greater than one year and short-term leases, which were presented on a combined basis in the prior year. Amounts for 2024 has been reclassified to conform to the current period's presentation.

The following table presents the lease balances within the balance sheet as of December 31, 2025 and 2024:

	2025	2024
Right-of-use assets		
Operating lease right-of-use asset	$ 1,068,452	$ 438,588
Operating lease liabilities		
Operating lease liabilities, current	$ 357,522	$ 23,646
Operating lease liability, non-current portion	947,886	603,050
Total operating lease liabilities	$ 1,305,408	$ 626,696

The following table presents undiscounted future minimum lease payments, which reconcile to the total lease liability as follows:

Years Ending December 31	
2026	453,460
2027	466,782
2028	386,956
2029	206,117
2030	70,276
Total undiscounted future minimum lease payments	1,583,591
Less amounts representing interest	278,183
Total lease liability	$ 1,305,408

For the years ending December 31, 2025 and 2024, supplemental cash flow information related to leases were as follows:

	2025	2024
Cash paid for amounts included in the measurement of lease liabilities		
Operating cash flows used for operating leases (including short term leases)	$ 142,118	$ 99,846
Weighted-average remaining lease term (years)		
Operating leases	3.54	8.59
Weighted-average discount rate		
Operating leases	10.82 %	12.25 %

During the year ended December 31, 2025 and 2024, the Company recognized $701,125 and $0, respectively, of right-of-use assets in exchange for corresponding operating lease liabilities. These non-cash transactions are excluded from the Statements of Cash Flows.

Note 10 – Income Taxes

Deferred income tax assets and liabilities consist of the following as of December 31:

	2025	2024
Deferred tax assets		
Net operating loss and tax credit carryforwards	$ 31,891,974	$ 20,464,532
Share-based compensation	938,949	543,347
Accumulated depreciation & amortization	3,970,286	3,027,937
Accrued expenses	696,707	—
Right-of-use lease liability	317,956	131,606
Other	97,372	21,565
Gross deferred tax assets	37,913,244	24,188,987
Deferred tax liabilities		
Right-of-use lease asset	(260,241)	(92,103)
Gross deferred tax liabilities	(260,241)	(92,103)
Net deferred income tax assets before valuation allowance	37,653,003	24,096,884
Less valuation allowance	(37,653,003)	(24,096,884)
Net deferred income tax assets	$ —	$ —

For the years ended December 31, 2025 and 2024, management has evaluated the various tax positions reflected in income tax returns for both federal and state jurisdictions. In assessing the ability to realize deferred tax assets, management considers whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. Management believes that there are no tax positions for which a liability for unrecognized tax benefits should be recorded as of December 31, 2025. The Company's federal income tax returns generally remain subject to examination by the Internal Revenue Service for three years from the date the return is due, including extensions for years in which the net operating loss is utilized. The Company's state income tax returns are subject to examination, four years from the date of filing. Deferred income tax calculations reflect the effects of temporary differences between the carrying amounts of assets and liabilities and their tax bases, as well as from net operating loss carryforwards. Federal net operating losses incurred after December 31, 2017, can only offset 80% of taxable income in tax years beginning after December 31, 2020. However, these net operating losses may be carried forward indefinitely instead of such carryforward being limited to twenty years under previous tax law.

On July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was enacted, introducing various federal tax changes, including extensions of certain 2017 Tax Cuts and Jobs Act ("TCJA") provisions and updates to individual and business tax rules. Management evaluated the provisions applicable to the Company and determined that OBBBA did not have a significant impact on the Company's financial statements for the year ended December 31, 2025.

The difference between the provision for income taxes attributable to income before taxes and the amounts that would be expected using the U.S. federal statutory income tax rate of 21% is as follows as of December 31:

	2025		2024	
Tax rate reconciliation				
Federal income tax statutory rate	$ (9,763,475)	21 %	$ (5,141,462)	21 %
Return to provision	16,287	— %	(258,856)	(1)%
Change in valuation allowance	9,555,947	(21)%	5,338,392	(20)%
Other	196,691	— %	75,839	(1)%
Effective tax rate	$ 5,450	— %	$ 13,913	(1)%

Deferred income tax assets represent amounts available to reduce income taxes payable on taxable income in future years.

The components of income tax expense are as follows for the years ended December 31:

	2025	2024
Current income tax (benefit)		
Federal	$ —	$ —
State	5,450	13,913
Total current	5,450	13,913
Deferred income tax		
Federal	—	—
State	—	—
Total deferred	—	—
Income tax expense	$ 5,450	$ 13,913

The net changes in federal valuation allowance for the years ended December 31, 2025 and 2024 were $9,555,947 and $5,338,392, respectively.

At December 31, 2025, the Company had tax effected federal income tax loss carryforwards of approximately $26,754,656, tax effected state income tax loss carryforwards of approximately $3,257,900 and federal research tax credits of approximately $1,899,417. Tax effected net operating losses of $4,650,380 were generated before January 1, 2018 and begin to expire in 2027 for federal tax purposes. $22,104,276 of tax effected net operating losses were generated after January 1, 2018, and have an indefinite carryover period.

Utilization of the net operating loss carry forwards and credits may be subject to a substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code of 1986, as amended, and similar state provisions.

Note 11 – Redeemable Convertible Preferred Stock

The Company has issued Series A redeemable convertible preferred stock (“Series A”), Series B redeemable convertible preferred stock (“Series B”), Series C redeemable convertible preferred stock (“Series C”), Series D redeemable convertible preferred stock (“Series D”), Series E-1 redeemable convertible preferred stock (“Series E-1”), Series E-2 redeemable convertible preferred stock (“Series E-2”), and Series F redeemable convertible preferred stock (“Series F”), collectively the (“Preferred Stock”).

In March 2025, the Company entered into a Series F preferred stock purchase agreement (the “Series F Agreement) pursuant to which the Company issued 12,349,423 shares of Series F redeemable convertible preferred stock at a price of $2.6317 per share for gross cash proceeds of $32,499,977. The Series F Agreement also required the Company to issue, and the investors to purchase, an additional 12,349,423 shares of Series F redeemable convertible preferred stock at the same price per share on or around October 15, 2025 for additional gross cash proceeds of $32,499,977 (the “Series F preferred stock tranche obligation”).

In 2022, the Company entered into a Series E preferred stock purchase agreement (the “Series E Agreement”) which provided for the initial issuance of 11,791,051 shares of Series E-2 at a price of $2.5443 per share for gross cash proceeds of $30,000,000. The Series E Agreement also provided the Company an obligation to issue, and the investors an obligation to purchase, an additional 11,791,051 shares of Series E-2 at a price of $2.5443 per share for gross cash proceeds of $30,000,000, when certain conditions were met (the “Series E-2 preferred stock tranche obligation”).

The Company classified the Series F and Series E-2 preferred stock tranche obligations as liabilities on its balance sheets as they each represent a freestanding financial instrument that may require the Company to transfer assets to settle its obligation (upon events that are outside of its control). The Series F and Series E-2 preferred stock

tranche obligations were initially recorded at fair value upon the date of issuance and were subsequently remeasured to fair value at each reporting date until settlement. Changes in the fair value of the Series F and Series E-2 preferred stock tranche obligations were recognized as a component of other income, net in the statements of operations.

The Series F preferred stock tranche obligation was settled in October 2025, with the issuance of 12,349,423 shares of Series F at a price of $2.6317 per share for gross cash proceeds of $32,499,977. The Series F preferred stock tranche obligation had an initial fair value of $680,600 and was subsequently remeasured to its fair value of $915,216 upon settlement in October 2025, with the change in fair value of $234,616 recognized as a component of other income, net in the statements of operations. As a result of the initial issuance of Series F in March 2025, as well as the settlement of the Series F preferred stock tranche obligation in October 2025, 24,698,846 shares of Series F were recorded at their fair value of $64,947,303, net of issuance costs of $287,267.

The Series E-2 preferred stock tranche obligation was partially settled in 2023 with the issuance of 5,895,531 shares of Series E-2 at a price of $2.5443 per share for gross cash proceeds of $15,000,000. The remaining Series E-2 preferred stock tranche obligation was settled in October 2024 with the issuance of the remaining 5,895,531 shares of Series E-2 at a price of $2.5443 per share for gross cash proceeds of $15,000,000. The remaining Series E-2 preferred stock tranche obligation had a fair value of $299,360 as of January 1, 2024 and was subsequently remeasured to its fair value of $311,800 upon settlement in October 2024, with the change in fair value of $12,440 recognized as a component of other income, net in the statements of operations. As a result of this issuance, the remaining Series E-2 preferred stock tranche obligation of $311,800 was settled and the 5,895,531 shares of Series E-2 were recorded at their fair value of $15,298,362, net of issuance costs of $13,358.

Preferred Stock consists of the following:

	December 31, 2025				
	Number of Shares Authorized	Number of Shares Issued and Outstanding	Original issuance price	Carrying Value	Liquidation Value
Series A	1,401,000	1,401,000	1.91259	$ 2,693,549	$ 3,215,447
Series B	4,229,000	3,321,000	3.73744	10,849,354	14,894,446
Series C	1,362,000	1,362,000	4.207	5,743,554	5,729,934
Series D	5,127,000	4,865,000	4.207	19,989,164	20,467,055
Series E-1	6,361,753	6,361,753	2.0354	15,840,765	12,948,713
Series E-2	23,994,804	23,582,102	2.5443	59,709,186	59,999,943
Series F	24,698,846	24,698,846	2.6317	64,947,303	64,999,954
	67,174,403	65,591,701		$ 179,772,875	$ 182,255,492

	December 31, 2024				
	Number of Shares Authorized	Number of Shares Issued and Outstanding	Original issuance price	Carrying Value	Liquidation Value
Series A	1,401,000	1,401,000	1.91259	$ 2,693,549	$ 3,215,447
Series B	4,229,000	3,321,000	3.73744	10,849,354	14,894,446
Series C	1,362,000	1,362,000	4.207	5,743,554	5,729,934
Series D	5,127,000	4,865,000	4.207	19,989,164	20,467,055
Series E-1	6,361,753	6,361,753	2.0354	15,840,765	12,948,713
Series E-2	23,994,804	23,582,102	2.5443	59,709,186	59,999,943
	42,475,557	40,892,855		$ 114,825,572	$ 117,255,538

Dividends

In the event dividends are declared by the Board of Directors on the common stock (except dividends on common stock payable in additional shares of common stock), the holders of the Preferred Stock shall be entitled to

receive a dividend per share on the Preferred Stock, as applicable, pro rata with the shares of common stock, as if such shares of Preferred Stock had been converted to shares of common stock, assuming for this purpose only that shares of redeemable convertible preferred stock are convertible into fractional shares, at the record date for the determination of stockholders entitled to such dividends. The right to receive dividends on shares of redeemable convertible preferred stock is non-cumulative, and no right to such dividends accrues to holders of redeemable convertible preferred stock by reason of the fact that dividends on such shares are not declared or paid in any years. For the years ended December 31, 2025 and 2024, no dividends had been declared or paid.

Liquidation Rights

In the event of any voluntary or involuntary liquidation, dissolution, or winding up of the Company, or in the event of a deemed liquidation event (as defined below) the holders of Preferred Stock are entitled to liquidation preferences.

Payment of liquidation preferences rights to preferred stockholders are in the order of: first, the Series F redeemable convertible preferred stock, then the Series E-2 and Series E-1 redeemable convertible preferred stock, then the Series D redeemable convertible preferred stock, then the Series C redeemable convertible preferred stock, then the Series B and A redeemable convertible preferred stock. The liquidation values for the Series F, Series E-2, Series E-1, Series D, and Series C redeemable convertible preferred stock are equivalent to an amount equal to the respective original issue price per share, adjusted for any recapitalization, stock split and the like, plus any dividends declared but unpaid thereon. The liquidation values for the Series B and Series A redeemable convertible preferred stock are equivalent the greater of (i) an amount equal to 1.2 multiplied by the respective original issue price per share, adjusted for any recapitalization, stock split and the like, plus any dividends declared but unpaid thereon, or (ii) such amount per share as would have been payable had all shares of Series B and Series A redeemable convertible preferred stock been converted into common stock immediately prior to such liquidation, dissolution or winding up. The remaining assets, if any, shall be distributed among the holders of the shares of common stock, Series C Preferred Stock, Series D Preferred Stock, Series E-1 Preferred Stock, Series E-2 Preferred Stock, and Series F Preferred Stock, pro rata based on the number of shares held by each such holder, treating for this purpose all such securities as if they had been converted to common stock pursuant to the terms of the Amended and Restated Certificate of Incorporation immediately prior to such liquidation, dissolution or winding up of the Corporation, or deemed liquidation event.

If upon the liquidation, dissolution, winding up of the Company, or deemed liquidation event, the assets of the Company legally available for distribution to the holders of the Preferred Stock are insufficient to permit the payment to such holders of the full liquidation preferences to which they are entitled, then the holders of the Company's common stock will receive nothing in respect of their equity holdings in the Company.

A deemed liquidation event is defined as a merger or consolidation of the Company that results in a change of control, or the sale, lease, transfer, exclusive license, or other disposition of substantially all of the assets of the Company to another entity that is less than a wholly owned subsidiary, unless the holders of at least a majority of the outstanding shares of Preferred Stock, voting together as a single class and on an as converted to common stock basis, and the holders of at least a majority of the outstanding shares of Series F, voting exclusively and as a separate class, elect otherwise by written notice sent to the Company prior to the effective date of any such event.

Conversion Rights

Each share of Preferred Stock is convertible at the option of the holder and at any time into common stock as determined by dividing the applicable original issue price by the applicable Conversion Price. Conversion Price is defined as initially the applicable original issue price for the applicable series of Preferred Stock, subject to certain adjustments in the event of any recapitalizations, stock splits and the like, and for certain subsequent dilutive issuances of common stock or deemed dilutive issuances of common stock, at a price per share less than the then applicable conversion prices of the Preferred Stock. Each share of each series of Preferred Stock was convertible into shares of common stock on a 1:3.483 basis.

Each share of the Preferred Stock shall automatically be converted into fully paid and nonassessable shares of common stock at the above then-effective respective conversion price upon, 1) the closing of a sale of shares of

common stock to the public at a price of at least $5.2634 per share (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to common stock), in a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, resulting in at least $75,000,000 of gross proceeds to the Company, before deductions of underwriting discounts, commissions, and expenses or, 2) the date and time, or the occurrence of an event, specified by vote or written consent of (x) the holders of at least a majority of the outstanding shares of Preferred Stock, voting together as a single class and on an as converted to common stock basis, and (y) the holders of at least a majority of the outstanding shares of Series F, voting exclusively and as a separate class.

Voting Rights

The holders of each share of Preferred Stock are entitled to one vote for each share of common stock into which it could be converted on all matters presented to the shareholders for vote.

Redeemable Convertible Preferred Stock Warrants

As of December 31, 2025 and 2024, the Company had 908,000 warrants for Series B redeemable convertible preferred stock ("Series B Preferred Warrants") outstanding, respectively. These warrants were issued during 2012 and 2013 in connection with the issuances of Series B redeemable convertible preferred stock. In addition, as of December 31, 2025 and 2024, the Company had 258,000 warrants for Series D redeemable convertible preferred stock ("Series D Preferred Warrants") outstanding. These warrants were issued in connection with the promissory notes issued in 2017 which were exercised and converted to shares of Series D preferred stock in 2017.

Note 12 – Common Stock

In March 2025, the Company's Board of Directors amended and restated the Company's Certificate of Incorporation to increase the number of authorized shares of common stock to 86,600,000 shares at $0.01 per share.

Note 13 – Share-Based Compensation

On December 15, 2022, the Board of Directors approved the Corporation's 2022 Equity Incentive Plan (the 2022 Plan) providing for the grants of non-qualified stock options, incentive stock options and other stock-based awards up to an aggregate of 7,575,181 shares of common stock, $0.01 par value per share. This consisted of the available reserve from the 2007 Equity Incentive Plan (the 2007 Plan) plus all returned shares. The 2022 Plan serves as the successor to and continuation of the 2007 Plan, and all options that were granted under the 2007 Plan (unless forfeited, exercised or expired) remained outstanding as of December 31, 2022. Awards issued under the 2007 Plan remain subject to the terms of the 2007 Plan, and unissued authorized 2007 shares became available under the 2022 Plan. No issued 2007 Plan awards were converted. The 2007 Plan contained an antidilution provision. Following a 1,000-for-1 common stock split in June 2022, the number of option shares for prior periods was retrospectively adjusted to reflect the split. No other terms of these existing awards were changed except for the number of option shares and the exercise price to reflect the stock split. Because the modification did not result in incremental fair value under ASC 718, no additional compensation expense was recognized in 2022.

Under the 2022 Plan, stock options generally vest and become exercisable in respect of 25% of the total number of Shares initially subject to the Options on the first anniversary of the Vesting Commencement Date, and in respect of 1/48th of the total number of Shares initially subject to the Option on each monthly anniversary of the Vesting Commencement Date thereafter, so that 100% of the Shares subject to the Option shall be vested on the fourth anniversary of the Vesting Commencement Date, in each case, subject to the Optionee remaining as a Service Provider (as defined in the Plan) through the applicable vesting date. Certain awards may vest immediately upon grant or may be subject to performance-based vesting conditions, as determined by the Board of Directors. During the year ended 2025, the Company granted two executive awards that include performance-based vesting conditions which are immaterial. The Board of Directors administers the 2022 Plan and determines the exercise prices of options based on the fair value of the Company's common stock as determined by an independent valuation, in certain instances, options have been granted with an exercise price in excess of fair market value at the date of grant.

The fair market value of stock options was estimated using the Black-Scholes valuation model. Since the Company does not have sufficient trading history of its common stock, it estimates the expected volatility of its stock options at their grant date by taking the weighted average historical volatility of a group of comparable publicly traded companies over a period of time equal to the expected life of the options. The Company uses the simplified method to calculate the expected term and contractual terms. Under the simplified method, the expected life is equal to the average of the share-based award's weighted average vesting period and its contractual term. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. There were no expected dividends. The following assumptions were used in estimating the fair value of option grants issue in 2025 and 2024:

	2025	2024
Expected term (in years)	3.3 – 6.1	5.0 – 6.1
Volatility	51.0% — 53.4%	49.5% — 51.0%
Risk-free interest rate	3.7% — 4.2%	3.9% — 4.7%
Dividend yield	—	—

Stock options - A summary of officer, employee, and non-employee options granted and outstanding, under the 2007 and 2022 Plans are presented below:

	Number of Options	Weighted-Average Exercise Prices	Weighted-Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value
Balance as of January 1, 2024	2,235,564	$ 3.13	7.67	$ 665,396
Options Granted	320,469	$ 3.24		
Options Exercised	(291,585)	$ 2.31		
Options Forfeited, Cancelled, or Expired	(174,419)	$ 3.31		
Balance as of December 31, 2024	2,090,029	$ 3.25	7.41	$ 1,069,594
Options Granted	2,092,274	$ 3.80		
Options Exercised	(107,329)	$ 2.93		
Options Forfeited, Cancelled, or Expired	(28,708)	$ 3.31		
Balance as of December 31, 2025	4,046,266	$ 3.51	7.90	$ 1,611,084
Vested and Exercisable at December 31, 2025	1,756,206	$ 3.30	6.45	

The following table summarizes information about stock options outstanding as of December 31, 2025:

	Options Outstanding			Options Vested	
Exercise price	Number of Shares	Weighted-Average Exercise Prices	Weighted-Average Remaining Contractual Life	Number of Shares	Weighted-Average Exercise Price
$ 1.45	2,871	$ 1.45	0.27	2,871	$ 1.45
$ 2.79	84,409	$ 2.79	3.02	84,409	$ 2.79
$ 1.39	35,887	$ 1.39	3.56	35,887	$ 1.39
$ 2.66	97,041	$ 2.66	4.69	97,041	$ 2.66
$ 2.88	43,066	$ 2.88	5.34	43,066	$ 2.88
$ 3.38	1,248,740	$ 3.38	6.99	1,082,421	$ 3.38
$ 3.41	44,157	$ 3.41	7.27	24,851	$ 3.41
$ 3.24	286,327	$ 3.24	8.51	109,257	$ 3.24
$ 4.11	99,604	$ 4.11	4.23	16,344	$ 4.11
$ 3.73	1,567,532	$ 3.73	8.75	260,059	$ 3.73
$ 3.94	536,632	$ 3.94	9.81	—	$ 3.94
	4,046,266	$ 3.51	7.90	1,756,206	$ 3.22

The following table summarizes information about stock options outstanding as of December 31, 2024:

	Options Outstanding			Options Vested	
Exercise Price	Number of Shares	Weighted-Average Exercise Prices	Weighted-Average Remaining Contractual Life	Number of Shares	Weighted-Average Exercise Price
$ 1.45	2,871	$ 1.45	1.27	2,871	$ 1.45
$ 2.79	91,586	$ 2.79	3.73	91,586	$ 2.79
$ 1.39	55,984	$ 1.39	4.41	55,984	$ 1.39
$ 2.66	109,099	$ 2.66	5.25	109,099	$ 2.66
$ 2.88	43,066	$ 2.88	6.34	43,066	$ 2.88
$ 3.73	120,912	$ 3.73	2.95	88,165	$ 3.73
$ 3.38	1,317,563	$ 3.38	7.90	815,024	$ 3.38
$ 3.41	50,873	$ 3.41	8.79	16,452	$ 3.41
$ 3.24	298,075	$ 3.24	9.51	1,076	$ 3.24
	2,090,029	$ 3.25	7.41	1,223,323	$ 3.18

The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying stock options and the fair value of the Company's common stock for stock options that were in-the-money at period end. The aggregate intrinsic value of options exercisable at December 31, 2025, was $1,111,740. The aggregate intrinsic value of all options exercised during the year ended December 31, 2025 was $91,655. The total fair value of options vested during the year ended December 31, 2025 was $1,125,864. The options granted during the year ended December 31, 2025 had a weighted average grant date fair value of $2.01. The options forfeited during the year ended December 31, 2025 had a weighted average grant date fair value of $1.81. The total compensation cost related to non-vested stock options to be recognized in the future was $4,051,822 over a weighted-average period of approximately 2.9 years at December 31, 2025.

The aggregate intrinsic value of options exercisable at December 31, 2024, was $708,758. The aggregate intrinsic value of all options exercised during the year ended December 31, 2024 was $275,850. The total fair value of options vested during the year ended December 31, 2024 was $840,253. The options granted during the year ended December 31, 2024 had a weighted average grant date fair value of $1.71. The options forfeited during the year ended December 31, 2024 had a weighted average grant date fair value of $1.65. The total compensation cost

related to non-vested stock options to be recognized in the future was $1,349,759 over a weighted-average period of approximately 2.3 years at December 31, 2024.

The Company recognized $1,446,702 and $758,127 of share-based compensation expense for the years ended December 31, 2025 and 2024. For the year ended December 31, 2025, $132,018 was recorded in research and development expenses and $1,314,684 was recorded in selling, general and administrative expenses. For the year ended December 31, 2024, all share-based compensation expense was recorded in selling, general and administrative expenses.

Note 14 – Net Loss Per Share

Net loss per share is calculated by dividing net loss attributable to common stockholders by the weighted-average number of shares of common stock outstanding during the period. Diluted earnings per share is calculated similarly but includes potential dilution from the exercise of stock options and stock awards and conversion of redeemable convertible preferred stock, except when the effect would be anti-dilutive. The following is a reconciliation of the numerators and denominators of the basic and diluted net loss per share computations for the years ended December 31, 2025 and 2024:

Net loss (numerator):	2025	2024
Net loss attributable to common stockholders	$ (46,498,188)	$ (24,603,014)
Share (denominator):		
Weighted average number of common shares outstanding used in basic computation	848,812	574,632
Common shares issuable upon the exercise of stock options	—	—
Common shares issuable upon conversion of redeemable convertible preferred stock and warrants on redeemable convertible preferred stock	—	—
Weighted average number of common shares outstanding used in diluted computation	848,812	574,632
Net loss attributable to common stockholders, per common share		
Basic	$ (54.78)	$ (42.82)
Diluted	$ (54.78)	$ (42.82)

The following table summarizes the as converted securities that were excluded from the diluted per share calculation because the effect of including these potential shares was anti-dilutive:

	2025	2024
Series A redeemable convertible preferred stock	402,239	402,239
Series B redeemable convertible preferred stock	953,488	953,488
Series C redeemable convertible preferred stock	391,042	391,042
Series D redeemable convertible preferred stock	1,396,784	1,396,784
Series E redeemable convertible preferred stock	8,597,145	8,597,145
Series F redeemable convertible preferred stock	7,091,256	—
Warrants on redeemable convertible preferred stock	364,390	364,390
Common shares issuable upon the exercise of stock options	4,046,266	2,090,029
Potentially dilutive securities	23,242,610	14,195,117

Note 15 – Commitments and Contingencies

From time to time, the Company may become a party to claims, legal actions, and complaints arising in the ordinary course of business. Management is not aware of any such matters which would have a material effect on its financial positions, results of operations, or cash flows. The Company relies on third-party manufacturers for the production of its IPGs and stimulation leads. Certain of these arrangements include non-cancelable purchase commitments and binding forecast obligations. The Company issues purchase orders based on production requirements, which are generally non-cancelable once accepted by the supplier. As of December 31, 2025 and 2024, the Company had outstanding non-cancelable purchase orders totaling approximately $7.1 million and $5.9 million, respectively. The December 31, 2025 purchase orders are expected to be fulfilled during 2026.

During September 2024, the Company entered into an updated IPG supply agreement that expanded the scope of its supply arrangements with the third-party manufacturer. The agreement includes minimum annual purchase commitments over a five-year period commencing upon the first commercial shipment of product under the agreement. The first commercial shipment is currently expected to occur in 2028. The agreement also requires the Company to provide rolling twelve-month forecasts, portions of which may become binding. As of December 31, 2025, no binding forecast commitments had been established under this agreement. The aggregate minimum purchase obligation over the five-year commitment period totals approximately $5.8 million.

Note 16 – Segment Information

The Company's measure of segment profit or loss is net loss, which is used by the CODM to measure actual results versus expectations, set performance metrics, and during the Company's budgeting and forecasting process to assess profitability and enable decision making. Significant segment expenses within net loss include cost of goods sold, research and development, and selling, general and administrative expenses. The only segment assets regularly reviewed by the CODM is cash and cash equivalents, which is reported on the balance sheets. No sales to an individual customer accounted for more than 10% of the Company's total revenue for the years ended December 31, 2025 and 2024.

During the year ended December 31, 2025, the Company reevaluated the financial information regularly provided to and reviewed by the CODM for purposes of assessing segment performance and allocating resources. As a result of this evaluation, the Company determined that sales and marketing, a previously disclosed significant segment expense category, is no longer separately reviewed by the CODM and is now evaluated together with general and administrative expenses. Accordingly, the Company has reflected this change within the current period presentation and the prior-period segment disclosures have been recast to conform to the current period presentation. This change reflects an update to the internal management reporting package and does not represent a change in the Company's single operating and reportable segment, or measurement of segment profit or loss.

The following table is representative of revenue and significant segment expense categories regularly provided to the CODM for purposes of managing the Company's single operating and reportable segment for the years ended December 31, 2025 and 2024. Segment revenue and net loss are consistent with the statements of operations.

	2025	2024
Revenue	$ 32,040,978	$ 15,644,398
Less:		
Cost of goods sold	6,065,955	3,193,173
Research and development	6,515,249	4,243,399
Selling, general and administrative expenses[1]	65,827,675	32,444,116
Other segment items[2]	130,287	366,724
Net loss	$ (46,498,188)	$ (24,603,014)

(1) Selling, general and administrative expenses include depreciation and amortization expense of $151,657 and $116,010 as of December 31, 2025 and 2024, respectively.
(2) Other segment items are comprised of interest expense, other income, net, and provision for income taxes, as shown on the statements of operations.

Note 17 – Employee Benefit Plan

The Company has a 401(k) retirement plan covering substantially all employees. The Company makes matching contributions of 4% of an employee's annual compensation, subject to certain limitations under the Internal Revenue Code. During 2025 and 2024, matching contributions of $1,008,202 and $563,668, respectively, were made to the plan.

Note 18 – Subsequent Events

Subsequent events are events or transactions that occur after the date of the financial statements but before the financial statements are issued. The Company recognizes in the financial statements the effects of all subsequent events that provide additional evidence about conditions that existed at the date of the balance sheet, including the estimates inherent in the process of preparing the financial statements. The Company does not recognize subsequent events that provide evidence about conditions that did not exist at the date of the balance sheet and issuance of the financial statements. Subsequent events have been evaluated as of March 11, 2026, which is the date the financial statements were available to be issued.

During January 2026, the Company entered into a Note Purchase Agreement with certain investors pursuant to which the Company issued convertible promissory notes in an aggregate principal amount of approximately $27.3 million at the initial closing. The notes bear payment-in-kind interest at a rate of 7.0% per annum and are convertible into equity securities of the Company upon the occurrence of certain events, including a qualified financing, change in control, or initial public offering. The agreement permits the Company to issue additional notes for total aggregate proceeds of up to $40 million. During February 2026 the Company issued additional notes of $12.7 million, for a total outstanding principal of $40 million. The Company has concluded that the issuance of the convertible promissory notes represents a nonrecognized subsequent event under ASC 855. Accordingly, no amounts related to this transaction have been reflected in the accompanying financial statements as of December 31, 2025.

Events Subsequent to Original Issuance of Financial Statements (Unaudited)

In connection with the reissuance of these financial statements, the Company has evaluated subsequent events through May 4, 2026, the date the financial statements were available to be reissued. The Company has concluded that no subsequent events have occurred that require disclosure.

Through and including , 2026 (the 25th day after the date of this prospectus), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This delivery requirement is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

10,000,000 Shares

Common Stock

BofA Securities

J.P. Morgan

Goldman Sachs & Co. LLC

BTIG

Wolfe | Nomura Alliance

, 2026

PART II

INFORMATION NOT REQUIRED IN THE PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution

The following table sets forth the expenses to be incurred in connection with the offering described in this Registration Statement, other than underwriting discounts and commissions, all of which will be paid by us. All amounts are estimates except the Securities and Exchange Commission's registration fee, the Financial Industry Regulatory Authority, Inc.'s filing fee and the Nasdaq listing fee.

		Amount to be paid
Securities and Exchange Commission registration fee	$	25,392
FINRA filing fee	$	15,500
Nasdaq listing fee	$	295,000
Printing and engraving expenses	$	275,000
Legal fees and expenses	$	3,125,000
Accounting fees and expenses	$	1,200,000
Transfer agent and registrar fees	$	4,500
Miscellaneous expenses	$	59,608
Total	$	5,000,000

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Item 14. Indemnification of Directors and Officers

Section 145 of the General Corporation Law of the State of Delaware (the Delaware General Corporation Law) provides that a corporation may indemnify directors and officers as well as other employees and individuals against expenses (including attorneys' fees), judgments, fines, and amounts paid in settlement actually and reasonably incurred by such person in connection with any threatened, pending, or completed actions, suits, or proceedings in which such person is made a party by reason of such person being or having been a director, officer, employee, or agent to the registrant. The Delaware General Corporation Law provides that Section 145 is not exclusive of other rights to which those seeking indemnification may be entitled under any bylaw, agreement, vote of stockholders or disinterested directors, or otherwise. Article 8 of the registrant's amended and restated certificate of incorporation provides for indemnification by the registrant of its directors, officers, and employees to the fullest extent permitted by the Delaware General Corporation Law. The registrant has entered into indemnification agreements with each of its current directors, executive officers, and certain other officers to provide these directors and officers additional contractual assurances regarding the scope of the indemnification set forth in the registrant's amended and restated certificate of incorporation and amended and restated bylaws and to provide additional procedural protections. There is no pending litigation or proceeding involving a director or executive officer of the registrant for which indemnification is sought.

Section 102(b)(7) of the Delaware General Corporation Law permits a corporation to provide in its certificate of incorporation that a director or officer of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for certain breaches of fiduciary duties as a director or an officer, except for liability for: (i) any breach of the director's or officer's duty of loyalty to the corporation or its stockholders; (ii) any act or omission not in good faith or which involved intentional misconduct or a knowing violation of law; (iii) in the case of directors, for unlawful payments of dividends or unlawful stock repurchases, redemptions, or other distributions; (iv) any transaction from which the director or officer derived an improper personal benefit; or (v) an officer in any action by or in the right of the corporation. The registrant's amended and restated certificate of incorporation provides for such limitation of liability.

The registrant maintains standard policies of insurance under which coverage is provided (a) to its directors and officers against loss rising from claims made by reason of breach of duty or other wrongful act and (b) to the registrant with respect to payments that may be made by the registrant to such officers and directors pursuant to the above indemnification provision or otherwise as a matter of law.

The proposed form of underwriting agreement filed as Exhibit 1.1. to this registration statement provides for indemnification of officers and directors of the registrant by the underwriters against certain liabilities.

Item 15. Recent Sales of Unregistered Securities

The following list sets forth information regarding all unregistered securities sold by us since January 1, 2023. No underwriters were involved in the sales and the certificates representing the securities sold and issued contain legends restricting transfer of the securities without registration under the Securities Act or an applicable exemption from registration.

- In December 2023, in connection with our entry into a loan and security agreement, we issued warrants to purchase up to an aggregate of $262,500 of (i) shares of Series E-2 redeemable convertible preferred stock at an exercise price of $2.5443 per share or (ii) shares of Series F redeemable convertible preferred stock at an exercise price of $2.6317 per share. The warrants will convert into warrants to purchase common stock upon completion of our initial public offering.
- In December 2023 and October 2024, we issued and sold to certain investors in a private placement an aggregate of 5,895,531 shares and 5,895,531 shares of Series E-2 redeemable convertible preferred stock, respectively, at a purchase price of $2.5443 per share, for aggregate consideration of approximately $30.0 million. All of our shares of Series E-2 redeemable convertible preferred stock will convert into shares of our common stock immediately prior to the completion of our initial public offering.
- In March 2025 and October 2025, we issued and sold to certain investors in a private placement an aggregate of 12,349,423 shares and 12,349,423 shares of Series F redeemable convertible preferred stock, respectively, at a purchase price of $2.6317 per share, for aggregate consideration of approximately $65.0 million. All of our shares of Series F redeemable convertible preferred stock will convert into shares of our common stock immediately prior to the completion of our initial public offering.
- Since January 2023, we have issued options to purchase an aggregate of 3,381,174 shares of common stock under our 2022 Equity Incentive Plan at exercise prices ranging from $3.24 to $7.91 per share. Since January 2023, we have issued an aggregate of 621,796 shares of our common stock upon exercise of stock options for an approximate aggregate consideration of $1,600,557.
- In January 2026 and February 2026, we issued and sold to certain investors in a private placement an aggregate principal amount of $40.0 million convertible promissory notes. Immediately prior to the closing of this offering, the aggregate principal amount and any accrued interest on the convertible promissory notes will automatically convert into shares of our common stock.

The offers, sales and issuances of the securities described in Items 15(a), 15(b), 15(c), 15(d), and 15(e) were exempt from registration under the Securities Act under Section 4(a)(2) of the Securities Act or Regulation D promulgated thereunder as transactions by an issuer not involving a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was an accredited person and had adequate access, through employment, business, or other relationships, to information about the registrant.

The offers, sales and issuances of the securities described in Item 15(f) and Item 15(g) were exempt from registration under the Securities Act under either (1) Rule 701 in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under Rule 701 or (2) Section 4(a)(2) of the Securities Act as transactions by an issuer not involving any public offering. The recipients of such securities were the registrant's employees, consultants or directors and received the securities under our 2022 Plan. The recipients of

securities in each of these transactions represented their intention to acquire the securities for investment only and not with view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions.

Item 16. Exhibit and Financial Statement Schedules

(a) Exhibits.

See the Exhibit Index immediately preceding the signature page hereto for a list of exhibits filed as part of this registration statement on Form S-1, which Exhibit Index is incorporated herein by reference.

(b) Financial Statement Schedules.

Schedules have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

EXHIBIT INDEX

Exhibit Number	Description
1.1*	Form of Underwriting Agreement, including Form of Lock-up Agreement.
3.1*	Amended and Restated Certificate of Incorporation of the Registrant, as currently in effect.
3.1.1*	Certificate of Amendment of Certificate of Incorporation of the Registrant.
3.1.2	Certificate of Amendment of Certificate of Incorporation of the Registrant.
3.2	Form of Amended and Restated Certificate of Incorporation of the Registrant, to be in effect upon the completion of this offering.
3.3*	Amended and Restated Bylaws of the Registrant, as currently in effect.
3.4*	Form of Amended and Restated Bylaws of the Registrant, to be in effect upon the completion of this offering.
4.1*^	Amended and Restated Registration Rights Agreement among the Registrant and certain of its stockholders, dated March 5, 2025.
4.2*^	Amended and Restated Shareholders' Agreement among the Registrant and certain of its stockholders, dated March 5, 2025.
4.3*	Specimen Common Stock Certificate of the Registrant.
4.4*	Warrant to Purchase Shares of Series Preferred Stock (Loan A) issued December 29, 2023, by the Registrant to Horizon Technology Finance Corporation.
4.5*	Warrant to Purchase Shares of Series Preferred Stock (Loan B) issued December 29, 2023, by the Registrant to Horizon Technology Finance Corporation.
4.6*	Form of Convertible Promissory Note.
5.1	Opinion of Latham & Watkins LLP.
10.1*+	Form of Indemnification Agreement between the Registrant and each of its directors and executive officers.
10.2*+	2007 Stock Option Plan, as amended.
10.2.1*+	Form of Stock Option Agreement under the 2007 Stock Option Plan, as amended.
10.3*+	2022 Equity Incentive Plan, as amended.
10.3.1*+	Form of Stock Option Agreement under the 2022 Equity Incentive Plan, as amended.
10.3.2*+	Form of Restricted Stock Purchase Agreement under the 2022 Equity Incentive Plan, as amended.
10.4*+	2026 Incentive Award Plan, to be in effect upon the completion of this offering.
10.4.1*+	Form of Option Award Agreement under the 2026 Incentive Award Plan.
10.4.2*+	Form of Restricted Stock Unit Award Agreement under the 2026 Incentive Award Plan.
10.5*+	2026 Employee Stock Purchase Plan, to be in effect upon the completion of this offering.

Exhibit Number	Description
10.6*+	Non-Employee Director Compensation Program.
10.7*^	Second Amended and Restated License Agreement by and between the Registrant and the Board of Regents of the University of Texas System on behalf of The University of Texas at Dallas, dated April 28, 2014.
10.8*^	Venture Loan and Security Agreement by and between the Registrant and Horizon Technology Finance Corporation, dated December 29, 2023.
10.9*^	Note Purchase Agreement by and among the Registrant and the purchasers party thereto.
10.10*+	Employment Agreement between the Registrant and Nelson Bunker Curnes, dated October 23, 2021.
10.11*+	Employment Agreement between the Registrant and Thomas Jordan Curnes II, dated October 23, 2021.
10.12*+	Restated Employment Agreement between the Registrant and Richard Foust, dated April 3, 2026, to be in effect upon the completion of this offering.
10.13*+	Restated Employment Agreement between the Registrant and Nelson Bunker Curnes, dated April 3, 2026, to be in effect upon the completion of this offering.
10.14*+	Restated Employment Agreement between the Registrant and Thomas Jordan Curnes II, dated April 3, 2026, to be in effect upon the completion of this offering.
10.15*+	Restated Employment Agreement between the Registrant and Douglas (Doug) Ellison, dated April 3, 2026, to be in effect upon the completion of this offering.
10.16*+	Restated Employment Agreement between the Registrant and Prashant Rawat, dated April 3, 2026, to be in effect upon the completion of this offering.
10.17*+	Restated Employment Agreement between the Registrant and Chase Leavitt, dated April 3, 2026, to be in effect upon the completion of this offering.
10.18*+	Executive and Key Employee Severance and Change in Control Plan, to be in effect upon the completion of this offering.
10.19*#^	Supply Agreement, effective September 24, 2024, by and between the Registrant and Greatbatch Ltd.
23.1	Consent of PricewaterhouseCoopers LLP.
23.2	Consent of Latham & Watkins LLP (included in Exhibit 5.1).
24.1*	Power of Attorney (see signature page to this Form S-1).
107.1	Filing Fee Table.

* Previously filed.
\+ Indicated management contract or compensatory plan.
\# Portions of the exhibit have been omitted as the Registrant has determined that: (i) the omitted information is not material; and (ii) the omitted information would likely cause competitive harm to the Registrant if publicly disclosed.
^ Pursuant to Item 601(a)(5) of Regulation S-K, the registrant has omitted certain of the schedules (or similar attachments) to this exhibit.

Item 17. Undertakings

The undersigned registrant hereby undertakes to provide to the underwriters at the completion specified in the underwriting agreements, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act of 1933 shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this Amendment No. 2 to the Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Austin, State of Texas, on the 4th day of May, 2026.

MOBIA MEDICAL, INC.

By: /s/ Richard Foust
Richard Foust
President & Chief Executive Officer

POWER OF ATTORNEY

Pursuant to the requirements of the Securities Act of 1933, as amended, this Amendment No. 2 to the Registration Statement on Form S-1 has been signed by the following persons in the capacities held on the dates indicated.

Signature	Title	Date
/s/ Richard Foust Richard Foust	President & Chief Executive Officer and Director (Principal Executive Officer)	May 4, 2026
/s/ Nelson Bunker Curnes Nelson Bunker Curnes	Chief Financial Officer and Director (Principal Financial and Accounting Officer)	May 4, 2026
* Dana G. Mead, Jr.	Chair of the Board of Directors	May 4, 2026
* Maxwell Bikoff	Director	May 4, 2026
* Thomas Jordan Curnes II	Director	May 4, 2026
* Edward Hanlon	Director	May 4, 2026
* William Harrington	Director	May 4, 2026
* Cynthia Lucchese	Director	May 4, 2026
* Casey Tansey	Director	May 4, 2026

* By: /s/ Richard Foust
Richard Foust
Attorney-in-Fact

Calculation of Filing Fee Tables

S-1

Mobia Medical, Inc.

Table 1: Newly Registered and Carry Forward Securities ☐Not Applicable

		Security Type	Security Class Title	Fee Calculation or Carry Forward Rule	Amount Registered	Proposed Maximum Offering Price Per Unit	Maximum Aggregate Offering Price	Fee Rate	Amount of Registration Fee	Carry Forward Form Type	Carry Forward File Number	Carry Forward Initial Effective Date	Filing Fee Previously Paid in Connection with Unsold Securities to be Carried Forward
Newly Registered Securities													
Fees to be Paid	1	Equity	Common stock, $0.01 par value per share	457(a)	5,250,000	$ 16.00	$ 84,000,000.00	0.0001381	$ 11,600.40				
Fees Previously Paid	2	Equity	Common stock, $0.01 par value per share	457(a)	6,250,000	$ 16.00	$ 100,000,000.00		$ 13,810.00				
Carry Forward Securities													
Carry Forward Securities													
				Total Offering Amounts:			$ 184,000,000.00		$ 25,410.40				
				Total Fees Previously Paid:					$ 13,810.00				
				Total Fee Offsets:					$ 0.00				
				Net Fee Due:					$ 11,600.40				

Offering Note

1 Includes the aggregate offering price of additional shares that the underwriters have the option to purchase to cover over-allotments, if any.

2 This Maximum Aggregate Offering Price was originally registered under 457(o) and is now converted to 457(a)

Table 2: Fee Offset Claims and Sources ☑Not Applicable

		Registrant or Filer Name	Form or Filing Type	File Number	Initial Filing Date	Filing Date	Fee Offset Claimed	Security Type Associated with Fee Offset Claimed	Security Title Associated with Fee Offset Claimed	Unsold Securities Associated with Fee Offset Claimed	Unsold Aggregate Offering Amount Associated with Fee Offset Claimed	Fee Paid with Fee Offset Source
Rules 457(b) and 0-11(a)(2)												
Fee Offset Claims												
Fee Offset Sources												
Rule 457(p)												
Fee Offset Claims												
Fee Offset Sources												

Table 3: Combined Prospectuses ☑Not Applicable

	Security Type	Security Class Title	Amount of Securities Previously Registered	Maximum Aggregate Offering Price of Securities Previously Registered	Form Type	File Number	Initial Effective Date

CERTIFICATE OF AMENDMENT
OF
AMENDED AND RESTATED CERTIFICATE OF INCORPORATION
OF
MOBIA MEDICAL, INC.

Pursuant to Section 242 of the
General Corporation Law of the State of Delaware

Mobia Medical, Inc., a corporation organized and existing under and by virtue of the General Corporation Law of the State of Delaware (the "***Corporation***"), does hereby certify as follows:

1. The Board of Directors of the Corporation duly adopted resolutions at a meeting recommending and declaring advisable that the Amended and Restated Certificate of Incorporation of the Corporation be amended and that such amendments be submitted to the stockholders of the Corporation for their consideration, as follows:

RESOLVED, that the first paragraph of Article IV of the Amended and Restated Certificate of Incorporation of the Corporation be amended and restated in its entirety to read as follows:

"Effective upon the time of the filing of this Certificate of Amendment to the Amended and Restated Certificate of Incorporation with the Secretary of State of the State of Delaware (the "**Amendment Filing Time**"), a one-for-3.483 reverse split of Common Stock (as defined below) shall become effective, pursuant to which each 3.483 shares of Common Stock outstanding and held of record by any stockholder of the Corporation (including treasury shares) immediately prior to the Amendment Filing Time shall be reclassified and combined into one validly issued, fully-paid and nonassessable share of Common Stock automatically and without any action by the holder thereof upon the Amendment Filing Time and shall represent one share of Common Stock from and after the Amendment Filing Time (such reclassification and combination of shares, the "**Reverse Stock Split**"). The par value of the Common Stock and the Preferred Stock (as defined below) following the Reverse Stock Split shall remain at $0.01 per share. No fractional shares of Common Stock shall be issued as a result of the Reverse Stock Split. In lieu thereof, any holder who would otherwise be entitled to receive a fractional share of Common Stock as a result of the Reverse Stock Split shall have such fractional share rounded down to the nearest whole share, and the Corporation shall pay to such holder, upon surrender of a certificate which formerly represented shares of Common Stock that were issued and outstanding immediately prior to the Amendment Filing Time, a cash payment (without interest) equal to such fraction to which such holder would otherwise be entitled multiplied by the fair market value per share of the Common Stock as determined in good faith by the Board of Directors of the Corporation. Concurrently with the effectiveness of the Reverse Stock Split, the conversion price applicable to each outstanding share of each series of Preferred Stock shall be proportionately increased (*i.e.*, multiplied by the reverse stock split ratio) in accordance with Section 4.5 of Part B of this Article IV, such that the number of shares of Common Stock

issuable upon conversion of each share of Preferred Stock shall be correspondingly decreased in proportion to the Reverse Stock Split.

Each stock certificate that, immediately prior to the Amendment Filing Time, represented shares of Common Stock that were issued and outstanding immediately prior to the Amendment Filing Time shall, from and after the Amendment Filing Time, automatically and without the necessity of presenting the same for exchange, represent that number of whole shares of Common Stock after the Amendment Filing Time into which the shares formerly represented by such certificate have been reclassified and combined (as well as the right to receive cash in lieu of fractional shares of Common Stock after the Amendment Filing Time); provided, however, that each person of record holding a certificate that represented shares of Common Stock that were issued and outstanding immediately prior to the Amendment Filing Time shall receive, upon surrender of such certificate, a new certificate evidencing and representing the number of whole shares of Common Stock after the Amendment Filing Time into which the shares of Common Stock formerly represented by such certificate shall have been reclassified and combined; and provided, further, that whether or not fractional shares would be issuable as a result of the Reverse Stock Split shall be determined on the basis of (i) the total number of shares of Common Stock that were issued and outstanding immediately prior to the Amendment Filing Time formerly represented by a certificate that the holder is at the time surrendering and (ii) the aggregate number of whole shares of Common Stock after the Amendment Filing Time into which such shares of Common Stock formerly represented by such certificate shall have been reclassified and combined, with any resulting fractional share being rounded down to the nearest whole share.

The total number of shares of all classes of stock which the Corporation shall have authority to issue is 1,017,174,403 shares divided into the following: (i) 950,000,000 shares of Common Stock, $0.01 par value per share (the "**Common Stock**"), and (ii) 67,174,403 shares of Preferred Stock, $0.01 par value per share (the "**Preferred Stock**"). The Preferred Stock may be divided into and issued in one or more series. The Board of Directors is hereby vested with authority to establish and designate such series from time to time, and within the limitations prescribed by law or set forth herein, to fix and determine the preferences, limitations and relative rights of the shares of any series so established."

RESOLVED, that Section 5.1 of Part B of Article IV of the Amended and Restated Certificate of Incorporation of the Corporation be amended and restated in its entirety to read as follows:

"5.1 Trigger Events. Upon either (a) the closing of the sale of shares of Common Stock to the public at a price of at least $18.3324 per share (subject to appropriate adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization with respect to the Common Stock), in a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, resulting in at least $75,000,000 of gross proceeds to the Corporation, before deductions of underwriting discounts, commissions and expenses, (b) the date and time, or the occurrence of an event, specified by vote or written consent of (x) the Requisite Majority, and (y) the Requisite Series F Holders, each

voting exclusively and as a separate class or (c) immediately prior to the closing of the Corporation's sale of its Common Stock in a firm commitment underwritten public offering pursuant to the Corporation's Registration Statement on Form S-1 (Reg. No. 333-295160) (the time of or immediately prior to any such closing or the date and time specified or the time of the event specified in such vote or written consent is referred to herein as the "Mandatory Conversion Time"), then (i) all outstanding shares of Preferred Stock shall automatically be converted into shares of Common Stock, at the then effective conversion rate and (ii) such shares may not be reissued by the Corporation."

2. The stockholders of the Corporation duly approved such amendments by written consent in accordance with Section 228 of the General Corporation Law of the State of Delaware.

3. Such amendments have been duly adopted in accordance with Section 242 of the General Corporation Law of the State of Delaware.

* * *

IN WITNESS WHEREOF, this Certificate of Amendment of the Amended and Restated Certificate of Incorporation has been executed by a duly authorized officer of the Corporation on May 1, 2026.

By: /s/ Richard Foust
Name: Richard Foust
Title: Chief Executive Officer

AMENDED AND RESTATED CERTIFICATE OF INCORPORATION
OF
MOBIA MEDICAL, INC.

Mobia Medical, Inc. (the "***Corporation***"), a corporation organized and existing under the General Corporation Law of the State of Delaware (the "***DGCL***"), does hereby certify as follows:

1. The name of the Corporation is Mobia Medical, Inc. The Corporation was incorporated under the name MicroTransponder, Inc. by the filing of its original Certificate of Incorporation (the "***Original Certificate***") with the Secretary of State of the State of Delaware (the "***Delaware Secretary***") on March 5, 2007; the Original Certificate was amended pursuant to a Certificate of Correction (the "***First Certificate of Correction***") filed with the Delaware Secretary on March 26, 2007; the Original Certificate (as amended by the First Certificate of Correction) was amended and restated pursuant to an Amended and Restated Certificate of Incorporation (the "***First Restated Certificate***") filed with the Delaware Secretary on February 19, 2008; the First Restated Certificate was amended and restated pursuant to an Amended and Restated Certificate of Incorporation (the "***Second Restated Certificate***") filed with the Delaware Secretary on January 29, 2009; the Second Restated Certificate was amended and restated pursuant to an Amended and Restated Certificate of Incorporation (the "***Third Restated Certificate***") filed with the Delaware Secretary on March 4, 2010; the Third Restated Certificate was amended pursuant to a Certificate of Correction (the "***Second Certificate of Correction***") filed with the Delaware Secretary on November 18, 2010; the Third Restated Certificate (as amended by the Second Certificate of Correction) was amended and restated pursuant to an Amended and Restated Certificate of Incorporation (the "***Fourth Restated Certificate***") filed with the Delaware Secretary on February 15, 2011; the Fourth Restated Certificate was amended and restated pursuant to an Amended and Restated Certificate of Incorporation (the "***Fifth Restated Certificate***") filed with the Delaware Secretary on May 31, 2012; the Fifth Restated Certificate was amended and restated pursuant to an Amended and Restated Certificate of Incorporation (the "***Sixth Restated Certificate***") filed with the Delaware Secretary on December 14, 2012; the Sixth Restated Certificate was amended and restated pursuant to an Amended and Restated Certificate of Incorporation (the "***Seventh Restated Certificate***") filed with the Delaware Secretary on September 14, 2015; the Seventh Restated Certificate was amended and restated pursuant to an Amended and Restated Certificate of Incorporation (the "***Eighth Restated Certificate***") filed with the Delaware Secretary on November 8, 2017; the Eighth Restated Certificate was amended pursuant to a Certificate of Amendment (the "***First Certificate of Amendment***") filed with the Delaware Secretary on August 27, 2020; the Eighth Restated Certificate (as amended by the First Certificate of Amendment) was amended and restated pursuant to an Amended and Restated Certificate of Incorporation (the "***Ninth Restated Certificate***") filed with the Delaware Secretary on June 3, 2022; the Ninth Restated Certificate was amended pursuant to a Certificate of Amendment (the "***Second Certificate of Amendment***") filed with the Delaware Secretary on December 29, 2023; the Ninth

Restated Certificate (as amended by the Second Certificate of Amendment) was amended and restated pursuant to an Amended and Restated Certificate of Incorporation (the "***Tenth Restated Certificate***") filed with the Delaware Secretary on March 4, 2025; the Tenth Restated Certificate was amended pursuant to a Certificate of Amendment (the "***Name Change Amendment***") filed with the Delaware Secretary on February 23, 2026, changing the name of the Corporation from "MicroTransponder, Inc." to "Mobia Medical, Inc."; and the Tenth Restated Certificate (as amended by the Name Change Amendment) was amended pursuant to a Certificate of Amendment (the "***Third Certificate of Amendment***") filed with the Delaware Secretary on May 1, 2026 (the Tenth Restated Certificate, as amended by the Third Certificate of Amendment, the "***Certificate of Incorporation***").

2. This Amended and Restated Certificate of Incorporation (this "***Restated Certificate***"), which amends, restates and further integrates the Certificate of Incorporation of the Corporation as heretofore in effect, has been approved by the Board of Directors of the Corporation (the "***Board of Directors***") in accordance with Sections 242 and 245 of the DGCL, and has been adopted by the written consent of the stockholders of the Corporation in accordance with Section 228 of the DGCL.

3. The text of the certificate of incorporation of the Corporation, as heretofore amended, is hereby amended and restated by this Restated Certificate to read in its entirety as set forth in EXHIBIT A attached hereto.

IN WITNESS WHEREOF, Mobia Medical, Inc. has caused this Restated Certificate to be signed by a duly authorized officer of the Corporation, on , 2026.

Mobia Medical, Inc.,
a Delaware corporation

By: _____
Name: Richard Foust
Title: President & Chief Executive Officer

[*Signature Page to Mobia Medical, Inc.'s Amended and Restated Certificate of Incorporation*]

EXHIBIT A

ARTICLE I

The name of the corporation is Mobia Medical, Inc. (the "***Corporation***").

ARTICLE II

The address of the Corporation's registered office in the State of Delaware is 251 Little Falls Drive, Wilmington, County of New Castle, 19808. The name of its registered agent at such address is Corporation Service Company.

ARTICLE III

The purpose of the Corporation is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law of the State of Delaware (the "***DGCL***") as it now exists or may hereafter be amended and supplemented.

ARTICLE IV

The Corporation is authorized to issue two classes of stock to be designated, respectively, "***Common Stock***" and "***Preferred Stock***." The total number of shares of capital stock which the Corporation shall have authority to issue is 1,000,000,000 shares divided into the following: (i) 950,000,000 shares of Common Stock, $0.01 par value per share (the "Common Stock"), and (ii) 50,000,000 shares of Preferred Stock, $0.01 par value per share (the "Preferred Stock"). The Preferred Stock may be divided into and issued into one or more series. The Board of Directors is hereby vested with authority to establish and designate such series from time to time, and within the limitations prescribed by law or set forth herein, to fix and determine the preferences, limitations, and relative rights of the shares of any series so established.

ARTICLE V

The designations and the powers, privileges and rights, and the qualifications, limitations or restrictions thereof in respect of each class of capital stock of the Corporation are as follows:

A. COMMON STOCK.

1. General. The voting, dividend, liquidation and other rights and powers of the Common Stock are subject to and qualified by the rights, powers and preferences of any series of Preferred Stock as may be designated by the Board of Directors of the Corporation (the "***Board of Directors***") and outstanding from time to time.

2. Voting. Except as otherwise provided herein or expressly required by law, each holder of Common Stock, as such, shall be entitled to vote on each matter

submitted to a vote of stockholders and shall be entitled to one (1) vote for each share of Common Stock held of record by such holder as of the record date for determining stockholders entitled to vote on such matter. Except as otherwise required by law, holders of Common Stock, as such, shall not be entitled to vote on any amendment to this Amended and Restated Certificate of Incorporation (this "***Restated Certificate***") (including any Certificate of Designation (as defined below)) that relates solely to the rights, powers, preferences (or the qualifications, limitations or restrictions thereof) or other terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together with the holders of one or more other such series, to vote thereon pursuant to this Restated Certificate (including any Certificate of Designation) or pursuant to the DGCL.

Subject to the rights of any holders of any outstanding series of Preferred Stock, the number of authorized shares of Common Stock or Preferred Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the requisite vote of the stockholders entitled to vote thereon, voting as a single class, irrespective of the provisions of Section 242(b)(2) of the DGCL.

3. Dividends. Subject to applicable law and the rights and preferences of any holders of any outstanding series of Preferred Stock, the holders of Common Stock, as such, shall be entitled to the payment of dividends on the Common Stock when, as and if declared by the Board of Directors in accordance with applicable law.

4. Liquidation. Subject to the rights and preferences of any holders of any shares of any outstanding series of Preferred Stock, in the event of any liquidation, dissolution or winding up of the Corporation, whether voluntary or involuntary, the funds and assets of the Corporation that may be legally distributed to the Corporation's stockholders shall be distributed among the holders of the then outstanding Common Stock pro rata in accordance with the number of shares of Common Stock held by each such holder.

B. PREFERRED STOCK

Shares of Preferred Stock may be issued from time to time in one or more series, each of such series to have such terms as stated or expressed herein and in the resolution or resolutions providing for the creation and issuance of such series adopted by the Board of Directors as hereinafter provided.

Authority is hereby expressly granted to the Board of Directors from time to time to issue the Preferred Stock in one or more series, and in connection with the creation of any such series, by adopting a resolution or resolutions providing for the issuance of the shares thereof and by filing a certificate of designation relating thereto in accordance with the DGCL (a "***Certificate of Designation***"), to determine and fix the number of shares of such series and such voting powers, full or limited, or no voting powers, and such designations, preferences and relative participating, optional or other special rights, and qualifications, limitations or restrictions thereof, including without limitation

thereof, dividend rights, conversion rights, redemption privileges and liquidation preferences, and to increase or decrease (but not below the number of shares of such series then outstanding) the number of shares of any series as shall be stated and expressed in such resolutions, all to the fullest extent now or hereafter permitted by the DGCL. Without limiting the generality of the foregoing, the resolution or resolutions providing for the creation and issuance of any series of Preferred Stock may provide that such series shall be superior or rank equally or be junior to any other series of Preferred Stock to the extent permitted by law and this Restated Certificate (including any Certificate of Designation). Except as otherwise required by law, holders of any series of Preferred Stock shall be entitled only to such voting rights, if any, as shall expressly be granted thereto by this Restated Certificate (including any Certificate of Designation).

The number of authorized shares of Preferred Stock may be increased or decreased (but not below the number of shares thereof then outstanding) irrespective of the provisions of Section 242(b)(2) of the DGCL.

ARTICLE VI

For the management of the business and for the conduct of the affairs of the Corporation it is further provided that:

A. Subject to the special rights of the holders of one or more outstanding series of Preferred Stock to elect directors, the directors of the Corporation shall be classified with respect to the time for which they severally hold office into three classes, designated as Class I, Class II and Class III. The initial Class I directors shall serve for a term expiring at the first annual meeting of stockholders following the initial registration of the Corporation's Common Stock pursuant to the Securities Exchange Act of 1934, as amended; the initial Class II directors shall serve for a term expiring at the second annual meeting of stockholders following such registration; and the initial Class III directors shall serve for a term expiring at the third annual meeting of stockholders following such registration. At each annual meeting of stockholders of the Corporation beginning with the first annual meeting of stockholders following the filing and effectiveness of this Restated Certificate, subject to any special rights of the holders of one or more outstanding series of Preferred Stock to elect directors, the successors of the class of directors whose term expires at that meeting shall be elected to hold office for a term expiring at the annual meeting of stockholders held in the third year following the year of their election. Each director shall hold office until his or her successor is duly elected and qualified or until his or her earlier death, resignation, retirement, disqualification or removal. No decrease in the number of directors shall shorten the term of any incumbent director. The Board of Directors is authorized to designate members of the Board of Directors already in office as Class I, Class II and Class III.

B. Except as otherwise expressly provided by the DGCL or this Restated Certificate, the business and affairs of the Corporation shall be managed by or under the direction of the Board of Directors. The number of directors which shall constitute

the whole Board of Directors shall be fixed exclusively by one or more resolutions adopted from time to time by the Board of Directors.

C. Subject to the special rights of the holders of one or more outstanding series of Preferred Stock to elect directors, the Board of Directors or any individual director may be removed from office at any time, but only for cause and only by the affirmative vote of the holders of at least two-thirds of the voting power of all of the then outstanding shares of voting stock of the Corporation entitled to vote at an election of directors.

D. Subject to the special rights of the holders of one or more outstanding series of Preferred Stock to elect directors, except as otherwise provided by law, any vacancies on the Board of Directors resulting from death, resignation, retirement, disqualification, removal or other causes and any newly created directorships resulting from any increase in the number of directors shall be filled exclusively by the affirmative vote of a majority of the directors then in office, even though less than a quorum, or by a sole remaining director (other than any directors elected by the separate vote of one or more outstanding series of Preferred Stock), and shall not be filled by the stockholders. Any director appointed in accordance with the preceding sentence shall hold office until the expiration of the term of the class to which such director shall have been appointed or until his or her earlier death, resignation, retirement, disqualification or removal.

E. Whenever the holders of any one or more series of Preferred Stock issued by the Corporation shall have the right, voting separately as a series or separately as a class with one or more such other series, to elect directors at an annual or special meeting of stockholders, the election, term of office, removal and other features of such directorships shall be governed by the terms of this Restated Certificate (including any Certificate of Designation). Notwithstanding anything to the contrary in this Article VI, the number of directors that may be elected by the holders of any such series of Preferred Stock shall be in addition to the number fixed pursuant to paragraph B of this Article VI, and the total number of directors constituting the whole Board of Directors shall be automatically adjusted accordingly. Except as otherwise provided in the Certificate of Designation(s) in respect of one or more series of Preferred Stock, whenever the holders of any series of Preferred Stock having such right to elect additional directors are divested of such right pursuant to the provisions of such Certificate of Designation(s), the terms of office of all such additional directors elected by the holders of such series of Preferred Stock, or elected to fill any vacancies resulting from the death, resignation, disqualification or removal of such additional directors, shall forthwith terminate (in which case each such director thereupon shall cease to be qualified as, and shall cease to be, a director) and the total authorized number of directors of the Corporation shall automatically be reduced accordingly.

F. In furtherance and not in limitation of the powers conferred by statute, the Board of Directors is expressly authorized to adopt, amend or repeal Bylaws of the Corporation. In addition to any vote of the holders of any class or series of stock of the Corporation required by applicable law or by this Restated Certificate (including any

Certificate of Designation in respect of one or more series of Preferred Stock) or the Bylaws of the Corporation, the adoption, amendment or repeal of the Bylaws of the Corporation by the stockholders of the Corporation shall require the affirmative vote of the holders of at least two-thirds of the voting power of all of the then outstanding shares of voting stock of the Corporation entitled to vote generally in an election of directors.

G. The directors of the Corporation need not be elected by written ballot unless the Bylaws so provide.

ARTICLE VII

A. Any action required or permitted to be taken by the stockholders of the Corporation must be effected at an annual or special meeting of stockholders of the Corporation and shall not be taken by written consent in lieu of a meeting. Notwithstanding the foregoing, any action required or permitted to be taken by the holders of any series of Preferred Stock, voting separately as a series or separately as a class with one or more other such series, may be taken without a meeting, without prior notice and without a vote, to the extent expressly so provided by the applicable Certificate of Designation relating to such series of Preferred Stock, if a consent or consents in writing, setting forth the action so taken, shall be signed by the holders of outstanding shares of the relevant series of Preferred Stock having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted and shall be delivered to the Corporation in accordance with the applicable provisions of the DGCL.

B. Subject to the special rights of the holders of one or more series of Preferred Stock, special meetings of stockholders of the Corporation may be called, for any purpose or purposes, at any time only by or at the direction of the Board of Directors, the Chair of the Board of Directors, the Chief Executive Officer or President, and shall not be called by any other person or persons.

C. Advance notice of stockholder nominations for the election of directors and of other business proposed to be brought by stockholders before any meeting of stockholders of the Corporation shall be given in the manner provided in the Bylaws of the Corporation.

ARTICLE VIII

No director or officer of the Corporation shall have any personal liability to the Corporation or its stockholders for monetary damages for any breach of fiduciary duty as a director or officer, except to the extent such exemption from liability or limitation thereof is not permitted under the DGCL as the same exists or hereafter may be amended. Any amendment, repeal or modification of this Article VIII, or the adoption of any provision of the Restated Certificate inconsistent with this Article VIII, shall not adversely affect any right or protection of a director or officer of the Corporation with respect to any act or omission occurring prior to such amendment, repeal, modification

or adoption. If the DGCL is amended after approval by the stockholders of this Article VIII to authorize corporate action further eliminating or limiting the personal liability of directors or officers, then the liability of a director or officer of the Corporation shall be eliminated or limited to the fullest extent permitted by the DGCL as so amended.

ARTICLE IX

The Corporation shall have the power to provide rights to indemnification and advancement of expenses to its current and former officers, directors, employees and agents and to any person who is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise.

ARTICLE X

Unless the Corporation consents in writing to the selection of an alternative forum, (a) the Court of Chancery (the "***Chancery Court***") of the State of Delaware (or, in the event that the Chancery Court does not have jurisdiction, the federal district court for the District of Delaware or other state courts of the State of Delaware) shall, to the fullest extent permitted by law, be the sole and exclusive forum for (i) any derivative action, suit or proceeding brought on behalf of the Corporation, (ii) any action, suit or proceeding asserting a claim of breach of a fiduciary duty owed by any director, officer or stockholder of the Corporation to the Corporation or to the Corporation's stockholders, (iii) any action, suit or proceeding arising pursuant to any provision of the DGCL or the bylaws of the Corporation or this Restated Certificate (as either may be amended from time to time) or (iv) any action, suit or proceeding asserting a claim against the Corporation governed by the internal affairs doctrine; and (b) subject to the preceding provisions of this Article X, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause or causes of action arising under the Securities Act of 1933, as amended, including all causes of action asserted against any defendant to such complaint. If any action the subject matter of which is within the scope of clause (a) of the immediately preceding sentence is filed in a court other than the courts in the State of Delaware (a "***Foreign Action***") in the name of any stockholder, such stockholder shall be deemed to have consented to (x) the personal jurisdiction of the state and federal courts in the State of Delaware in connection with any action brought in any such court to enforce the provisions of clause (a) of the immediately preceding sentence and (y) having service of process made upon such stockholder in any such action by service upon such stockholder's counsel in the Foreign Action as agent for such stockholder.

Any person or entity purchasing or otherwise acquiring any interest in any security of the Corporation shall be deemed to have notice of and consented to this Article X. This Article X is intended to benefit and may be enforced by the Corporation, its officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional or entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the

documents underlying the offering. Notwithstanding the foregoing, the provisions of this Article X shall not apply to suits brought to enforce any liability or duty created by the Securities Exchange Act of 1934, as amended, or any other claim for which the federal courts of the United States have exclusive jurisdiction.

If any provision or provisions of this Article X shall be held to be invalid, illegal or unenforceable as applied to any circumstance for any reason whatsoever, (a) the validity, legality and enforceability of such provisions in any other circumstance and of the remaining provisions of this Article X (including, without limitation, each portion of any paragraph of this Article X containing any such provision held to be invalid, illegal or unenforceable that is not itself held to be invalid, illegal or unenforceable) shall not in any way be affected or impaired thereby and (b) the application of such provision to other persons or entities and circumstances shall not in any way be affected or impaired thereby.

ARTICLE XI

A. Notwithstanding anything contained in this Restated Certificate to the contrary, in addition to any vote required by applicable law, the following provisions in this Restated Certificate may be amended, altered, repealed or rescinded, in whole or in part, or any provision inconsistent therewith or herewith may be adopted, only by the affirmative vote of the holders of at least 66 2/3% of the total voting power of all the then outstanding shares of stock of the Corporation entitled to vote thereon, voting together as a single class: Part B of Article V, Article VI, Article VII, Article VIII, Article IX, Article X, and this Article XI.

B. If any provision or provisions of this Restated Certificate shall be held to be invalid, illegal or unenforceable as applied to any circumstance for any reason whatsoever: (i) the validity, legality and enforceability of such provisions in any other circumstance and of the remaining provisions of this Restated Certificate (including, without limitation, each portion of any paragraph of this Restated Certificate containing any such provision held to be invalid, illegal or unenforceable that is not itself held to be invalid, illegal or unenforceable) shall not, to the fullest extent permitted by applicable law, in any way be affected or impaired thereby and (ii) to the fullest extent permitted by applicable law, the provisions of this Restated Certificate (including, without limitation, each such portion of any paragraph of this Restated Certificate containing any such provision held to be invalid, illegal or unenforceable) shall be construed so as to permit the Corporation to protect its directors, officers, employees and agents from personal liability in respect of their good faith service to or for the benefit of the Corporation to the fullest extent permitted by law.

Exhibit 5.1

650 Town Center Drive, 20th Floor
Costa Mesa, California 92626-1925
Tel: +1.714.540.1235 Fax: +1.714.755.8290
www.lw.com

LATHAM & WATKINS LLP

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May 4, 2026

Mobia Medical, Inc.
2802 Flintrock Trace, Suite 226
Austin, TX 78738

Re: Registration Statement on Form S-1 (Registration No. 333-295160);
Up to 11,500,000 shares of common stock, $0.01 par value per share

To the addressee set forth above:

We have acted as special counsel to Mobia Medical, Inc., a Delaware corporation (the "***Company***"), in connection with the proposed issuance of up to 11,500,000 shares (including shares subject to the underwriters' option to purchase additional shares) of common stock, $0.01 par value per share (the "***Shares***"). The Shares are included in a registration statement on Form S-1 under the Securities Act of 1933, as amended (the "***Act***"), filed with the Securities and Exchange Commission (the "***Commission***") on April 17, 2026 (Registration No. 333-295160) (as amended, the "***Registration Statement***"). The term "Shares" shall include any additional shares of common stock registered by the Company pursuant to Rule 462(b) under the Act in connection with the offering contemplated by the Registration Statement. This opinion is being furnished in connection with the requirements of Item 601(b)(5) of Regulation S-K under the Act, and no opinion is expressed herein as to any matter pertaining to the contents of the Registration Statement or related Prospectus, other than as expressly stated herein with respect to the issue of the Shares.

As such counsel, we have examined such matters of fact and questions of law as we have considered appropriate for purposes of this letter. With your consent, we have relied upon certificates and other assurances of officers of the Company and others as to factual matters without having independently verified such factual matters. We are opining herein as to the General Corporation Law of the State of Delaware, and we express no opinion with respect to any other laws.

Subject to the foregoing and the other matters set forth herein, it is our opinion that, as of the date hereof, when the Shares shall have been duly registered on the books of the transfer agent and registrar therefor in the name or on behalf of the purchasers, and have been issued by the Company against payment therefor

(not less than par value) in the circumstances contemplated by the form of underwriting agreement most recently filed as an exhibit to the Registration Statement, the issue and sale of the Shares will have been duly authorized by all necessary corporate action of the Company, and the Shares will be validly issued, fully paid and nonassessable. In rendering the foregoing opinion, we have assumed that the Company will comply with all applicable notice requirements regarding uncertificated shares provided in the General Corporation Law of the State of Delaware.

This opinion is for your benefit in connection with the Registration Statement and may be relied upon by you and by persons entitled to rely upon it pursuant to the applicable provisions of the Act. We consent to your filing this opinion as an exhibit to the Registration Statement and to the reference to our firm in the Prospectus under the heading "Legal Matters." We further consent to the incorporation by reference of this letter and consent into any registration statement filed pursuant to Rule 462(b) with respect to the Shares. In giving such consent, we do not thereby admit that we are in the category of persons whose consent is required under Section 7 of the Act or the rules and regulations of the Commission thereunder.

Sincerely,

/s/ Latham & Watkins LLP

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the use in this Registration Statement on Form S-1 of Mobia Medical, Inc. of our report dated March 11, 2026, except for the effects of the revision discussed in Note 3 to the financial statements, as to which the date is April 27, 2026, and except for the effects of the reverse stock split discussed in Note 3 to the financial statements, as to which the date is May 4, 2026, relating to the financial statements of Mobia Medical, Inc., which appears in this Registration Statement. We also consent to the reference to us under the heading “Experts” in such Registration Statement.

/s/ PricewaterhouseCoopers LLP
Los Angeles, California
May 4, 2026