myomo®

my own motion

2024 Annual Report

2024 Letter to Shareholders – A Year of Transformation, Growth and Impact

Dear Fellow Shareholders,

2024 was a pivotal year for Myomo. We achieved significant milestones that fundamentally transformed our business, broadened access to the MyoPro® device for thousands of prospective patients and set the foundation for sustainable and profitable growth.

MyoPro users now able to perform Activities of Daily Living

Unlocking Access with Medicare Reimbursement

We achieved a major milestone when on April 1, 2024, the Centers for Medicare & Medicaid Services (CMS) began reimbursing the MyoPro under Medicare Part B. This coverage opened access to an estimated 50% of seniors with standard fee-for-service Medicare who are living with upper limb paralysis due to stroke, spinal cord injury or other neurological conditions. CMS now reimburses a custom MyoPro on a lump-sum basis within the brace category of durable medical equipment based on a patient's medical condition and necessity.

While many commercial insurance plans and the Veterans Administration (VA) have been reimbursing for the MyoPro for over 10 years, the addition of Medicare coverage marks a major inflection point for Myomo. For the first time, we are able to serve a vastly expanded patient population — delivering not just medical devices, but renewed independence and hope to people who previously had no viable option to facilitate the activities of daily living.

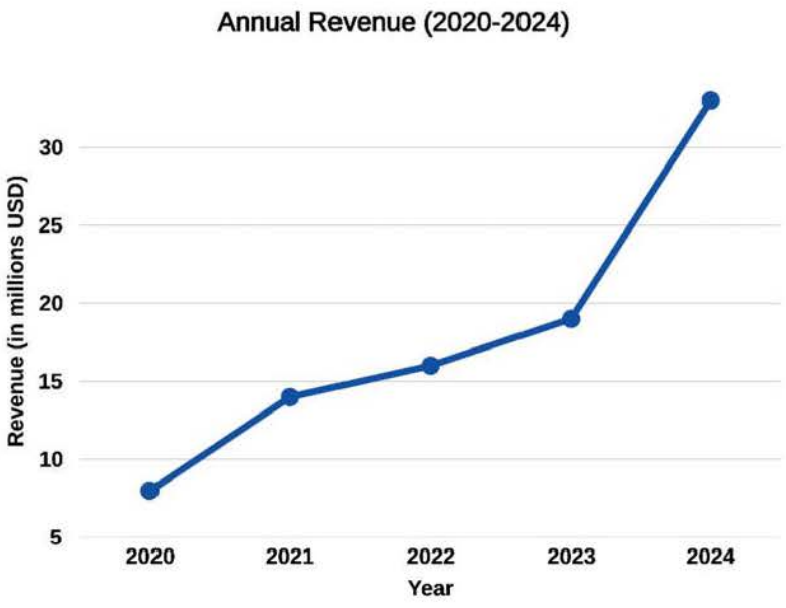
2024 Financial Highlights: Strong Growth and Operating Momentum

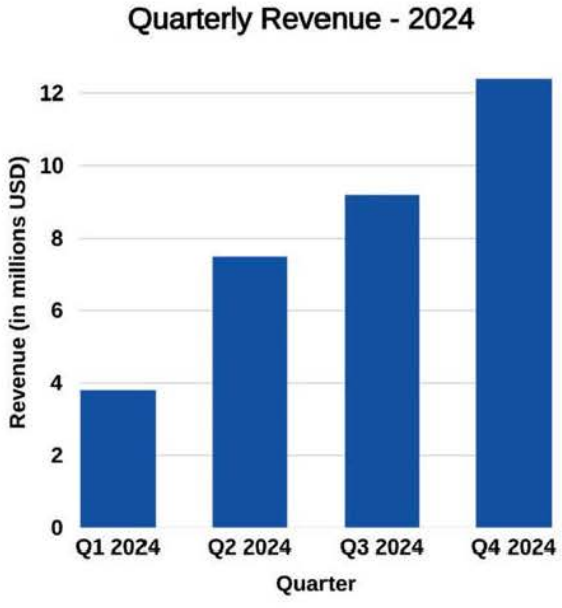
We achieved record revenue in 2024, delivering over 600 MyoPro units to patients.

Key Financial Milestones:

- **$32.6 million in 2024 revenue**, up 69% from 2023
- **Q4 free cash flow of $2.5 million**, our first cash-flow positive quarter
- **$15.8 million in net proceeds** raised in a December equity offering
- **Approximately $25 million in cash** on the balance sheet at year-end
- **Expanded credit facility** with Silicon Valley Bank for up to $7 million in capital

This financial performance reflects both the growing demand for our solution and the scalability of our business model.





Scaling Our Operations to Meet Demand

To meet rising demand for our MyoPro, we increased the size of our workforce by 90%, growing from 100 employees at the start of the year to 190 by year-end. We added headcount across intake coordinators, reimbursement staff, manufacturing personnel and field clinicians, including Certified Prosthetist Orthotists (CPOs), Occupational Therapists (OTs) & Physical Therapists (PTs) for our direct provider business. In January 2025, we relocated our headquarters to a 35,000 sq. ft. facility in Burlington, Mass., to support our expected growth with vastly expanded manufacturing capabilities.

45 Blue Sky in Burlington, Mass.


Production Line

Building an Important New MyoPro Distribution Channel

Medicare reimbursement catalyzed renewed interest among Orthotics and Prosthetics (O&P) clinics in the U.S., which are now actively pursuing MyoPro distribution. There are more than 3000 such clinics across the country, ranging from Hanger Clinics with approximately 900 offices nationwide, to smaller local and regional clinics. In 2024, we established an O&P channel team of business development managers and clinical specialists who trained over 160 CPOs to evaluate and support patients. Our goal is to create a network of MyoPro Centers of Excellence across the country to expand access to the MyoPro to individuals with chronic arm paralysis.

MyoPro Center of Excellence Training Classes

Strengthening Payer Relations and Expanding Coverage

Since the large majority of MyoPro braces are paid for by health insurance plans (Payers), we have worked extensively over the past five years to expand the number of Payers who cover MyoPro for their beneficiaries. We have delivered over 3,000 devices to patients covered by Payers including United Healthcare, Aetna, Cigna, Humana, various Blue Cross Blue Shield (BCBS) plans, the VA — and now Medicare.

Reimbursement determinations are made on a case-by-case basis and require a pre-authorization from commercial Payers based on medical necessity. While Medicare Advantage plans are required to cover what Medicare covers, these Payers can apply their own clinical guidelines. Like many other healthcare providers dealing with Medicare Advantage, we've also experienced a greater number of denials last year than in the past. We support each patient's appeal of these unjust denials, and it has been widely reported that agencies of the U.S. government are investigating the reimbursement practices of several Medicare Advantage organizations.

To facilitate patient access to a MyoPro, our Medical Affairs team, led by Chief Medical Officer Dr. Harry Kovelman, has been reaching out to Payer Medical Directors to establish coverage policies and enter into agreements as an in-network provider. As of this writing, we have signed or have pending contracts with a number of state BCBS plans covering 18.6 million lives. We plan to enter into additional contracts this year so that more eligible patients can obtain their own MyoPro.

Global Expansion: Progress in Europe and China – Navigating Tariffs

Our international business represented 14% of 2024 revenue, driven by strong growth in Germany where more than 100 O&P clinics are certified to provide the MyoPro. We are successfully working with Payers such as Barmer, TKK and others to obtain reimbursement from the Statutory Health Insurers as mandated by German Social Court rulings.

Our joint venture in China with Beijing Ryzur Medical Device Co. - Jiangxi Myomo – is progressing toward NMPA (China FDA) approval. With local production established and a clinical study underway, we anticipate launching the MyoPro in China by the end of 2025, unlocking access to an estimated 14 million people with upper limb paralysis. Myomo will receive license payments over the next 10 years based on the volume of units produced and delivered to rehab hospital customers and individual patients.

With respect to tariffs, the situation as of the date of this letter remains fluid. Key imported materials incorporated into the MyoPro include motors for the elbow and grasp motor assemblies, batteries, battery chargers, and laptop computers. Our current estimate is that tariffs are expected to have a less than a 100 basis point (1%) impact on gross margin in 2025. We are in the process of reviewing the steps that we can take to mitigate the impact. We also export the MyoPro to foreign countries, particularly Germany. We are not aware of any retaliatory tariffs at this time that could be applied to the MyoPro upon import.

Innovating the Future of Neuro-Robotics

To maintain our market-leading position, we are investing in both near-term product enhancements and long-term innovation, with priority programs including the following:

- **MARK2:** Mobile Arm Rehab Kit: A newer, 3D-printed model of our universal-size orthosis for use in clinical evaluations and training.
- **MyoPro2X**: This enhanced version of the MyoPro2+ reflects our commitment to continuous improvements for product usability and performance.
- **MyoPro3 Platform**: Development of this next-generation model is underway with a focus on greater system computational power and software capabilities, and advancements in drive mechanisms, materials, biosensing and control.
- **Expanded R&D Team:** The investment in a larger team includes new leaders in Product Management, Program Management, and Research along with various specialists in robotics, software, and systems engineering.
- **Ongoing Research:** Collaborations continue with top-tier research institutions including the Cleveland VA, Kessler Institute in New Jersey, the University of

Utah and several UK hospitals to build upon the base of published clinical studies in support of MyoPro's safety and effectiveness.

We also launched the Myomo Academy in 2024 with the mission of providing world-class clinical education to our provider partners and further differentiating our brand in the marketplace.

Marketing and Awareness: Reaching More Patients than Ever Before

As we enter 2025, we plan to expand our U.S. distribution channel by hiring additional clinicians for our direct provider business, as well as recruiting and training additional O&P channel partners. In January we attended Hanger LIVE, the clinical educational meeting of the country's largest O&P provider, where we trained dozens of CPOs on the MyoPro. We are also organizing regional training sessions to increase the number of O&P clinics that can provide the MyoPro to their stroke patients, many of whom they already serve with other braces for their arm and leg paralysis.

With a significantly larger addressable market, we intend to nearly double our advertising spend in 2025 to more than $6 million so that we can educate more patients, family members and clinicians on the benefits of MyoPro. For far too long stroke survivors have been told, "Get used to it, you'll never move your arm or hand again for the rest of your life." We're demonstrating that this outdated view no longer applies for many patients.

A Human-Centered Mission: Stories that Inspire

Yet beyond the numbers, our mission is grounded in improving lives. Gordon (left), a 58 year-old stroke survivor, husband and father, regained use of his right arm after 12 years thanks to the MyoPro. With help from our partner clinic, Arise Prosthetics, and Medicare coverage, Gordon is now taking care of his family at home and is back in the gym. He also serves as a MyoPro Ambassador to support other stroke survivors so they can get their life back with our technology and clinical support.

Board Leadership and Governance

During 2024, we welcomed Heather C. Getz to our board of directors. Heather is an accomplished financial and operational executive in the healthcare industry, and she is serving as Chair of our Audit Committee.


Heather C. Getz

I would also like to thank Amy Knapp and Yitzchak Jacobovitz for their service on Myomo's board, as their terms as directors will expire at the upcoming Shareholder Meeting. I'm pleased that each of them will serve in an ongoing advisory role to the company, with Mr. Jacobovitz attending board meetings as an observer.

Looking Ahead: A Clear Path to Greater Impact

Myomo entered 2025 with a strong balance sheet, a scalable infrastructure and expanding commercial and clinical networks. With Medicare coverage in place, we are focused on execution – increasing manufacturing scale, improving patient access, entering into additional Payer contracts and delivering sustainable, profitable growth. These strategies support our mission to improve the quality of life for individuals who no longer have the use of one or both arms, allowing them to function at home, at work or in the community.

On behalf of Myomo's board of directors and my fellow team members, thank you for your support as we continue to build the leading medical robotics company for restoring independence to individuals with upper limb paralysis.

Sincerely,

Paul R. Gudonis

Chairman and CEO

April 25, 2025

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

FORM 10-K

(Mark One)a

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

For the fiscal year ended December 31, 2024

or

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

For the transition period from to .

Commission File Number 001-38109

MYOMO, INC.

(Exact name of registrant as specified in its charter)

Delaware	**47-0944526**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
45 Blue Sky Dr., Suite 101, Burlington, Massachusetts	**01803**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code (617) 996-9058

Securities registered under Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	**MYO**	**NYSE American**

Securities registered under Section 12(g) of the Act: None

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes: ☒ No: ☐

Indicate by check mark whether the registrant has submitted electronically, every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes Oxley Act (15 U.S.C.7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule12b-2 of the Act). Yes: ☐ No: ☒

The aggregate market value of the voting and non-voting common stock held by non-affiliates of the registrant, based on the last sale price for such stock on June 28, 2024, the last business day of the registrant's most recently completed second fiscal quarter. was $67,219,172. For purposes of this calculation, shares held by stockholders whose ownership exceeded 5% of the registrant's common stock outstanding were deemed to be held by affiliates. Exclusion of such shares should not be construed to indicate that any such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the registrant or that such person is controlled by or under common control with the registrant. At March 1, 2025, the registrant had 34,381,125 shares of common stock, par value $0.0001 per share, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Form 10-K incorporates information by reference from the registrant's definitive proxy statement to be filed with the Securities and Exchange Commission within 120 days after the close of the fiscal year ended December 31, 2024.

Auditor Firm Id: 688 Auditor Name: Marcum, LLP Auditor Location: New York, NY, USA

MYOMO, INC

2024 FORM 10-K ANNUAL REPORT
TABLE OF CONTENTS

PART I

SUMMARY OF RISKS ASSOCIATED WITH OUR BUSINESS

Our business involves significant risks, some of which are described below. The summary risk factors listed below should be read together with the text of the full risk factors that follow this summary. You should carefully consider the risks described below, as well as the other information in this Annual Report on Form 10-K, including our financial statements and the related notes, "Management's Discussion and Analysis of Financial Condition and Results of Operations" as well as in other documents that we file with the SEC. The occurrence of any of the events or developments described in this report could have a material adverse effect on our business, financial condition, results of operations, growth prospects and stock price. In such an event, the market price of our common stock could decline, 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.

- We have a history of operating losses. Investments in advertising, research and development ("R&D") and clinical, reimbursement and manufacturing capacity could result in a delay in our ability to achieve cash flow breakeven on a quarterly basis.
- Our direct billing revenues are concentrated with a small number of payers, including the Centers for Medicare and Medicaid Services ("CMS"). Adverse changes in the reimbursement policies of these payers regarding the MyoPro could have an adverse effect on our business.
- We may not be able to obtain adequate levels of third-party payer reimbursement, including reimbursement by Medicare, for our products.
- If CMS amends, restricts, or retracts coverage requirements, its billing contractors and insurers offering Medicare Advantage insurance plans may restrict what they reimburse for the MyoPro, which would have an adverse effect on our business.
- We currently rely, and in the future will rely, on sales of our MyoPro products for our revenue, and we may not be able to achieve or maintain market acceptance.
- We depend on a single third-party to manufacture key subassemblies for the MyoPro, and a limited number of third-party suppliers for certain components of the MyoPro.
- The industries in which we operate are highly competitive and subject to rapid technological change. The publishing of fees for the Healthcare Common Procedure Coding System ("HCPCS"), billing codes for our products may attract competition. If our competitors are better able to develop and market products that are safer, more effective, less costly, easier to use, or are otherwise more attractive, we may be unable to compete effectively with other companies.
- We sell to orthotics and prosthetics providers who are free to market products that compete with the MyoPro, and we rely on these providers to market and promote our products in accordance with their U.S. Food and Drug Administration, or ("FDA"), listings, select appropriate patients and provide adequate follow-on care.
- The market for myoelectric braces is new and the rate of adoption is uncertain, and important assumptions about the potential market for our products may be inaccurate.
- Defects in our products or the software that drives them could adversely affect the results of our operations.
- We are subject to extensive governmental regulations relating to the design, development, manufacturing, labeling and marketing of our products, and a failure to comply with such regulations could lead to withdrawal or recall of our products from the market.

- We depend on certain patents that are licensed to us. We do not control these patents and any loss of our rights to them could prevent us from manufacturing our products.
- Our internal computer systems, or those of our customers, collaborators or other contractors, may be subject to cyber-attacks or security breaches, which could result in a material disruption of our product development programs.
- Our success depends in part on our ability to obtain and maintain protection for the intellectual property relating to or incorporated into our products.
- The market price of our common stock has been and may continue to be volatile.
- Since we sell products in several overseas markets, we are subject to foreign currency fluctuations, which may reduce our revenue per unit in dollars.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements (within the meaning of the federal securities law) that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this Annual Report on Form 10-K regarding our strategy, future operations, future financial position, future net sales, gross margin expectations, projected costs, projected expenses, prospects and plans and objectives of management are forward-looking statements. The words "anticipates," "believes," "estimates," "expects," "intends," "may," "plans," "projects," "will," "would," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We have based these forward-looking statements on our current expectations and projections about future events. Although we believe that the expectations underlying any of our forward-looking statements are reasonable, these expectations may prove to be incorrect, and all of these statements are subject to risks and uncertainties. Should one or more of these risks and uncertainties materialize, or should underlying assumptions, projections, or expectations prove incorrect, our actual results, performance, or financial condition may vary materially and adversely from those anticipated, estimated, or expected. We have included important factors in the cautionary statements included in this Annual Report on Form 10-K, particularly in the section entitled "Risk Factors," that we believe could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures, investments or terminations of distribution arrangements that we may make. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events, or otherwise, except as required by law.
The following discussion should be read in conjunction with our financial statements and the related notes contained elsewhere in this Annual Report on Form 10-K and in our other Securities and Exchange Commission filings.
Unless the context requires otherwise, references to "Myomo," "we," "our," and "us" in this Annual Report on Form 10-K refer to Myomo, Inc.

We own various U.S. federal trademark registrations, certain foreign trademark registrations and applications, and unregistered trademarks, including the following registered marks referred to in this Annual Report on Form 10-K: "MyoPro ® ", "MYOMO" ®, "MyoPal" ® and "MyoCare" ®. All other trademarks or trade names referred to in this Annual Report on Form 10-K are the property of their respective owners. Solely for convenience, the trademarks and trade names in this Annual Report on Form 10-K are referred to without the symbols ® and ™, but such references should not be construed as any indicator that their respective owners will not assert, to the fullest extent possible under applicable law, their rights thereto.

Item 1. Business

Overview

We are a wearable medical robotics company that offers functional improvement for those with neuromuscular disorders and upper limb paralysis. We develop and market the MyoPro product line. A MyoPro is a myoelectric-controlled upper limb brace, or orthosis. The orthosis is a rigid brace used for the purpose of supporting a patient's weak or paralyzed arm to enable and help improve functional activities of daily living, or ADLs, in the home and community. It is custom-fabricated by trained professionals during a custom fabrication process for each individual user to meet their specific needs. Our products are designed to help improve function in adults and adolescents with neuromuscular conditions due to brachial plexus injury, stroke, traumatic brain injury, spinal cord injury and other neurological disorders. We primarily provide devices directly to patients and bill their insurance companies directly, a sales channel we refer to as direct billing. Under direct billing, we evaluate, measure and fit the MyoPro devices using our own clinical staff or as circumstances dictate, utilize the clinical consulting services of orthotics and prosthetics, or O&P, professionals, for which they are paid a fee. We also sell our products through various other sales channels, including through O&P providers, which we expect to be a larger contributor to revenue in the future, the Veterans Administration, or VA, and to certain accounts and geographic markets outside the United States. We operate as one business segment.

Our goal is to address the need to help regain function to individuals who have suffered partial paralysis and can no longer support or move their arm or hand despite the best efforts of surgeons and rehabilitation therapists. Our solution, the MyoPro custom fabricated limb orthosis, is for the upper limbs. The concept was originally pioneered in the 1960s, refined in the labs of the Massachusetts Institute of Technology, or MIT, and made commercially feasible through our efforts. Partial paralysis is severe muscle weakness or loss of voluntary movement in one or more parts of the body. The MyoPro is listed in the United States with the FDA as a Class II (510(k)-exempt) device (Biofeedback Device). We believe it is the only device commercially available in the United States that is able to help neuromuscular-impaired people who have been through therapy and have been left with partial paralysis regain function in weak arms and hands using their own muscle signals. The device consists of a portable arm brace made of a lightweight metal and includes advanced signal processing software, non-invasive sensors, small motors, a lightweight battery unit, and 3D printed materials which are unique for each patient's arm and hand measurements. The product is worn to support the arm and hand and as a functional aid for reaching and grasping and has also been shown to have therapeutic benefits for some users to increase motor control.

The MyoPro's control technology utilizes an advanced human-machine interface based on non-invasive, patented electromyography, or EMG, control technology that continuously monitors and senses, but does not stimulate, the affected muscles. The patient self-initiates movement through his or her weakened muscle signals that indicate the intention to move. In addition to supporting the weakened limb, the MyoPro functions as a neuro-muscular orthotic by helping regain function to the impaired limb similarly to a myoelectric prosthetic for an amputee. It is prescribed by physicians and provided by trained clinical professionals as a custom-fabricated myoelectric elbow-wrist-hand orthosis.

In addition to stroke patients, we believe our technology may be used on medically appropriate patients to improve upper extremity movement in patients with peripheral nerve injury, spinal cord injury, cerebral palsy, traumatic brain injury, and other neurological disorders, depending on the individual patient's condition.

Our strategy is to establish ourselves as the market leader in myoelectric limb orthotics, and to build a set of products, software applications, and value-added services based upon our patented technology platform, sized for adults, adolescents and children. We expect to introduce the MyoPro3, which will include further improvements over the MyoPro2+, and our MyoPal device for pediatric use at a future date.

The addressable market in the United States for products directed at all individuals with upper extremity paralysis, such as our MyoPro, is based on an estimated prevalence of 1% of the population, which is the prevalence of people who have suffered a stroke in the U.S., or an estimated 3 million existing cases of upper extremity paralysis. Of that population, we estimate that up to 20% of such individuals may be medically qualified candidates for a MyoPro whose insurance may reimburse for the device, which now includes Medicare Part B beneficiaries. In addition, we

estimate that approximately 250,000 new patients are added to the prevalence population each year in the United States as a result of strokes, brachial plexus injuries and other afflictions. Though not all these new chronic patients are suitable for a MyoPro, we believe that between 25,000-50,000 of these patients per year could be. According to the National Institutes of Health, it is estimated that nearly 75% of all strokes occur in people aged 65 and over. With the Centers for Medicare and Medicaid Services, or CMS, reimbursing on a lump sum basis for the MyoPro and Medicare Advantage plans obligated to follow suit, assuming medical necessity is demonstrated, we believe our market opportunity is substantial.

To assess whether an individual is a medically-qualified candidate for a MyoPro, we and our channel partners utilize a variety of techniques to evaluate patients, including tele-health video conference sessions, in-person evaluations, screening days at various locations, and evaluations at clinical facilities where therapists and physicians refer patients for a MyoPro, which requires a physician's prescription to be reimbursed by insurance. We use various media to educate individuals about the MyoPro solution for their impaired limbs, and we receive referrals from O&P providers and healthcare facilities such as VA Medical Centers.

In many cases, private health insurance companies reimburse providers for the MyoPro device. If we are serving the patient directly, then we bill the payer as the provider. If an O&P provider is responsible for working with and delivering the MyoPro to the patient, then we sell the custom-fabricated MyoPro device to the O&P provider at a wholesale price, to which they add their clinical services. In November 2018, CMS issued two billing codes for the MyoPro, L8701 and L8702. In November 2023, CMS reclassified the MyoPro into the brace benefit category, effective January 1, 2024. Previously, CMS had classified the MyoPro as durable medical equipment, reimbursed on a rental basis. With the classification as a brace, the MyoPro is eligible to be reimbursed on a lump sum basis by CMS similar to other commercial insurance payers. On February 29, 2024, CMS published final payment determinations for the MyoPro Motion W (L8701) and for the MyoPro Motion G (L8702), which became effective April 1, 2024. These fees were subsequently updated to approximately $34,300 for the Motion W and approximately $67,500 for the Motion G, effective January 1, 2025. The fees are subject to an annual inflationary adjustment.

We hold 35 patents in the United States and various countries, which expire at various times from 2027 through 2042, and we have 12 pending patent applications in the United States and international markets. Our intellectual property also consists of trade secrets related to myoelectric control software and mechanical designs from over ten years of R&D and product development activity.

We are headquartered in Burlington, Massachusetts.

Market Opportunity: Common Causes of Arm Paralysis

Stroke

According to the Centers for Disease Control and Prevention, or the CDC, stroke is one of the leading causes of disability in the United States affecting approximately 800,000 people per year. We have working relationships with rehabilitation facilities in the United States, including the Mayo Clinic, Cleveland Clinic, Spaulding Rehabilitation Hospital, Loma Linda University Medical Center, Kennedy Krieger Institute, and numerous VA Medical Centers, and we have developed an appropriate set of inclusion criteria to determine which persons that are affected by stroke would be medically qualified for the intervention.

Many stroke survivors are left with hemiparesis, a partial paralysis of one side of the body, which impacts the ability to use their arm and/or hand. Occupational therapy is the common treatment recommended to regain native function for these individuals, and some do recover some movement of the upper limb. However, after a period of therapy, many patients plateau and continued therapy does not tend to result in significant further improvement. These chronic patients then enter the prevalence population and become potential candidates for the MyoPro, which we believe is the most effective alternative for regaining function for these individuals.

Vehicular and Workplace Accidents

One application for the MyoPro is to support the weak arm and help regain arm function to individuals who have suffered peripheral nerve injuries. A common outcome of vehicular and workplace accidents is damage to the nerves in the shoulder known as the brachial plexus. Many individuals recover from their related trauma with the exception of

the ability to control their elbow and/or hand. Nerve transfer surgery is often a solution; however, these procedures are not always restorative. In some cases, patients undergo amputation and receive myoelectric prosthetics rather than deal with a paralyzed arm.

Spinal Cord Injuries

According to the Christopher and Dana Reeve Foundation, spinal cord injuries are second only to strokes as a cause of paralysis, resulting in 27% of cases of paralysis. The level of paralysis depends on where the injury occurs. Currently, medically qualified individuals for a MyoPro include those with incomplete spinal cord injuries having sufficient remaining EMG signal strength to initiate movement of the devices, as determined by the clinician using a MyoPro demonstration unit.

Cerebral Palsy

Based on data provided by the CDC, the prevalence of cerebral palsy, or CP, in the United States is approximately 73,000 for children ages 6-11 years old. CP is caused by brain injury or brain malformation that occurs before, during, or immediately after birth while the infant's brain is under development.

Birth Brachial Plexus Injuries

During birth, some newborns suffer an injury to the brachial plexus nerve, which can result in arm paralysis. According to Boston Children's Hospital, one to three births out of 1,000 involve a brachial plexus injury, with roughly 20-30% resulting in arm paralysis. We have been testing our planned pediatric device on children who have suffered this nerve damage to assess its ability to improve function in upper limbs, and this new version of the MyoPro, which we refer to as MyoPal, is expected to be available to these patients in the next one to two years.

Progressive Conditions

The MyoPro has been prescribed in a few cases for individuals with progressive conditions such as multiple sclerosis. For individuals with these conditions, the MyoPro is used for functional improvement that may help provide strength conservation and help to extend the time they can maintain independence. As users continue to progress with their condition, settings can be adjusted to provide increasing amounts of assistance.

Arm Paralysis Solutions & Treatments

The standard of care for treating paralysis varies by diagnosis. In the case of neurological injuries such as stroke, occupational / physical therapy is the standard of care. Each year, stroke and other survivors undergo months of rehabilitation. Unfortunately, many are left with long term hemiparesis, which is weakness on one side of the body. Interventions such as electrical stimulation, static braces, and continued therapy are available, and yet the prevalence of chronic upper limb paralysis is in the millions.

Our Solutions

Although commercial products for powered prosthetics have been available since the 1970s, we believe that powered orthotics have been held back by issues related to weight, comfort, and the technological capability of microprocessors and software. The MyoPro is a custom fabricated limb orthosis. It is created individually for each patient, which is done by using 3D printing techniques for the orthotic components, where the measurements can be obtained either in-person or remotely. Using remote measurement for the orthotic components can reduce the number of in-person visits by our clinical field staff.

Orthotic devices are provided by clinical professionals who fit these devices. According to the American Orthotics and Prosthetics Association, there are more than 2,000 member O&P facilities located in the United States. Additionally, the VA has been a pioneer in O&P. In fact, the design of the MyoPro Motion G powered grasp product is rooted in research conducted at the Boston-area VA in the 1990s. This research demonstrated that it is technically feasible to design a myoelectric elbow-hand orthosis; however, we believe that the product was not commercially practical until we were able to incorporate recent technological developments such as improved microprocessors and software, lightweight materials and motors, and smaller batteries to create an acceptable orthosis for users.

The MyoPro can enable individuals to self-initiate and control movements of a partially paralyzed or weakened limb using their own muscle signals. When the user tries to move, our patented EMG control system uses sensors to detect the weak muscle signal and to activate a motor to move the limb in the desired direction. The user is in control of their own limb; the brace amplifies their weak muscle signal to regain function to the affected joint. Importantly, the EMG-driven device requires that users are actively engaged throughout the movement; if they stop trying to move, the device stops. With our product, someone who has upper extremity paralysis from a brachial plexus injury, stroke or other neuromuscular disorder can experience improved function in performing ADLs including feeding, reaching and lifting.

Each MyoPro brace is custom fabricated for each patient for optimum fit, mobility and performance. To qualify for a MyoPro, candidates must meet a comprehensive set of requirements determined by a trained clinical professional during an evaluation. These criteria include long term partial paralysis, detection of a muscle signal sufficient to control the device, demonstrated cognitive abilities, and lack of other conditions that might limit the effectiveness or safety of the device such as use of certain pharmaceuticals, high levels of pain, or limits to range of motion, as well as falling within measurement limitations for the arm and hand to be able to fit into the device. Finally, candidates must have meaningful and achievable functional goals that can realistically be accomplished with the device that cannot otherwise be achieved with other interventions.

Should the individual qualify, we (in the case of direct billing) or the O&P provider will determine whether the device may be covered by the individual's health insurance. If reimbursement is approved and the individual is a suitable candidate for a MyoPro, then the fabrication and fitting process is undertaken:

- First, we capture the shape of the patient's arm, using our shape capture kit, which can be completed in-person or remotely. Once the patient's arm measurements are captured, the orthotic parts are 3D printed by a subcontractor based on these measurements. The fabrication of the brace is completed in-house.
- Fabrication typically takes approximately 2 weeks. Once the brace is fabricated, it is delivered to the patient either by us, an O&P practice, or a trained professional at a VA hospital, who will fit the device on the patient. During this fitting, the device will be calibrated to the user's individual muscle signal profile using our proprietary software, and adjustments to the brace can be made to optimize fit.
- The patient is provided with initial training and a set of take-home tasks to practice with the brace donned. We also provide a video game platform called MyoGames, which offers the patient an additional means to master the device. We or the O&P provider will also refer the MyoPro user to a local therapist for continued training and practice with their new device, and we have a staff of occupational therapists and other qualified clinicians who train and support these therapists. In addition, under our MyoCare program, a coach is assigned to each patient that is provided a device by us, and follows and guides the patient for the first year of the patient's journey with the MyoPro in order to maximize each patient's outcomes with the device.

We believe that the use of the MyoPro is compelling since it enables functional improvement that can help users improve their ability to perform ADLs, which may allow them to return to work or improve their ability to be independent and remain at home. According to the CDC, 7% of adults aged 65 and over in the United States require daily help with ADLs. For patients without caregivers, such long term, full-time support services cost approximately $62,400 annually according to The KFF. This approximates the cost to a payer for a MyoPro, which is paid once. With more than 70 million baby boomers now in, or headed into their retirement years, we believe that it is vital to keep beneficiaries in the lowest cost of care setting — the home.

Research and Development

We are committed to investing in a robust product development program and to supporting a variety of clinical research studies to enhance our products, increase the body of evidence to support prescribing and reimbursing our devices, and to grow our range of product offerings. Our R&D team is comprised of engineers with a mix of BS and MS degrees in electrical engineering, mechanical engineering, robotics engineering and computer science and augmented by outside resources as needed. The R&D team seeks to combine innovative research conducted over the last 50 years with cutting edge innovations in robotics, machine learning, material science and artificial intelligence to

continue to enhance our products and product offerings. Our regulatory, clinical, and customer service personnel work closely with our suppliers and providers to promote compliance with quality standards and good manufacturing processes, which we believe result in a high-quality product and limited customer issues.

We have continually enhanced our product offerings by increasing functionality for users by the addition of a multi-articulated wrist and introducing a powered grasp for the hand. Our flagship product is the MyoPro 2, introduced in June 2017, which features improvements in control technology, new configuration software and user interface, and a longer-lasting, pop-out battery for extended use of the brace and convenient replacement. In January 2022, we introduced the MyoPro2+, which is a lighter and more advanced version of the device, which includes 3D printed orthotics capability, software enhancements and a new design that facilitates easier donning and doffing of the device. An update to the MyoPro 2+ is scheduled to be released in the second half of 2025.

We plan, depending on available resources, to continually improve our system architecture and develop new product innovations based on our product roadmap and clinician feedback to increase the value and breadth of our product offerings.

Clinical Research Studies

Evidence of effectiveness involving myoelectric orthotics dates back to 1967. We have partnered with leading researchers to study the impact of the technology to regain function to a paralyzed joint as well as the real-world benefit that comes from being able to independently perform ADLs in the home, vocational tasks at work, and community activities such as shopping. In 2023, a study was published based on data obtained from our internal outcomes patient registry that compared functional task performance while wearing a MyoPro. The results showed that the MyoPro provides stabilizing support to the weak warm of individuals after a stroke and enables individuals to use their impaired arm to complete functional tasks independently in the home environment. An additional study has been completed and published that used a validated outcome measure called Disabilities of the Arm, Shoulder and Hand, or DASH, to study improvements in the arms of patients that wear a MyoPro. The results showed statistically significant and clinically meaningful improvement in DASH scores. In addition to this research, several institutions have active funded research programs. In February 2022, researchers with the Cleveland VA published a study showing clinically significant gains in motor function in individuals with chronic moderate-to-sever arm weakness. Currently funded studies include a randomized control trial by the Kessler Foundation, using the MyoPro to study the restoration of upper extremity motor function in people with spinal cord injury, and a recently initiated randomized control trial at the Cleveland VA using the MyoPro for stroke patients using motor learning in therapy and home use. Researchers at the University of Utah published a paper reporting that stroke survivors can achieve proportional EMG control, regardless of their age, time since their stroke, clinical spasticity rate, and history of botulism toxin injections. This work constitutes an important step toward the advancement of more intuitive and dexterous myoelectric upper extremity orthosis which may improve the quality of life.

Sales and Marketing

Our strategic goal is to develop and commercialize products that become the standard of care for individuals with paralysis who cannot be successfully treated with conventional interventions such as rehabilitation therapy. Our strategy is to establish ourselves as a market leader in myoelectric-controlled orthotics by building a set of products, software applications, and value-added services based upon our patented technology platform. With a first-mover advantage in the U.S. and a presence in international markets such as Germany and the United Kingdom, we believe we are well-positioned to meet the large global need that we believe exists for individuals with upper limb paralysis.

To generate awareness and interest in our products, we perform in-services for therapists and physicians, and we directly educate and inform those individuals who are potential candidates for our products. In addition, we utilize digital ads on various platforms as well as television ads. Once the prospective patient contacts us or is referred to us, either our trained clinical staff or a trained O&P provider evaluates the patient for their suitability as a candidate. In instances where we are the provider, the initial clinical screening is often conducted using a telehealth platform. Next, the patient's medical records are collected and reviewed to make sure the device is appropriate for their condition and a prescription is typically obtained from the patient's physician in conjunction with a face-to-face visit. Once these documents are obtained and reviewed to ensure our inclusion criteria are met, we will proceed to measure the patient's arm, manufacture and provide the device to a qualifying Medicare patient. For patients with Medicare Advantage or other commercial insurance, our patient advocacy team submits a pre-authorization request to the patient's insurer. If we receive a pre-authorization, we will proceed to complete the aforementioned activities resulting in the delivery of a

MyoPro to the patient. This process is what we refer to as direct billing. We also call on hospitals and O&P practices that provide our products to their patients as well as indirect sales through O&P providers in Europe and Australia. The MyoPro product line has been approved by the VA system for impaired veterans, and more than 130 VA facilities have ordered devices for their patients.

Since we began marketing our products directly to patients in 2019, our business development efforts have focused on developing a pipeline of patients in our reimbursement process and expanding the number of payers reimbursing for our products. As of December 31, 2024, 1,389 patients were in our reimbursement pipeline, a 33% increase compared to 1,042 patients in the pipeline at December 31, 2023. As of December 31, 2024, 272 MyoPro units were in backlog, which we define as patients for whom we received insurance authorization, or in the case of Medicare Part B patients, those who have been qualified for delivery through receipt of required medical documentation, but revenue has not been recognized. This represents an 18% increase over 230 patients in backlog at December 31, 2023. The estimated maximum potential revenue value of the backlog is approximately $13.6 million.

To bring the MyoPro to what we believe is the large number of potential patients outside of the United States, in July 2017 we met the criteria to apply the CE mark under the European Union (EU) Medical Devices Directive (93/42/EEC), or EU MDD, which is a manufacturer's declaration that the product complies with the essential requirements of such legislation, so that the MyoPro can be marketed in the EU. The EU Medical Devices Regulation (EU) No. 2017/745, or the EU MDR, repealed and replaced the EU MDD on May 26, 2021 and we therefore worked with our EU-Authorized Representative to ensure all EU MDR requirements were met, which enabled us to establish a new declaration of conformity under the EU MDR to allow continued CE mark application. In October 2017, we obtained our medical device license for Canada, enabling us to provide the MyoPro to patients in that country. We have entered into agreements with O&P providers in the United Kingdom, Denmark, Germany, Italy and Australia, and have received a number of MyoPro orders from providers outside the United States in 2024, primarily from Germany.

Competition

An individual with difficulty walking has a wide range of technological alternatives from canes and crutches to powered wheelchairs and exoskeleton suits. However, those with paralysis of the arm, wrist, and hand, whose physical challenges that we seek to address, have few options to regain function.

Rehabilitation Therapy

Rehabilitation therapy is the standard of care for upper extremity paralysis and a prerequisite to qualifying for a myoelectric orthosis such as the MyoPro. After a stroke or other traumatic injury, a large portion of survivors regain much or all of their function. However, every year there are many survivors whose upper extremities remain paralyzed despite best efforts of rehabilitation therapists.

Non-Powered Braces

Some individuals are able to accomplish their functional goals with braces that are non-powered or use springs to offset forces of gravity or muscle tightness, referred to as spasticity. Medical professionals who evaluate patients for myoelectric orthotics screen out individuals who could accomplish their goals with a simpler, less costly intervention such as these braces.

Exoskeleton Suits

During the last few years, a number of companies have emerged to provide exoskeleton suits that enable those with lower extremity paralysis to stand and walk again. Companies in this space include Lifeward, Ekso Bionics, and Cyberdyne. It is possible that companies may begin to compete with solutions such as ours for the upper extremity.

Potential New Products from O&P Manufacturers

If our business grows, interest may develop among new or existing manufacturers of other O&P devices that compete with the MyoPro, which may or may not challenge the validity of our intellectual property. Some new products have

been introduced that compete with the MyoPro from companies such as Neurolutions in the United States and Vincent Systems and HKK in Germany.

Intellectual Property

Our intellectual property efforts have focused on improvements to the patents that we licensed from MIT, which expired in 2023. Myomo has 35 of its own issued patents. These additional patents cover our MyoPro Motion G product. The Motion G product, which allows for the movement of multiple joints as compared to a single joint, which is the technology that underlies the patents previously licensed from MIT. The Motion G generated 98% of our product revenue for the year ended December 31, 2024. In January 2013, Myomo's patent entitled *Powered Orthotic Device* was granted in Europe (European Patent No. 2079361), which is validated (currently in force) in six European countries. In June 2014, a substantially similar patent was granted in Japan (Japanese Patent No. 5557529). In November 2013 and January 2015, Myomo's first two U.S. patents were issued entitled *Powered Orthotic Device and Method of Using Same* (U.S. Pat. Nos. 8,585,620 and 8,926,534, respectively). On July 26, 2016, Myomo's third U.S. patent was issued (U.S. Pat. No. 9,398,994). In September 2020, Myomo's fourth U.S. patent was issued entitled *Powered Orthotic Device and Method of Using the Same* (U.S. Pat No. 10758394B2). In 2023, Myomo was issued two additional U.S. patents, *Self Donning Powered Orthotic Device* (U.S. Pat No. 11712360) and *Powered Orthotic Device and Method of Using Same* (U.S. Pat No. 11826275). Similar patents have been issued in China, Hong Kong, and Japan and is validated (currently in force) in six European countries (European Patent No. 3307225). We also have 8 pending U.S. patent applications and 4 foreign applications under examination. We plan to continue to file additional patent applications over time. The longest term of our patents extends intellectual property rights until 2042.

In terms of trademarks, the terms Myomo, MyoPro, MyoPal and MyoCare are registered as trademarks with the U.S. Patent & Trademark Office. Our trademarks were initially registered in 2013 and 2014, and we have been making the required filings to maintain our trademarks.

Government Regulation

The MyoPro device and our operations including our supply chain and distribution channels are subject to regulation by the FDA and various other U.S. federal and state agencies. Under the Federal Food, Drug, and Cosmetic Act, or FFDCA, medical devices are classified as Class I, Class II or Class III, depending on the degree of risk associated with the device, what is known about the type of device, and the extent of control needed to provide reasonable assurance of safety and effectiveness. Classification of a device is important because the class to which a device is assigned determines, among other things, the necessity and type of FDA premarket review. We have elected to list the MyoPro Family of products under a Class II device classification regulation for biofeedback devices. Under the classification regulation, we believe our device remains 510(k)-exempt as a battery powered, external limb orthosis device that is indicated for muscle relaxation or muscle re-education are generally 510(k)-exempt under the classification regulation. While we believe our device to be exempt from FDA premarket review, our device is subject to FDA's post-market requirements, which include compliance with the applicable portions of the FDA's Quality System Regulation, or QSR, facility registration and product listing, reporting of adverse medical events, and appropriate, truthful and non-misleading labeling, advertising, and promotional materials.

We are also subject to regulation by foreign governmental agencies in connection with international sales. These agencies enforce laws and regulations that govern the development, testing, manufacturing, labeling, advertising, marketing and distribution, and market surveillance of our medical device products. In the EU, medical devices are regulated under the Medical Devices Regulation (EU) No. 2017/745, or the EU MDR, which repealed and replaced the previous Medical Devices Directive 93/42/EEC, or EU MDD, on May 26, 2021.

The EU MDR, among other things:

- strengthens the rules on placing devices on the market (e.g., reclassification of certain devices and wider scope than the EU MDD) and reinforces surveillance once they are available;
- establishes explicit provisions on manufacturers' responsibilities for the follow up of the quality, performance and safety of devices placed on the market;
- establishes explicit provisions on importers' and distributors' obligations and responsibilities;
- imposes an obligation to identify a responsible person who is ultimately responsible for all aspects of compliance with the requirements of the new regulation;

- improves the traceability of medical devices throughout the supply chain to the end user or patient through the introduction of a unique identification number, to increase the ability of manufacturers and regulatory authorities to trace specific devices through the supply chain and to facilitate the prompt and efficient recall of medical devices that have been found to present a safety risk; and
- sets up a central database (EUDAMED) to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU.

Under the EU MDR, all medical devices placed on the market in the EU must meet the relevant general safety and performance requirements laid down in Annex I to the EU MDR, including the requirement that a medical device must be designed and manufactured in such a way that, during normal conditions of use, it is suitable for its intended purpose. In addition, a medical device must be safe and effective and must not compromise the clinical condition or the safety of patients. To demonstrate compliance with such general safety and performance requirements, medical device manufacturers must undergo a conformity assessment procedure, which varies according to the type of medical device and its (risk) classification. Demonstration of conformity with the general safety and performance requirements includes a clinical evaluation. Specifically, a manufacturer must demonstrate that the device achieves its intended performance during normal conditions of use, that the known and foreseeable risks, and any adverse events, are minimized and acceptable when weighed against the benefits of its intended performance, and that any claims made about the performance and safety of the device are supported by suitable evidence. Except for low-risk medical devices (Class I non-sterile, non-measuring devices), where the manufacturer can self-declare the conformity of its products with the general safety and performance requirements (except for any parts which relate to sterility or metrology), a conformity assessment procedure requires the intervention of a notified body. Notified bodies are independent organizations designated by EU member states to assess the conformity of devices before being placed on the market. A notified body would typically audit and examine a product's technical dossiers and the manufacturers' quality system. If satisfied that the relevant product conforms to the relevant essential requirements, the notified body issues a certificate of conformity, which the manufacturer uses as a basis for its own declaration of conformity. The manufacturer may then apply the CE mark to the device, which allows the device to be placed on the market throughout the EU.

All manufacturers placing medical devices on the market in the EU must comply with the EU medical device vigilance system which has been reinforced by the EU MDR. Under this system, serious incidents and field safety corrective actions , or FSCAs must be reported to the relevant authorities of the EU member states. These reports will have to be submitted through EUDAMED – once functional – and aim to ensure that, in addition to reporting to the relevant authorities of the EU member states, other actors such as the economic operators in the supply chain will also be informed. Until EUDAMED is fully functional, the corresponding provisions of the EU MDD continue to apply. A serious incident is defined as any incident, which, directly or indirectly, led, might have led or might lead to the death of a patient or user or other person, or to a temporary or permanent serious deterioration of a patient's, user's or other person's state of health, or a serious public health threat. In addition, among the new requirements of the EU MDR, manufacturers (and authorized representatives) must have available within their organization at least one person responsible for regulatory compliance, or PRRC, who possesses the requisite expertise in the field of medical devices. The PRRC is notably responsible for compliance with post-market surveillance and vigilance requirements. The European Commission has adopted various standards applicable to medical devices and there are additionally harmonized standards relating to the design and manufacture of medical devices (such as the international management system standard for medical systems set by the International Organization for Standardization or ISO, ISO13485:2016) which are not mandatory however, if complied with, indicate that the device satisfies the applicable element of the general safety and performance requirements.

The aforementioned EU rules are generally applicable in the European Economic Area, or EEA, which consists of the EU member states plus Norway, Liechtenstein and Iceland.

The UK formally left the EU on January 31, 2020. In respect of medical devices, since the end of the Brexit transitional period on January 1, 2021, new regulations require medical devices to be registered with the Medicines and Healthcare products Regulatory Agency, or MHRA (the UK medicines and medical devices regulator) before being placed on the Great Britain market. If a manufacturer of a device placed on the market in Great Britain is based outside of the UK, the manufacturer must appoint a UK responsible person with a registered place of business in the UK to act on the manufacturer's behalf in respect of certain activities (e.g. device registration). CE marks issued by EU notified bodies to place medical devices on the market in the EU will remain valid in the UK up until, at the latest,

June 30, 2028 (for CE marks issued under the EU MDD) or June 30, 2030 (for CE marks issued under the EU MDR), following which a UK Conformity Assessed, or UKCA, mark will be required to place a device on the Great Britain market. Manufacturers may choose to use the UKCA mark on a voluntary basis prior to such dates. UKCA marking will, however, not be recognized in the EU. The EU regulatory framework on medical devices continues to apply in Northern Ireland under the Windsor Framework and medical devices in Northern Ireland may either carry an EU CE mark or a UK and Northern Ireland CE mark, or CE UK(NI), although devices bearing the CE UK(NI) marking will not be accepted on the EU market.

We, together with Cogmedix, our primary contract manufacturer, actively maintain a quality management system for product design and development, manufacturing, distribution, and customer feedback processes in accordance with FDA's QSR and ISO 13485:2016. In February 2024, the FDA issued the Quality Management System Regulation Final Rule to amend the QSR, incorporating by reference ISO 13485:2016. The rule will become effective on February 2, 2026. Until then, manufacturers are required by the FDA to comply with the QSR. Following the introduction of a product, the FDA and comparable foreign agencies may engage in periodic audits of our quality management system, the product performance, and our advertising and promotional materials. These regulatory controls, as well as any changes in the policies of the FDA or comparable foreign agencies, can affect the time and cost associated with the development, introduction and continued availability of new products. We work to anticipate these factors in our product development processes.

In addition to our EU authorization as outlined above, we have a Medical Device License for Canada. In addition, Myomo has obtained certification of our Quality System, or QS, to the Medical-Device-Single-Audit-Program, or MDSAP. This certifies compliance of the QS for sales in the United States, Canada, Brazil, Australia, and Japan. If we enter into other jurisdictions with additional international partners, we will need to seek the appropriate government approval to supply the devices in these countries. If we fail to comply with applicable foreign regulatory requirements, we may be subject to various administrative and legal actions against us, such as product recalls, product seizures and other civil and criminal sanctions.

Healthcare and Privacy Laws and Regulation

As an accredited Medicare provider, we are subject to broadly applicable fraud and abuse and other healthcare laws and regulations. Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, CMS, other divisions of the Department of Health and Human Services, or HHS, such as the Office for Civil Rights or the Office of Inspector General, the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments.

Additionally, healthcare providers and third-party payers play a primary role in the recommendation of medical devices and other medical items and services. Arrangements with providers, consultants, third-party payers and customers are subject to broadly applicable fraud and abuse, anti-kickback, false claims laws, reporting of payments to physicians and teaching hospitals, patient privacy laws and regulations and other healthcare laws and regulations that may constrain our business and/or financial arrangements. Restrictions under applicable federal and state healthcare and privacy laws and regulations, include the following:

- the federal Anti-Kickback Statute, which makes it illegal for any person, including a medical device manufacturer and DME suppliers (or a party acting on its behalf), to knowingly and willfully solicit, receive, offer or pay any remuneration (including any kickback, bribe or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, or in return for, that is intended to induce or reward referrals, including the purchase, recommendation, order of a medical device or DME for which payment may be made under a federal healthcare program, such as Medicare or Medicaid. A person or entity need not have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus imprisonment and exclusion from government healthcare programs. In addition, the government may assert that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act, or FCA. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;

- the federal civil and criminal false claims laws, including the FCA, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false, fictitious or fraudulent; knowingly making, using or causing to be made or used, a false statement or record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payers if they are deemed to "cause" the submission of false or fraudulent claims. DME companies that submit claims directly to payers may also be liable under the FCA for the direct submission of such claims. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. When an entity is determined to have violated the FCA, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;

- the federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer or remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state health care program, unless an exception applies;

- the Health Insurance Portability and Accountability Act, or HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payer (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their respective implementing regulations, including the Final Omnibus Rule published in January 2013, which impose requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information, relating to the privacy, security and transmission of individually identifiable health information. HITECH also created tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;

- the federal Physician Payments Sunshine Act, created under the ACA, and its implementing regulations, which require manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to HHS, under the Open Payments Program, information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members; and

- analogous state and foreign law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers or patients; state laws that require device companies to comply with the industry's voluntary compliance guidelines and the applicable compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and local laws that require the licensure of sales representatives; state laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers or marketing expenditures and pricing information; data privacy

and security laws and regulations in foreign jurisdictions that may be more stringent than those in the United States (such as the European Union, which adopted the General Data Protection Regulation, which became effective in May 2018); state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and may not have the same effect, thus complicating compliance efforts; and state laws related to insurance fraud in the case of claims involving private insurers.

Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities could, despite efforts to comply, be subject to challenge under one or more of such laws. Moreover, efforts to ensure that our business arrangements comply with applicable healthcare laws may involve substantial costs. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, disgorgement, monetary fines, exclusion from participation in Medicare, Medicaid and other federal healthcare programs, integrity and oversight agreements to resolve allegations of non-compliance, contractual damages, reputational harm, diminished profits and future earnings, and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. In addition, the commercialization of any of our products outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

Health Insurance Reimbursement

In the United States and markets in other countries, patients who are prescribed medical devices for their conditions and providers delivering the prescribed devices generally rely on third-party payers to reimburse all or part of the associated healthcare costs. MyoPro devices are typically reimbursed by the patient's health insurance plan, which include government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations. To obtain approval for reimbursement, payers require various items which may include a physician's written order, a history of the patient's medical condition and past treatment, and demonstration of medical necessity. Factors payers consider in determining reimbursement are based on whether the product is: a covered benefit under its health plan; safe, effective, and medically necessary; appropriate for the specific patient; cost effective, and neither experimental nor investigational.

Our Patient Advocacy Team assists patients in developing and submitting this documentation for coverage of the prescribed MyoPro. Since the MyoPro is a relatively new device, payers may not be familiar with the device, and in some cases, payers may deem it to be experimental or investigational and establish non-coverage policies for the device. National and regional commercial plans, worker's compensation programs, auto insurance carriers, Medicare Advantage plans, and some state Medicaid plans have paid for the MyoPro orthosis on a lump sum basis. Beginning January 1, 2024, CMS reimburses for the MyoPro on a lump sum basis. For payers other than CMS, the reimbursement process usually requires obtaining a pre-authorization for the MyoPro from the patient's insurer, and if the authorization request is initially denied by the payer, we may provide support to the patient, or the O&P provider as the case may be, in appealing the decision. We have been successful in obtaining coverage for the MyoPro on a case by case basis and we continue to follow up on other cases in our reimbursement pipeline which are pending an insurance decision.

As of January 1, 2019, two HCPCS codes for the MyoPro, L8701 and L8702, issued by CMS, went into effect. CMS elected to classify the MyoPro for Medicare beneficiaries as DME to be provided to patients under a capped rental payment system. In November 2023, CMS reclassified the MyoPro billing codes (L8701 and L8702) into the brace benefit category, which makes the MyoPro eligible to be reimbursed on a lump sum, rather than a rental basis. In conjunction with our reclassification into the brace benefit category, on February 29, 2024, CMS published final payment determinations for the MyoPro Motion W (L8701) and for the MyoPro Motion G (L8702) which became effective April 1, 2024. These fees were subsequently updated to approximately $34,300 for the Motion W and approximately $67,500 for the Motion G, effective January 1, 2025. Published fees are subject to annual inflationary adjustments. Currently, the DME MACs are reimbursing claims upon submission and may conduct post-reimbursement audits in the future to determine if claims for medically appropriate patients are being submitted.

Medicare Advantage insurance plans are obligated to reimburse for the MyoPro, so long as the device is deemed to be medically necessary for their beneficiaries as well as not experimental or investigational. Such determinations by these payers continue to be determined on a case-by-case basis.

Based on the final published fees, our O&P partners, as well as others whom we do not work with today, may find the fees sufficient to cover the cost of the MyoPro device, the clinical services to evaluate and fit patients, and the other support services associated with provisioning of products to patients, which may result in higher sales volume from that channel in 2025 and beyond.

Current and Future Legislation

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could affect our ability to profitably sell MyoPro. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

In the United States, there have been and continue to be a number of legislative initiatives and legal challenges to contain healthcare costs. For example, in March 2010, the ACA was passed, which substantially changed the way healthcare is financed by both governmental and private insurers, and significantly impacted the United States medical device industry to which we sell our products. Among other things, the ACA:

- established a 2.3% excise tax on sales of medical devices with respect to any entity that manufactures or imports specified medical devices offered for sale in the United States, although this provision was subsequently repealed in December 2019;
- established a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in and conduct comparative clinical effectiveness research;
- implemented payment system reforms, including a national pilot program to encourage hospitals, physicians and other providers to improve the coordination, quality and efficiency of certain health care services through bundled payment models; and
- created an independent payment advisory board that will submit recommendations to reduce Medicare spending if projected Medicare spending exceeds a specified growth rate.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. 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. It is unclear how other healthcare reform measures in Congress or through executive orders, if any, to challenge repeal or replace the ACA, will impact our business.

In addition, other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, resulted in aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in 2013, and, due to subsequent legislative amendments, will remain in effect until 2032. The American Taxpayer Relief Act of 2012 further reduced Medicare payments to several types of providers, including hospitals and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

In response to perceived increases in healthcare costs in recent years, there have been and continue to be proposals by the Presidential administrations, members of Congress, state governments, regulators and third-party payers to control these costs and, more generally, to reform the United States healthcare system, including by repealing or replacing the ACA. Many elements of health care reform such as comparative effectiveness research, payment system reforms including shared savings pilots and other provisions could meaningfully change the way healthcare is developed and

delivered, and may materially adversely impact numerous aspects of our business, results of operations and financial condition.

Manufacturing

Myomo's custom fabricated orthosis is comprised of two elements. The first is the electromechanical kit. The kit consists of the motor units, processor, sensors, and battery. Manufacturing for the electromechanical kit is provided by our supplier Cogmedix, a wholly owned subsidiary of Coughlin Companies in Worcester, MA. The second element is the custom fabrication of the orthosis itself from measurements obtained either in person or remotely. A third-party, AB Corp, creates the orthotic parts from these measurements and the fabrication of the device is done in our facility in Burlington, Massachusetts.

Coverage for the MyoPro from CMS is expected to increase sales volumes for the MyoPro. In January 2025, we completed the move of our manufacturing operations from Boston to our new headquarters facility in Burlington, MA. We have double the manufacturing floor space compared to our prior facility in Boston, and our available manufacturing space will increase again when we take possession of an additional 7,500 square feet of manufacturing space in June 2025. Our current capacity is 120 units per month, and we have the ability to expand manufacturing capacity in this facility, as demand increases. If the volume and geographic reach of our sales expand further, we may seek additional sources for manufacturing and custom fabrication of the devices as our needs may require, or expand our manufacturing space and capacity.

Employees and Human Capital

As of December 31, 2024, we employed a total of 184 full time employees and 1 part time employee. All employees are subject to contractual agreements that specify requirements for confidentiality, ownership of newly developed intellectual property and restrictions on working for competitors as well as other matters. None of our employees are represented by labor unions or covered by collective bargaining agreements, and we have experienced no work stoppages. We consider our relationship with our employees to be good.

We believe that our future success largely depends upon our continued ability to attract and retain highly skilled employees and personnel. Our plan to increase clinical, reimbursement and manufacturing capacity in 2025 involves the hiring more than 100 additional employees by the end of 2025. Our human capital resources objectives include 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. We provide our employees with competitive salaries and bonuses, opportunities for equity ownership, support for programs that enable continued learning and growth and an employment package that promotes well-being across all aspects of their lives, including health care, retirement planning and paid time off. We value diversity at all levels and seek to make our workforce as diverse and inclusive as we can and offer advancement opportunities based on merit and performance.

Corporate Information

We were incorporated in the state of Delaware on September 1, 2004. On June 9, 2017, we executed our initial public offering, and our common stock trades under the symbol "MYO." Our principal executive offices are located at 45 Blue Sky Drive, Suite 101, Burlington, MA 01803, and our telephone number is (617) 996-9058.

Where You Can Find More Information

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 are available through the investor relations portion of our website (www.myomo.com) free of charge as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission, or SEC. Information on our investor relations page and on our website is not part of this Annual Report on Form 10-K or any of our other securities filings unless specifically incorporated herein or therein by reference. In

addition, our filings with the SEC may be accessed through the SEC's Electronic Data Gathering, Analysis and Retrieval (EDGAR) system at www.sec.gov. All statements made in any of our securities filings, including all forward-looking statements or information, are made as of the date of the document in which the statement is included, and we do not assume or undertake any obligation to update any of those statements or documents unless we are required to do so by law. In addition, our Code of Business Conduct and Ethics and Charters of our Audit Committee, Compensation Committee, Technology, Quality, and Regulatory Committee, Nominating and Corporate Governance Committee and Lead Independent Director are available on our website and are available in print to any stockholder who requests such information.

Item 1A. Risk Factors

The following important factors, among others, could cause our actual operating results to differ materially from those indicated or suggested by forward-looking statements made in this Annual Report on Form 10-K or presented elsewhere by management from time to time. Investors should carefully consider the risks described below before making an investment decision. The risks described below are not the only ones we face. Additional risks not presently known to us or that we currently believe are not material may also significantly impair our business operations. Our business could be harmed by any of these risks. The trading price of our common stock could decline due to any of these risks, and investors may lose all or part of their investment.

Risks Associated with Our Business

Risks Related to Our Operating and Financial Results

We have a history of operating losses. Investments in advertising, R&D and clinical, reimbursement and manufacturing capacity could result in a delay in our ability to achieve cash flow breakeven on a quarterly basis.

We have a history of losses since inception. For the years ended December 31, 2024 and 2023 we incurred net losses of $6.2 million and $8.1 million, respectively. At December 31, 2024, we had an accumulated deficit of approximately $103.1 million. The extent and duration of future operating and net losses will depend on our ability to increase the number of patients entering our pipeline in a manner that does not significantly increase our advertising cost per pipeline addition, increase revenues to absorb the headcount and additional clinical, reimbursement and manufacturing capacity we expect to add during 2025, the ability of our supply chain to meet our volume requirements without disruption and our ability to compensate for additional R&D spending expected in 2025. However, there can be no assurance that we can cost effectively grow our revenues without requiring additional capital.

Our cash, cash equivalents, short-term investments and restricted cash at December 31, 2024 were approximately $25.2 million. On December 6, 2024, we completed a public offering of our common stock, generating net proceeds of approximately $15.8 million. On July 11, 2024, we entered into a Loan and Security Agreement with Silicon Valley Bank, a division of First-Citizens Bank & Trust Company ("Silicon Valley Bank"), which provides us the ability to borrow up to $4.0 million against eligible accounts receivable. The line of credit remains undrawn as of the issuance date of these financial statements. Availability under the line of credit is approximately $1.0 million as of December 31, 2024. In February 2025, we entered into an amendment to the Loan and Security Agreement, which among other things, provided for a $3 million term loan facility which could be drawn at any time until February 28, 2026. On January 19, 2024, we completed a registered direct offering of our common stock and pre-funded warrants, generating net proceeds of approximately $5.4 million. We believe that our existing cash, cash equivalents, short-term investments and restricted cash at December 31, 2024 will be sufficient to fund our operations for the twelve months from the date of this report. If we encounter obstacles such as those that have been referred to above, we may not be able to return to operating cash flow breakeven on a quarterly basis, and additional capital may be required.

Our direct billing revenues are concentrated with a small number of payers, including CMS. Adverse changes in the reimbursement policies of these payers regarding the MyoPro could have an adverse effect on our business.

Revenues from providing the MyoPro directly to patients, a sales channel we refer to as direct billing, represented 78% and 71% of product revenues for the years ended December 31, 2024 and 2023, respectively. In 2024, we began providing the MyoPro to Medicare Part B patients. Revenues from patients with Medicare Part B represented 63% of direct billing revenues (49% of total revenues) for the year ended December 31, 2024. Our historical focus on patients

with commercial insurers who have previously reimbursed for the MyoPro also impacts our payer concentration. Beginning in September 2021, a large Medicare Advantage insurer that has historically reimbursed for the MyoPro began denying claims after having granted a pre-authorization and after we delivered the devices to patients, and these post-service denials currently continue. Revenues from patients insured by this payer represented 23% and 54% of direct billing revenues (18% and 35% of total revenue) during the years ended December 31, 2024 and 2023, respectively. With a small number of exceptions, appeals filed with the payer have been successful and these claims have ultimately been paid. However, this payer is now providing us with fewer pre-authorizations to serve new patients, requiring additional appeals efforts. This is common with other Medicare Advantage plans as well. If CMS were to change their coverage and reimbursement criteria for the MyoPro, or the aforementioned commercial payer and other Medicare Advantage payers further reduce the number of MyoPro's that they will authorize for their insured patients, our revenues and cash flows would be negatively impacted, which would have an adverse effect on our business.

We may experience significant fluctuations in our quarterly and annual results.

Fluctuations in our quarterly and annual financial results have resulted and will continue to result from numerous factors, including:

- timing, number and dollar value of reimbursements of our products by insurance payers;
- changes in the mix of products we sell;
- strategic actions by us, such as acquisitions of businesses, products, or technologies;
- effects of domestic and foreign economic conditions and exchange rates on our industry and/or customers;
- the divestiture or discontinuation of a product line or other revenue generating activity;
- the relocation and integration of manufacturing operations and other strategic restructuring;
- regulatory actions which may necessitate recalls of our products or warning letters that negatively affect the markets for our products;
- costs incurred by us in connection with the termination of contractual and other relationships, including distributorships;
- our ability to collect outstanding accounts receivable;
- the expiration or exhaustion of deferred tax assets such as net operating loss carryforwards;
- increased product and price competition, due to reimbursement of our products by Medicare, the regulatory landscape, market conditions or other factors;
- technology changes to enhance individual data privacy that could negatively impact our ability to market our products to prospective candidates and could result in increased advertising costs;
- market reception of our new or improved product offerings; and
- the loss of any significant customer.

These factors, some of which are not within our control, may cause the price of our common stock to fluctuate substantially. If our quarterly operating results fail to meet or exceed the expectations of securities analysts or investors, our stock price could drop suddenly and significantly. We believe quarterly comparisons of our financial results are not always meaningful and should not be relied upon as an indication of our future performance.

Continued inflation may materially impact our financial operations or results of operations.

While decreasing recently, inflation has and is expected to remain elevated for the near future. Inflationary factors, such as increases in the cost of our raw materials, manufacturing, interest rates and overhead costs may adversely affect our operating results. The price and availability of key components used to manufacture our products has been increasing and may continue to fluctuate significantly. In addition, the cost of labor internally or at our third-party manufacturers could increase significantly due to regulation or inflationary pressures. Additionally, the cost of logistics and transportation fluctuates in large part due to the price of oil, and availability can be limited due to

political and economic issues. Although we do not believe that inflation has had a material impact on our financial position or results of operations to date, we may experience some effect in the near future, especially if inflation rates continue to rise.

Significant political, trade, regulatory developments, and other circumstances beyond our control, could have a material adverse effect on our financial condition or results of operations.

We sell our products in countries throughout the world. Significant political, trade, or regulatory developments in the jurisdictions in which we may sell our products, such as those stemming from the change in U.S. federal administration, are difficult to predict and may have a material adverse effect on us. These developments may include tariffs or changes in reimbursement policies for Medicaid and Medicare. For example, on February 1, 2025, the U.S. imposed a 25% tariff on imports from Canada and Mexico, which were subsequently suspended for a period of one month, and a 10% additional tariff on imports from China. Historically, tariffs have led to increased trade and political tensions. In response to tariffs, other countries have implemented retaliatory tariffs on U.S. goods. While we have not been affected by such developments as of the date of this annual report on Form 10-K, we cannot provide any assurance that changes in political, trade, regulatory, and economic conditions, including U.S. trade policies, will not have a material adverse effect on our financial condition or results of operations.

Risks related to our Reliance on Third Parties

We may not be able to obtain third-party payer reimbursement, including reimbursement by Medicare, for our products.

Sales of our device depend, in part, on the extent to which our products are covered by third-party payers, such as government health programs, commercial insurance and managed healthcare organizations. See section titled "Business Section – Government Regulation – Health Insurance Reimbursement", in this Annual Report on Form 10-K. Third-party payers are increasingly challenging the prices charged, examining the medical necessity and creating additional restrictions on coverage, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payers may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication. In addition, CMS may issue local or national coverage determinations which could result in more restrictive coverage for our products. The coverage determination process is often a time-consuming and costly process that requires us to provide scientific and clinical support for the use of our products to each payer separately, with no assurance that coverage and adequate reimbursement will be obtained. In addition, the absence of in-network contracts with Medicare Advantage plans or commercial insurers could result in utilization management for out-of-network patients. Currently, we are almost entirely dependent on third parties to cover the cost of our products to patients and rely on their reimbursement for the cost of our products. If CMS, the U.S. Department of Veterans Affairs (the "VA") health insurance companies and other third-party payers do not provide adequate coverage or reimbursement for our products, then our sales will be limited to clinical facilities and individuals who can pay for our devices without reimbursement. To our knowledge, from inception through December 31, 2024, fewer than 50 units have been self-paid or funded by non-profit foundations. Some commercial health insurance plans have published statements that they will not cover the cost of the MyoPro for their members. In the event we are unsuccessful in obtaining additional coverage and adequate reimbursement for our products from third-party payers, our sales will be significantly constrained. Currently, reimbursement for the cost of our products is obtained primarily on a case-by-case basis until such time, if any, we obtain broad coverage policies with Medicare and third-party payers. There can be no assurance that we will be able to obtain these broad coverage policies or that Medicare or its local administrative billing contractors will not establish more restrictive coverage requirements for the MyPro in the future (for example, in the form of a local or national coverage determination). See section titled *"Business Section – Government Regulation – Health Insurance Reimbursement*", in this Annual Report on Form 10-K.

In connection with Medicare reimbursement, in November 2023 CMS reclassified the MyoPro from the durable medical equipment benefit to the brace benefit category effective January 1, 2024, thereby allowing for lump sum reimbursement. Such lump sum reimbursements based on the fees posted by CMS, are now being made. CMS published final payment determinations for the MyoPro Motion W (L8701) and the MyoPro Motion G (L8702), effective April 1, 2024. These fees were subsequently updated to approximately $34,300 for the Motion W and

approximately $67,500 for the Motion G, effective January 1, 2025. The fees are subject to annual inflationary adjustments. Our claims can be reviewed on a case-by-case basis at any time by CMS.

There can be no assurance that the final fees will be sufficient to permit us to generate gross margin required to allow us to operate on a profitable basis. Third-party payers also may continue to deny or limit coverage, limit reimbursement or reduce their levels of payment, or our costs of production may increase faster than increases in reimbursement levels. In addition, we may not obtain coverage and reimbursement approvals in a timely manner. Our failure to operate profitably could negatively impact market acceptance of MyoPro.

If CMS amends, restricts, or retracts coverage requirements, its billing contractors and insurers offering Medicare Advantage insurance plans may restrict what they reimburse for the MyoPro, which would have an adverse effect on our business.

Revenues from patients who are covered by Medicare Advantage insurance plans have become a significant portion of our overall revenues. Approximately 25% and 57% of our product revenues were derived from patients with Medicare Advantage insurance plans for the years ended December 31, 2024 and 2023, respectively. Since CMS published reimbursement amounts for the MyoPro in April 2024, revenues from Medicare Part B patients represented 49% of total revenue for the year ended December 31, 2024. If CMS amends, restricts, or retracts its November 2023 rule classifying MyoPro as a brace, amends or retracts any published fees, or establishes more restrictive inclusion criteria for coverage, our Medicare revenues could be negatively impacted and insurers offering Medicare Advantage insurance plans may no longer cover or adequately reimburse for the MyoPro. As a result, our overall revenues and cash flows would be negatively impacted, which could have an adverse effect on our business. See "Risks Related to our Reliance on Third Parties—We may not be able to obtain third-party payer reimbursement, including reimbursement by Medicare, for our products" for additional information about CMS coverage decisions.

We currently rely, and in the future will rely, on sales of our MyoPro products for our revenue, and we may not be able to expand market acceptance or grow revenues in the orthotics and prosthetics channel.

We currently rely, and in the future will rely, on sales of our MyoPro products for our revenue. MyoPro products are relatively new products, and continuing market acceptance and adoption will depend on educating people with limited upper extremity mobility and healthcare providers as to the distinct features, ease-of-use, improved quality of life and other benefits of MyoPro systems compared to alternative technologies and treatments. Our products may not be perceived to have sufficient potential benefits compared with these alternatives, which include rehabilitation therapy or amputation with a prosthetic replacement. Also, healthcare providers such as orthotics and prosthetics ("O&P") practices and the VA want to see good outcomes for their patients and certainty of third-party reimbursement. Accordingly, healthcare providers may not recommend the MyoPro until there is sufficient evidence to convince them to alter the treatment methods they typically recommend. This evidence may include prominent healthcare providers or other key opinion leaders in the upper extremity paralysis community recommending the MyoPro as effective in providing identifiable immediate and long-term health benefits, and the publication of additional peer-reviewed clinical studies demonstrating its value. Additionally, because the MyoPro is a prescription device, patients require the prescription of a healthcare provider to access our products and to have the device reimbursed by insurance.

Expanding market acceptance of MyoPro products could be negatively impacted by many other factors, including, but not limited to:

- patient outcomes not meeting expectations;
- lack of sufficient evidence supporting the benefits of MyoPro over competitive products or other available treatment, or lifestyle management to accommodate the disability;
- patient resistance to wearing an external device or making required insurance co-payments;
- limitations on the ability of patients to complete evaluations and fittings, including adverse changes in their health, or other environmental, social and economic barriers to patient access;
- results of clinical studies relating to MyoPro or similar products;
- claims that MyoPro, or any component thereof, infringes on patent or other intellectual property rights of third parties;

- perceived risks associated with the use of MyoPro or similar products or technologies; 2
- the introduction of new competitive products or greater acceptance of competitive products;
- adverse regulatory or legal actions relating to MyoPro or similar products or technologies; and
- problems arising from the insourcing of our manufacturing capabilities, or our existing manufacturing and supply relationships with third parties.

Any factors that negatively impact sales of MyoPro would adversely affect our business, financial condition and operating results.

We depend on a single third-party to manufacture key subassemblies for the MyoPro and a limited number of third-party suppliers for certain components of the MyoPro.

While we are the manufacturer of record with the U.S. Food and Drug Administration, (the "FDA") for the MyoPro device we sell, we have contracted with Cogmedix, Inc. ("Cogmedix"), a contract manufacturer with expertise in the medical device industry, for the contract manufacture of certain subassemblies and the sourcing of some of our components and raw materials. Pursuant to this contract, Cogmedix manufactures subassemblies for the MyoPro pursuant to our specifications at its facility in West Boylston, Massachusetts. As the manufacturer of the MyoPro, we ultimately remain responsible to the FDA for overseeing Cogmedix's manufacturing activities to ensure that they conform with product specifications and applicable laws and regulations, including FDA's good manufacturing practice requirements for medical devices. Any failure to effectively oversee the regulatory compliance of the product and contract manufacturing activities by Cogmedix can lead to potential enforcement actions, including civil or criminal liabilities, as well as recalls with the FDA. We may terminate our relationship with Cogmedix at any time upon sixty (60) days' written notice. For our business strategy to be successful, Cogmedix must be able to manufacture our subassemblies in sufficient quantities, and to source raw materials and components, in compliance with regulatory requirements and quality control standards, in accordance with agreed upon specifications, at acceptable costs and on a timely basis. Increases in our product sales, whether forecasted or unanticipated, or supply chain constraints that may arise for any number of reasons, could strain the ability of Cogmedix to manufacture an increasingly large supply of our current or future subassemblies in a manner that meets these various requirements. In addition, although we are not restricted from engaging an alternative manufacturer, the process of moving our manufacturing activities would be time consuming and costly, and may limit our ability to meet our sales commitments, which could harm our reputation and could have a material adverse effect on our business. Further, any new contract manufacturer would need to be compliant with FDA regulations the international management system standard for medical systems set by the International Organization for Standardization ("ISO"), ISO 13485:2016.

We also rely on third-party suppliers, including AB Corp, for 3D printed orthotic components. Some third-party suppliers contract directly with Cogmedix, to supply certain components of the MyoPro products. Cogmedix does not have long-term supply agreements with most of their suppliers and, in many cases, makes purchases on a purchase order basis. We do not have any long-term supply agreements directly with Cogmedix's suppliers. Our ability and Cogmedix's ability to secure adequate quantities of such products may be limited. Suppliers may encounter problems that limit their ability to manufacture components for our products, including financial difficulties or damage to their manufacturing equipment or facilities. If we, or Cogmedix, fail to obtain sufficient quantities of high-quality components to meet demand on a timely basis, or fail to effectively oversee the regulatory compliance of the supply chain, we could face regulatory enforcement, have to conduct recalls, lose customer orders, our reputation may be harmed, and our business could suffer.

Cogmedix generally uses a small number of suppliers for the MyoPro products. Depending on a limited number of suppliers exposes us to risks, including limited control over pricing, availability, quality and delivery schedules. If any one or more of our suppliers ceases to provide sufficient quantities of components in a timely manner or on acceptable terms, Cogmedix would have to seek alternative sources of supply. It may be difficult to engage additional or replacement suppliers in a timely manner. Failure of these suppliers to deliver products at the level our business requires would limit our ability to meet our sales commitments, which could harm our reputation and could have a material adverse effect on our business. Cogmedix also may have difficulty obtaining similar components from other suppliers that are acceptable to the FDA or other regulatory agencies, and the failure of Cogmedix's suppliers to comply with strictly enforced regulatory requirements could expose us to regulatory action including warning letters,

product recalls, termination of distribution, product seizures or civil penalties. It could also require Cogmedix to cease using the components, seek alternative components or technologies and we could be forced to modify our products to incorporate alternative components or technologies, which could result in a requirement to seek additional regulatory approvals. Any disruption of this nature or increased expenses could harm our commercialization efforts and adversely affect our operating results.

We also rely on a limited number of suppliers for certain materials and components used by the MyoPro and do not maintain any long-term supply agreement with respect to these materials and components. If we fail to obtain sufficient quantities of these materials and components in a timely manner, our reputation may be harmed and our business could suffer.

While we currently believe we have sufficient inventory in our supply chain in the near term, if we, or any third parties in our supply chain for materials which are used in either the manufacture of our products are adversely impacted by infections or restrictions from public heath crises, or other factors, our supply chain may be disrupted and our ability to manufacture and ship our products may be limited. While many companies continue to experience shortages of certain electronic components, so far we and our contract manufacturing partners have been able to procure the electronic components necessary for the manufacture of our products, but we are dealing with longer lead times and delivery delays for certain critical components. There can be no assurance that such supplies will become less constrained in the future.

Risks Related to Capital Requirements

We may not have sufficient funds to meet our future capital requirements.

Our cash, cash equivalents, short-term investments and restricted cash at December 31, 2024 was approximately $25.2 million. On December 6, 2024, we completed a public offering, selling 3,450,000 shares at $5.00 per share, generating net proceeds after fees and expenses of approximately $15.8 million. On July 11, 2024, we entered into a Loan and Security Agreement with Silicon Valley Bank, which provides us the ability to borrow up to $4.0 million against eligible accounts receivable. The line of credit is undrawn as of the issuance date of these financial statements. Availability under the line of credit is approximately $1.0 million as of December 31, 2024. In February 2025, we entered into an amendment to the Loan and Security Agreement, which among other things, provided for a $3 million term loan facility which could be drawn at any time until February 28, 2026. On January 19, 2024, we completed a registered direct offering of our common stock and pre-funded warrants, generating net proceeds of approximately $5.4 million.

Our ability to grow our business is dependent on our ability to generate sufficient cash flows from operations or to raise additional capital to meet our obligations, if necessary. We believe that our existing cash and cash equivalents will be sufficient to enable us to fund our operations for at least the next twelve months from the issuance date of these financial statements. If additional capital is required to achieve operating cash flow breakeven, we may be unable to obtain additional funds on reasonable terms, or at all. Our ability to secure financing and the cost of raising such capital are dependent on numerous factors, including general economic and capital markets conditions, credit availability from lenders, investor confidence and the existence of regulatory and tax incentives that are conducive to raising capital. Uncertainty in the financial markets has caused banks and financial institutions to decrease the amount of capital available for lending and has significantly increased the risk premium of such borrowings. In addition, such turmoil and uncertainty has significantly limited the ability of companies to raise funds through the sale of equity or debt securities. If we are unable to raise additional funds, we may need to delay, modify or abandon some or all of our business plans or cease operations. If we raise funds through the issuance of debt, the amount of any indebtedness that we may raise in the future may be substantial, and we may be required to secure such indebtedness with our assets and may have substantial interest expenses. If we default on any future indebtedness, our lenders could declare all outstanding principal and interest to be due and payable and our secured lenders may foreclose on the facilities securing such indebtedness. Usage of our line of credit requires us to meet financial and operating covenants, which could place limits on our operations, decrease our liquidity and increase the amount of cash flow required to service our debt. If we raise funds through the issuance of equity securities, such issuance could result in dilution to our stockholders and the newly issued securities may have rights senior to those of the holders of our common stock.

Our level of indebtedness and debt service obligations could adversely affect our financial condition and may make it more difficult for us to fund our operations.

In July 2024, we entered into a Loan and Security Agreement (the "Loan Agreement") with Silicon Valley Bank. Pursuant to the terms of the Loan Agreement, we may request advances on a revolving line of credit whereby we may borrow up to $4 million (the "Revolving Line"), which Revolving Line may be increased to $5.5 million at Silicon Valley Bank's sole discretion upon the occurrence of certain events. The Revolving Line is secured on a first priority basis by all of our assets other than intellectual property and certain customary exceptions. In February 2025, we entered into an amendment to the Loan and Security Agreement, which among other things, provided for a $3 million term loan facility which could be drawn at any time until February 28, 2026. To the extent we use the Revolving Line, or the term loan facility, such indebtedness may create additional financing risk for us, particularly if our business or prevailing financial market conditions are not conducive to paying off or refinancing our outstanding debt obligations at maturity. This indebtedness could also have important negative consequences, including the fact that:

- we will need to repay our indebtedness by making payments of interest and principal, which will reduce the amount of money available to finance our operations; and
- our failure to comply with the restrictive covenants under the Loan Agreement could result in an event of default that, if not cured or waived, would accelerate our obligation to repay this indebtedness, and Silicon Valley Bank could seek to enforce our security interest in the assets securing such indebtedness.

Risks Related to Competitors and Our Market

The industries in which we operate are highly competitive and subject to rapid technological change. The publishing of fees for the Healthcare Common Procedures Coding System ("HCPCS") billing codes for our products may attract competition. If our competitors are better able to develop and market products that are safer, more effective, less costly, easier to use, or are otherwise more attractive, we may be unable to compete effectively with other companies.

Industrial and medical robotics is characterized by intense competition and rapid technological change, and we will face competition on the basis of product features, clinical outcomes, price, services and other factors. We are experiencing competition in the United States from companies such as Neurolutions, and in Germany from companies such as Vincent Systems and HKK Bionics. Publication of fees by CMS under our HCPCS billing codes L8701 and L8702 is also expected to attract competition in the United States. Competitors may include large medical device and other companies, some of which have significantly greater financial and marketing resources than we do, and firms that are more specialized than we are with respect to particular markets. Our competition may respond more quickly to new or emerging technologies, undertake more extensive marketing campaigns, and have greater financial, marketing and other resources than we do or may be more successful in attracting potential customers, employees and strategic partners.

Our competitive position will depend on multiple complex factors, including our ability to maintain and grow market acceptance for our products, develop new products, implement production and marketing plans, secure regulatory clearances or approvals, if necessary, for products under development and protect our intellectual property. In some instances, competitors may also offer, or may attempt to develop, alternative therapies for disease states that may be delivered without a medical device. The development of new or improved products, processes or technologies by other companies may render our products or proposed products obsolete or less competitive. The entry into the market of manufacturers located in low-cost manufacturing locations may also create pricing pressure, particularly in developing markets. Our future success depends, among other things, upon our ability to compete effectively against current technology, as well as to respond effectively to technological advances, and upon our ability to successfully implement our marketing strategies and execute our research and development plans.

We sell to O&P providers who are free to market products that compete with the MyoPro, and we rely on these providers to market and promote our products in accordance with their FDA listings, select appropriate patients and provide adequate follow-on care.

Our reliance on our relationships with qualified O&P providers in the U.S., Germany and other international markets to market and sell our products is expected to increase. We believe that an increasing percentage of our sales will be generated through these channels in the future. However, none of these partners are required to sell or provide our products exclusively. If a key independent O&P provider were to cease to distribute our products, our sales could be adversely affected. In such a situation, we may need to seek alternative independent providers or increase our reliance on our direct billing channel, which may not prevent our sales from being adversely affected. Additionally, to the extent that we enter into contracts with O&P providers, the terms of the arrangements could cause our gross margin to be lower than if we directly marketed and sold our products.

If these independent O&P providers do not follow our inclusion/exclusion criteria for patient selection or do not provide adequate follow-on care, then our reputation may be harmed by patient dissatisfaction. This could also lead to product returns and adversely affect our financial condition. When issues with O&P providers have arisen in the past, we have supplied additional training and documentation and/or ended the business relationship.

The sales and marketing of medical devices is under increased scrutiny by the FDA and other enforcement bodies. If our sales and marketing activities fail to comply with FDA regulations, such as regulations for the labeling and advertising of our products, or other applicable laws, we may be subject to warnings or enforcement actions from the FDA or other enforcement bodies. For example, we are restricted from promoting our products for any use that is beyond the scope of their applicable FDA classification regulation. Such promotion could result in enforcement action by the FDA, which may include, but is not limited to untitled letters or warning letters, injunctions, recall or seizure of our products, and imposition of FDA's premarket clearance or approval requirements.

The market for myoelectric braces is relatively new and the rate of adoption is uncertain, and important assumptions about the potential market for our products may be inaccurate.

The market for myoelectric braces, or orthotics, is relatively new and the rate of adoption is uncertain. Our estimates of market size are derived from statistics regarding the number of strokes and other afflictions, but not necessarily limited to those with upper extremity impairment. Accordingly, it is difficult to predict the future size and rate of growth of the market. We cannot be certain whether the market will continue to develop or if orthotics will achieve and sustain a level of market acceptance and demand sufficient for us to continue to generate revenue and achieve profitability.

Limited sources exist to obtain reliable market data with respect to the number of mobility-impaired individuals and the occurrence of upper extremity paralysis in our target markets. In addition, there are no third-party reports or studies regarding what percentage of those with upper extremity paralysis would be able to use orthotics in general, or our current or planned future products in particular. In order to use our current products marketed to those with upper extremity paralysis, users must meet a set of inclusion criteria and not have a medical condition which disqualifies them from being an appropriate candidate. Future products for those with upper extremity paralysis may have the same or other restrictions. Our business strategy is based, in part, on our estimates of the number of upper extremity impaired individuals and the incidence of upper extremity injuries in our target markets and the percentage of those groups that would be able to use our current and future products. Our assumptions and estimates may be inaccurate and may change.

If the upper extremity orthotics market fails to develop or develops more slowly than we expect, or if we have relied on sources or made assumptions or estimates that are not accurate, our business could be adversely affected.

In addition, because we operate in a new market, the actions of our competitors could adversely affect our business. Adverse events such as product defects or legal claims with respect to competing or similar products could cause

reputational harm to the market on the whole. Further, adverse regulatory findings or reimbursement-related decisions with respect to other products could negatively impact the entire market and, accordingly, our business.

Risks Related to Our Products

We may receive a significant number of warranty claims or our MyoPro may require significant amounts of service after sale.

Sales of MyoPro products generally include a three-year warranty for parts and labor, other than for normal wear and tear. As the number and complexity of the features and functionalities of our products increase, we may experience a higher level of warranty claims. If product returns or warranty claims are significant or exceed our expectations, we could incur unanticipated expenditures for parts and services, which could have a material adverse effect on our operating results.

Defects in our products or the software that drives them could adversely affect the results of our operations.

The design, manufacture and marketing of the MyoPro products involve certain inherent risks. Manufacturing or design defects, unanticipated use of the MyoPro, or inadequate disclosure of risks relating to the use of MyoPro products can lead to injury or other adverse events. In addition, because the manufacturing of our products is outsourced to Cogmedix, we may not always be aware of manufacturing defects that could occur and corrective or preventive actions implemented by Cogmedix may not be effective at resolving such defects. Such adverse events could lead to recalls or safety alerts relating to MyoPro products (either voluntary or required by the FDA or similar governmental authorities in other countries), and could result, in certain cases, in the removal of MyoPro products from the market. A recall could result in significant costs. To the extent any manufacturing defect occurs, our agreement with Cogmedix contains a limitation on Cogmedix's liability, and therefore we could be required to incur the majority of related costs. A defect in connection with the fabrication of our products may result in significant costs in connection with lawsuits or refunds. Product defects or recalls could also result in negative publicity, damage to our reputation or, in some circumstances, delays in new product approvals.

MyoPro users may not use MyoPro products in accordance with safety protocols and training, which could enhance the risk of injury. Any such occurrence could cause delay in market acceptance of MyoPro products, damage to our reputation, additional regulatory filings, product recalls, increased service and warranty costs, product liability claims and loss of revenue relating to such hardware or software defects.

The medical device industry has historically been subject to extensive litigation over product liability claims. We have not been subject to such claims to date, but we may become subject to product liability claims alleging defects in the design, manufacture or labeling of our products in the future. A product liability claim, regardless of its merit or eventual outcome, could result in significant legal defense costs and high punitive damage payments. Although we maintain product liability insurance, the coverage is subject to deductibles and limitations, and may not be adequate to cover future claims. Additionally, we may be unable to maintain our existing product liability insurance in the future at satisfactory rates or in adequate amounts.

While there is long-term clinical data supporting the safety of our existing MyoPro products, updates to our products inherently have uncertain safety risks as they enter the market.

While clinical data have established the safety of MyoPro products, our products undergo periodic updates for various reasons, including performance and reliability improvements and cost reductions. For example, in January 2022, we announced the availability of MyoPro2+. Because MyoPro users generally do not have feeling in their upper extremities, they may not immediately notice adverse effects from updates to the MyoPro, which could exacerbate their impact. If MyoPro products are shown to present new risks or to be unsafe or cause such unforeseen effects in the future, our business and reputation could be harmed, including through field corrections, withdrawals, removals, mandatory product recalls, suspension or withdrawal of FDA registration, significant legal liability or harm to our business reputation.

Risks Related to Collaborations and Licensing Agreements

We may enter into collaborations, licensing arrangements, joint ventures, strategic alliances or partnerships with third parties that may not result in the development of commercially viable products or the generation of significant future revenues.

In the ordinary course of our business, in the future we may enter into collaborations, in-licensing arrangements, joint ventures, strategic alliances or partnerships to develop the MyoPro and to pursue new markets. We are selling the MyoPro in several European countries, as well as Australia. In January 2021, we announced that we had entered into a joint venture with Beijing Ryzur Medical Investment Co., Ltd. ("Ryzur Medical"), to manufacture and sell the products containing our technology in China, including Hong Kong, Taiwan and Macau. The company is named Jiangxi Myomo Medical Assistive Appliance Co., Ltd. (the "JV Company"). In December 2021, we entered into a technology license agreement and a trademark license agreement with the JV Company, under which we were entitled to receive a license fee of $2.7 million and the JV Company will commit to purchase a minimum of $10.75 million of MyoPro control units over the next ten years. During 2023, we received full payment of the $2.7 million initial license fee and have received payment for MyoPro control units of $50,000. This and any other of these relationships may require us to incur non-recurring and other charges, increase our near and long-term expenditures, issue securities that dilute our existing stockholders or disrupt our management and business. In addition, proposing, negotiating and implementing collaborations, licensing arrangements, joint ventures, strategic alliances or partnerships may be a lengthy and complex process. We may not identify, secure, or complete any such transactions or arrangements in a timely manner, on a cost-effective basis, on acceptable terms or at all. We have limited institutional knowledge and experience with respect to these business development activities, and we may also not realize the anticipated benefits of any such transaction or arrangement. In particular, these collaborations may not result in the development of products that achieve commercial success or result in significant revenues and could be terminated prior to developing any products. Any delays in entering into new strategic partnership agreements related to our products could delay the development and commercialization of our products in certain geographies, which would harm our business prospects, financial condition and results of operations.

If we pursue collaborations, additional licensing arrangements and joint ventures, strategic alliances or partnerships, we may not be able to consummate them, or we may not be in a position to exercise sole decision decision-making authority regarding the transaction or arrangement, which could create the potential risk of creating impasses on decisions, and our collaborators may have economic or business interests or goals that are, or that may become, inconsistent with our business interests or goals. It is possible that conflicts may arise with our collaborators. Our collaborators may act in their self-interest, which may be adverse to our best interest, and they may breach their obligations to us. Any such disputes could result in litigation or arbitration which would increase our expenses and divert the attention of our management. Further, these transactions and arrangements are contractual in nature and may be terminated or dissolved under the terms of the applicable agreements.

Risks Related to Our Business Operations and Management

If we fail to properly manage our anticipated growth, including in O&P channel and international markets, our business could suffer.

As we grow our revenues from Medicare Part B patients and expand the number of locations which provide the MyoPro products, including O&P practices in the United States, and future planned international distribution, we expect that it will place significant strain on our management team and on our financial resources. Failure to manage our growth effectively could cause us to mis-allocate management or financial resources and result in losses or weaknesses in our infrastructure, systems, processes and controls, which could materially adversely affect our business. Additionally, our anticipated growth will increase the demands placed on our suppliers, resulting in an increased need for us to manage our suppliers and monitor for quality assurance.

Moreover, there are significant costs and risks inherent in selling our products, particularly in international markets, including: (a) time and difficulty in building a widespread network of distribution partners; (b) increased shipping and distribution costs, which could increase our expenses and reduce our margins; (c) potentially lower margins in some regions; (d) longer collection cycles in some regions; (e) compliance with foreign laws and regulations; (f) compliance

with anti-bribery, anti-corruption, and anti-money laundering laws, such as the Foreign Corrupt Practices Act and the Office of Foreign Assets Control regulations, by us, our employees, and our business partners; (g) currency exchange rate fluctuations and related effects on our results of operations; (h) economic weakness, including inflation, or political instability in foreign economies and markets; (i) compliance with tax, employment, immigration, and labor laws for employees living or traveling abroad; (j) workforce uncertainty in countries where labor unrest is more common than in the United States; (k) business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters, including earthquakes, typhoons, floods and fires; and (l) other costs and risks of doing business internationally, such as new tariffs which may be imposed. For example, we have entered into a joint venture with Ryzur Medical, to manufacture and sell the products containing the Company's technology in China, including Hong Kong, Taiwan and Macau. In connection with this joint venture, we may encounter challenges in working with our joint venture partners, including with respect to compliance with local laws and domestic laws related to foreign operations.

These and other factors could harm our ability to implement planned growth in international operations and, consequently, harm our business, results of operations, and financial condition. Further, we may incur significant operating expenses as a result of our planned expansion activities, and they may not be successful. We have limited experience with regulatory environments and market practices internationally, and we may not be able to penetrate or successfully operate in new markets. We may also encounter difficulty growing the O&P channel while simultaneously being a direct provider to patients in the United States. and expanding into international markets because of limited brand recognition. These factors may lead to delayed or limited acceptance of our products by patients in these markets. Accordingly, if we are unable to expand O&P channel revenues in the United States., expand internationally or manage our international operations successfully, we may not achieve the expected benefits of this expansion and our financial condition and results of operations could be harmed.

We depend on the knowledge and skills of our senior management.

We have benefited substantially from the leadership and performance of our senior management and other key employees. We do not carry key person insurance. Our success will depend on our ability to retain our current management and key employees. Competition for these key persons in our industry is intense and we cannot guarantee that we will be able to retain our personnel. The loss of the services of certain members of our senior management or key employees could prevent or delay the implementation and completion of our strategic objectives or divert management's attention to seeking qualified replacements.

We may seek to grow our business through acquisitions of complementary products or technologies, and the failure to manage acquisitions, or the failure to integrate them with our existing business, could have a material adverse effect on our business, financial condition and operating results.

From time to time, we may consider opportunities to acquire other products or technologies that may enhance our products or technology or advance our business strategies. Potential acquisitions involve numerous risks, including:

- problems assimilating the acquired products or technologies;
- issues maintaining uniform standards, procedures, controls and policies;
- unanticipated costs associated with acquisitions;
- diversion of management's attention from our existing business;
- risks associated with entering new markets in which we have limited or no experience; and
- increased legal and accounting costs relating to the acquisitions or compliance with regulatory matters.

We have no current commitments with respect to any acquisition and no current plans to seek acquisitions; however, depending on industry and market conditions, we may consider acquisitions in the future. If we do proceed with acquisitions, we do not know if we will be able to identify acquisitions we deem suitable, whether we will be able to successfully complete any such acquisitions on favorable terms or at all, or whether we will be able to successfully

integrate any acquired products or technologies. Our potential inability to integrate any acquired products or technologies effectively may adversely affect our business, operating results and financial condition.

Risks Related to Government Regulation

Risks Related to Healthcare Industry

We are subject to extensive governmental regulations relating to the design, development, manufacturing, labeling and marketing, delivery and billing of our products, and a failure to comply with such regulations could lead to withdrawal or recall of our products from the market.

Our products are regulated as medical devices in the United States under the FFDCA, as implemented and enforced by the FDA. Under the FFDCA, medical devices are classified into one of three classes–Class I, Class II or Class III–depending on the degree of risk associated with the medical device, what is known about the type of device, and the extent of control needed to provide reasonable assurance of safety and effectiveness. Classification of a device is important because the class to which a device is assigned determines, among other things, the necessity and type of FDA pre-market review. This determination is required prior to marketing the device.

In 2012, we listed the MyoPro device as a Class I, 510(k)-exempt, limb orthosis with the FDA. From time to time, the FDA may disagree with the classification regulation under which a registrant lists their device. For example, the FDA may disagree with a registrant's determination to classify their device as a Class I medical device. Instead, the FDA may determine the device to be a Class II or Class III device requiring the submission of a premarket notification, or 510(k), or a premarket approval application for premarket clearance or approval. As the FDA is now giving more attention to the differentiated performance of myoelectric controlled orthotics, we elected to change our device listing to be under a Class II classification regulation for biofeedback devices. Under the classification regulation, we believe our device remains 510(k)-exempt as a prescription battery powered external limb orthosis that is indicated for functional improvement, a device which is generally 510(k)-exempt under the classification regulation. In the event that the FDA determines that our devices, whether by functionality or marketing claims, exceed the limitations on 510(k)-exemption such that premarket clearance or approval is required (i.e., that our device is intended for a use different from the intended use of a legally marketed device in the generic type of device under the applicable classification regulation or that our modified device operates using a different fundamental scientific technology than such a legally marketed device), should be classified as Class II devices or Class III devices requiring premarket clearance or approval, or should FDA decide to reclassify our device as a Class II or Class III device requiring premarket clearance or approval, we could be precluded from marketing our devices for clinical use within the United States for months or longer depending on the requirements of the classification. Obtaining premarket clearance or approval could significantly increase our regulatory costs, including expense associated with required preclinical (animal) and clinical (human) trials, more extensive mechanical and electrical testing and other costs.

We are registered with the FDA as a manufacturer for medical devices. We are also subject to regulation by foreign governmental agencies in connection with international sales. The agencies enforce laws and regulations that govern the development, testing, manufacturing, labeling, advertising, marketing and distribution, and market surveillance of our medical device products. Following the introduction of a product, the governmental agencies will periodically review our product development methodology, quality management systems, and product performance. We are under a continuing obligation to ensure that all applicable regulatory requirements, such as the FDA's medical device good manufacturing practice / Quality System Regulation ("QSR") requirements and the FDA's medical device reporting requirements for certain device-related adverse events and malfunction, continue to be met. Our facilities are subject to periodic and unannounced inspection by U.S. and foreign regulatory agencies to audit compliance with the QSR, and comparable foreign regulations.

The process of complying with the applicable QSR, medical device reporting, and other requirements can be costly and time consuming, and could delay or prevent the production, manufacturing or sale of the MyoPro. If the FDA determines that we fail to comply with applicable regulatory requirements, they may issue an inquiry or an untitled or warning letter with one or more citations of non-compliance. These inquiries or letters, if not closed promptly, can result in fines, delays or suspensions of regulatory clearances, closure of manufacturing sites, seizures or recalls of products and damage to our reputation. Similarly, if we fail to comply with applicable foreign regulatory requirements,

we may be subject to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution. Recent changes in enforcement practice by the FDA and other agencies have resulted in increased enforcement activity, which increases the compliance risk that we and other companies in our industry are facing.

In addition, governmental agencies of the United States or other countries may impose new requirements regarding registration, labeling or prohibited materials that may require us to modify or re-register the MyoPro once it is already on the market or otherwise impact our ability to market the MyoPro in the United States or other countries. For example, on February 2, 2024, the FDA published a final rule to amend its QSR requirements to align more closely with the international consensus standards for medical devices by converging with quality management system ("QMS") requirements used by other regulatory authorities from other countries. Specifically, the final rule does so primarily by incorporating by reference the 2016 edition of the ISO 13485 standard. The amended regulation is referred to as the Quality Management System Regulation ("QMSR") and is effective February 2, 2026. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing authorization that we may have obtained, which could have a material adverse effect on our business, prospects, results of operations, financial condition and our ability to achieve or sustain profitability. The process of complying with these governmental regulations can be costly and time consuming, and could delay or prevent the production, manufacturing or sale of the MyoPro. For instance, the FDA may issue mandates, known as 522 orders, requiring us to conduct post-market surveillance studies of our devices. Failure to comply could result in enforcement of the FFDCA against us or our products including an agency request that we recall our MyoPro products.

Our relationships with healthcare providers and physicians and third-party payers will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

We are subject to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, which may constrain the business or financial arrangements and relationships through which we sell, market and distribute our products. In particular, the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry (e.g., healthcare providers, physicians and third-party payers), 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 commission(s), certain customer incentive programs and other business arrangements generally. Marketing and promotional programs may also be affected by the application of healthcare privacy laws relating to the use of information gathered by social media companies in advertising activities. We are also subject to patient information and privacy and security regulation by both the federal government and the states and foreign jurisdictions in which we conduct business. See section titled "*Business – Government Regulation – Healthcare Privacy Laws and Regulations*", in this Annual Report on Form 10-K.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform. Federal and state enforcement bodies often scrutinize interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business.

The failure to comply with any of these laws or regulatory requirements subject entities to possible legal or regulatory action. Because of the breadth of these laws and the narrowness of the statutory exceptions and regulatory safe harbors available, it is possible that some of our business activities, could, despite efforts to comply, be subject to challenge under one or more of such laws. It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. Depending on the circumstances, failure to meet applicable regulatory requirements can result in civil, criminal and administrative penalties, damages, fines, disgorgement, individual imprisonment, exclusion from participation in federal and state funded healthcare programs, contractual damages, reputational harm and the curtailment or restricting of our operations, as well as additional reporting

obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Any action for violation of these laws, even if successfully defended, could cause us to incur significant legal expenses and divert management's attention from the operation of the business. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way. Efforts to ensure that our business arrangements will comply with applicable healthcare laws may involve substantial costs. In addition, the commercialization of any of our products outside the United States will also likely subject us to foreign equivalents of the healthcare laws mentioned above, among other foreign laws.

If we or our third-party manufacturers or key suppliers fail to comply with the applicable good manufacturing practice requirements, including FDA's Quality System Regulation, our manufacturing operations could be interrupted.

We and our third-party manufacturers and key suppliers are also required to comply with the FDA's QSR which covers the methods and documentation of the production, control, quality assurance, labeling, packaging, storage and shipping of our products. In February 2024, the FDA issued the QMSR Final Rule to amend the QSR, incorporating by reference, ISO 13485:2016. The rule will become effective on February 2, 2026. Until then, manufacturers are required by the FDA to comply with the QSR. We, Cogmedix, our electromechanical kit manufacturer, and other key suppliers are also subject to the regulations of foreign jurisdictions regarding the manufacturing process with respect to the market for our products abroad.

We continue to monitor our quality management, as well as that of our third-party manufacturers and suppliers to improve our overall level of compliance. Our facilities and those of our third-party manufacturers and key suppliers are subject to periodic and unannounced inspection by U.S. and foreign regulatory agencies to audit compliance with the QSR and comparable foreign regulations. If our facilities or the facilities of our third-party manufacturers and suppliers are found to be in violation of applicable laws and regulations, or if we or our third-party manufacturers and suppliers fail to take satisfactory corrective action in response to an adverse inspection, the regulatory authority could take enforcement action, including any of the following sanctions:

- untitled letters, warning letters, Form 483 findings (results from quality system inspections), fines, injunctions, consent decrees and civil penalties;
- customer notifications or repair, replacement or refunds;
- detention, recalls or seizure of our products;
- operating restrictions or partial suspension or total shutdown of production;
- withdrawing our FDA registration;
- refusing to provide certificates to foreign governments with respect to exports; and
- pursuing criminal prosecution.

Any of these sanctions could impair our ability to produce the MyoPro in a cost-effective and timely manner in order to meet our customers' demands and could have a material adverse effect on our reputation, business, results of operations and financial condition. We may also be required to bear other costs or take other actions that may have a negative impact on our future sales and our ability to generate profits.

Our employees, principal investigators, consultants and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements and insider trading.

It is not always possible to identify and deter misconduct by employees and other third parties, and the precautions we take to detect and prevent this activity 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 comply with these 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 have a significant impact on our business, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of noncompliance with

these laws, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could adversely affect our ability to operate our business, financial condition and results of operations.

We face risks in connection with the Affordable Care Act ("ACA") or its possible replacement or modifications and other ongoing healthcare legislative and regulatory reform measures.

The United States and many foreign jurisdictions have enacted or proposed legislative and regulatory changes affecting the healthcare system that could affect our ability to profitably sell our products. Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

Payers, whether domestic or foreign, or governmental or private, are developing increasingly sophisticated methods of controlling healthcare costs and those methods are not always specifically adapted for new technologies. In the United States, there have been and continue to be a number of legislative and regulatory initiatives and judicial challenges to contain healthcare costs. See section titled "*Business – Government Regulations – Current and Future Legislation*", in this Annual Report on Form 10-K.

We expect that the ACA, as well as other healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding, more rigorous coverage criteria, lower reimbursement, and new payment methodologies. This could lower the price that we receive for our products. Any denial or narrowing of coverage or reduction in reimbursement from Medicare or other government-funded programs may result in a similar denial or reduction in payments from private payers, including Medicare Advantage plans, which may prevent us from being able to generate sufficient revenue, attain profitability or commercialize our products. Litigation and legislative efforts to change or repeal the ACA are likely to continue, with unpredictable and uncertain results. It is not clear how these developments, or other future potential changes to the ACA, will change the reimbursement model and market outlook for O&P devices such as the MyoPro. We intend to monitor industry trends relative to the ACA to assist in our determination of how the MyoPro can fit into patient care protocols with providers such as rehabilitation hospitals and surgery centers. If reimbursement policies change significantly, the demand for MyoPro products may be impacted.

Risks Related to Cybersecurity and Data Protection

Our internal computer systems, or those of our customers, collaborators or other contractors, may be subject to cyber-attacks, compromises or security incidents, which could result in a material disruption of our product development programs.

Despite the implementation of security measures, our internal computer systems and infrastructures and those of our customers, collaborators, contractors, or other third parties are vulnerable to damage, compromise or interruption from computer viruses, unauthorized access, misuse, or other security compromises or breaches. Cyber-attacks are increasing in their frequency, sophistication and intensity, and have become increasingly difficult to detect. Cyber-attacks could include the deployment of harmful malware, ransomware, denial-of-service attacks, wrongful conduct by employees, vendors, or other third parties, hostile foreign governments, industrial espionage, social engineering and business email compromises, and other means to affect service reliability and threaten or compromise the security, confidentiality, integrity and availability of systems and information. Cyber-attacks also could include phishing attempts or e-mail fraud to cause payments or information to be transmitted to an unintended recipient. We have in the past experienced threats and security incidents related to our data and systems, and we may in the future experience other threats, compromises, breaches, or incidents. A cyber-attack or security compromise or incident could cause interruptions in our operations and could result in a material disruption of our business operations, damage to our reputation or a loss of revenues.

In the ordinary course of our business, we collect and store confidential and/or proprietary information or other sensitive information, including, among other things, personal information about our employees and patients, intellectual property, and proprietary business information. Any cyber-attack or security compromise or incident that

leads to unauthorized access, use, disclosure, loss, corruption or other compromise of confidential and/or proprietary information or other sensitive information could harm our reputation, cause us not to comply with federal and/or state breach notification laws and foreign law equivalents and otherwise subject us to liability under laws and regulations, including those that protect the privacy and security of personal information. In addition, we could be subject to risks caused by misappropriation, misuse, leakage, falsification or intentional or accidental release or loss of information maintained in the information technology systems, infrastructure, and networks of our company and our vendors, including personal information of our employees, and patients, and company and vendor confidential data. In addition, outside parties may attempt to penetrate our systems and infrastructure or those of our vendors or fraudulently induce our personnel or the personnel of our vendors to disclose sensitive information in order to gain access to our data and/or systems. If an incident or compromise of our information technology systems or infrastructure or those of our vendors occurs, the market perception of the effectiveness of our security measures could be harmed and our reputation and credibility could be damaged.

We could be required to expend significant amounts of money and other resources to detect, mitigate and respond to these threats, compromises, or breaches and to repair or replace information technology systems infrastructure or networks and could suffer financial loss or the loss of valuable confidential and/or proprietary information. In addition, we could be subject to regulatory actions, inquiries, investigations, orders, penalties, fines, and/or claims made by individuals and groups in private litigation, including those involving privacy and security issues related to data collection and use practices and other data privacy and security laws and regulations, including claims for misuse or inappropriate disclosure of data, as well as unfair or deceptive practices. Although we develop and maintain systems and controls designed to prevent these events from occurring, and we have a process designed to identify and mitigate threats, the development and maintenance of these systems, controls and processes is costly and requires ongoing monitoring and updating as technologies change and efforts to overcome security measures become increasingly sophisticated. Moreover, despite our efforts, instances of unauthorized access to our computer systems have occurred in the past, though these events have not resulted in financial loss or disruption to our operations. The possibility of these events occurring in the future cannot be eliminated entirely. There can be no assurance that any measures we take will prevent or adequately address cyber-attacks or security compromises or incidents that could adversely affect our business.

We, our collaborators and our service providers may be subject to a variety of privacy and data protection laws, regulations and contractual obligations, which may require us to incur substantial compliance costs, and any failure or perceived failure by us to comply with them could expose us to fines or other penalties and otherwise harm our business and operations.

In the United States, several layers of federal and state data protection laws and regulations may apply to our business, including HIPAA, the Federal Trade Commission ("FTC") Act and state consumer privacy and health data privacy laws. For example, the California Consumer Privacy Act ("CCPA") is a comprehensive privacy law that creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households in California. The CCPA requires covered companies to provide certain disclosures to consumers about its data collection, use and sharing practices, and to provide affected California residents with ways to opt-out of certain sales or transfers of personal information. The CCPA went into effect on January 1, 2020 and the California State Attorney General became empowered to commence enforcement actions against violators as of July 1, 2020. Further, as of January 1, 2023, the California Privacy Rights Act, created additional obligations with respect to processing and storing personal information.

Similar consumer privacy laws have passed or come into force in numerous U.S. states. Like the CCPA, these laws grant consumers rights in relation to their personal information and impose new obligations on regulated businesses, including, in some instances, broader data security requirements. In addition, federal and state legislators and regulators have signaled their intention to further regulate health and other sensitive information, and new and strengthened requirements relating to this information could impact our business. At the state level, some states have passed or proposed laws to specifically regulate health information. For example, Washington's My Health My Data Act, which went into effect in March 2024, requires regulated entities to obtain consent to collect health information, grants consumers certain rights, including to request deletion, and provides for robust enforcement mechanisms, including enforcement by the Washington state attorney-general and a private right of action for consumer claims. At the federal level, the FTC has used its authority over "unfair or deceptive acts or practices" to impose stringent requirements on the collection and disclosure of sensitive categories of personal information, including health

information. Moreover, the FTC's expanded interpretation of a "breach" under its Health Breach Notification Rule could impose new disclosure obligations that would apply in the event of a qualifying breach.

European data collection is governed by restrictive regulations governing the use, processing, and cross-border transfer of personal information.

The collection and use of personal data, including personal health data in the European Economic Area ("EEA") and the UK is governed by the provisions of the EU General Data Protection Regulation ("EU GDPR") (with regards to the EEA) and the UK General Data Protection Regulation ("UK GDPR") (with regards to the UK), as well as applicable data protection laws in effect in the member states of the EEA and in the UK (including the UK Data Protection Act 2018). In this Annual Report on Form 10-K, "GDPR" refers to both the EU GDPR and the UK GDPR, unless specified otherwise. The GDPR applies to the processing of personal data by any company established in the EEA/UK and to companies established outside the EEA/UK to the extent they process personal data in connection with the offering of goods or services to data subjects in the EEA/UK or the monitoring of the behavior of data subjects in the EEA/UK. The GDPR imposes a broad range of strict requirements on companies subject to the GDPR, such as including requirements relating to having legal bases or conditions for processing personal data relating to identifiable individuals and transferring such information outside the EEA/UK , including to the United States., providing details to those individuals regarding the processing of their personal data, implementing safeguards to keep personal data secure, having data processing agreements with third parties who process personal data, providing information to individuals regarding data processing activities, responding to individuals' requests to exercise their rights in respect of their personal data, where required obtaining consent of the individuals to whom the personal data relates, reporting security and privacy breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments, and record-keeping. In the event of any non-compliance with the GDPR and any supplemental EEA Member State or UK national data protection laws, we could be subject to warning letters, mandatory audits, orders to cease/change the use of data, and financial penalties, including fines of up to €20,000,000 (£17.5 million for the UK GDPR) or 4% of total annual global revenue, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR.

The GDPR imposes strict rules on the transfer of personal data outside of the EEA or the UK to countries that do not ensure an adequate level of protection, like the United States in certain circumstances unless adequate safeguards (such as the European Commission approved standard contractual clauses ("SCCs") or the UK International Data Transfer Agreement/Addendum, ("UK IDTA") and transfer impact assessments carried out when relying on the SCCs and UK IDTA. The international transfer obligations under the EU data protection laws will require significant effort and cost and may result in us needing to make strategic considerations around where EEA and UK personal data is transferred and which service providers we can utilize for the processing of EEA and UK personal data. Any inability to transfer personal data from the EEA and UK to the United States in compliance with data protection laws may impede our ability to conduct trials and may adversely affect our business and financial position. Although the UK is regarded as a third country under the EU GDPR, the European Commission ("EC") has now issued a decision recognizing the UK as providing adequate protection under the EU GDPR and, therefore, transfers of personal data originating in the EEA to the UK remain unrestricted. Like the EU GDPR, the UK GDPR restricts personal data transfers outside the UK to countries not regarded by the UK as providing adequate protection. The UK government has confirmed that personal data transfers from the UK to the EEA remain free flowing.

The UK's data protection regime is independent from but aligned to the EU's data protection regime. However, following the UK's exit ("Brexit") from the European Union ("EU"), there will be increasing scope for divergence in application, interpretation and enforcement of the data protection laws between these territories. For example, the UK Government has announced plans to introduce a Digital Information and Smart Data Bill ("Data Reform Bill") into the UK legislative process to reform the UK's data protection regime following Brexit. If passed, the final version of the Digital Reform Bill may have the effect of further altering the similarities between the UK and EEA data protection regimes and threaten the UK adequacy decision from the EU Commission, which may lead to additional compliance costs and could increase our overall risk. The respective provisions and enforcement of the EU GDPR and UK GDPR may further diverge in the future and create additional regulatory challenges and uncertainties. This lack of clarity on future UK laws and regulations and their interaction with EU laws and regulations could add legal risk, complexity

and cost to our handling of European personal data and our privacy and data security compliance programs, and could require us to implement different compliance measures for the UK and the EEA.

Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with any European and UK-based activities.

Risks Related to Our Intellectual Property

Our success depends in part on our ability to obtain and maintain protection for the intellectual property relating to or incorporated into our products.

Our success depends in part on our ability to obtain and maintain protection for the intellectual property relating to or incorporated into our products. We seek to protect our intellectual property through a combination of patents, trademarks, confidentiality and assignment agreements with our employees and certain of our contractors and confidentiality agreements with certain of our consultants, scientific advisors and other vendors and contractors. In addition, we rely on trade secrets law to protect our proprietary software and product candidates or products in development.

The patent position of myoelectric orthotic inventions can be highly uncertain and involves many new and evolving complex legal, factual and technical issues. Patent laws and interpretations of those laws are subject to change and any such changes may diminish the value of our patents or narrow the scope of protection. In addition, we may fail to apply for or be unable to obtain patents necessary to protect our technology or products or enforce our patents due to lack of information about the exact use of technology or processes by third parties. Also, we cannot be sure that any patents will be granted in a timely manner or at all with respect to any of our patent pending applications or that any patents that are granted will be adequate to protect our intellectual property for any significant period of time or at all.

Litigation to establish or challenge the validity of patents, or to defend against or assert against others infringement, unauthorized use, enforceability or invalidity claims, can be lengthy and expensive and may result in our patents being invalidated or interpreted narrowly and our not being granted new patents related to our pending patent applications. Even if we prevail, litigation may be time consuming and force us to incur significant costs, and any damages or other remedies awarded to us may not be valuable and management's attention could be diverted from managing our business. In addition, U.S. patents and patent applications may be subject to interference proceedings, and U.S. patents may be subject to re-examination and review in the U.S. Patent and Trademark Office. Foreign patents may also be subject to opposition or comparable proceedings in the corresponding foreign patent offices. Any of these proceedings may be expensive and could result in the loss of a patent or denial of a patent application, or the loss or reduction in the scope of one or more of the claims of a patent or patent application.

In addition, we seek to protect our trade secrets, know-how and confidential information that is not patentable by entering into confidentiality and assignment agreements with our employees and certain of our contractors and confidentiality agreements with certain of our consultants, scientific advisors and other vendors and contractors. However, we may fail to enter into the necessary agreements, and even if entered into, these agreements may be breached or otherwise fail to prevent disclosure, third-party infringement or misappropriation of our proprietary information, may be limited as to their term and may not provide an adequate remedy in the event of unauthorized disclosure or use of proprietary information. Enforcing a claim that a third-party illegally obtained and is using our trade secrets is expensive and time consuming, and the outcome is unpredictable. We also have taken precautions to initiate reasonable safeguards to protect our information technology systems. However, these measures may not be adequate to safeguard our proprietary information, which could lead to the loss or impairment thereof or to expensive litigation to defend our rights against competitors who may be better funded and have superior resources. In addition, unauthorized parties may attempt to copy or reverse engineer certain aspects of our products that we consider proprietary or our proprietary information may otherwise become known or may be independently developed by our competitors or other third parties. If other parties are able to use our proprietary technology or information, our ability

to compete in the market could be harmed. Further, unauthorized use of our intellectual property may have occurred, or may occur in the future, without our knowledge.

If we are unable to obtain or maintain adequate protection for intellectual property, or if any protection is reduced or eliminated, competitors may be able to use our technologies, resulting in harm to our competitive position.

We are not able to protect our intellectual property rights in all countries.

Filing, prosecuting, maintaining and defending patents on each of our products in all countries throughout the world would be prohibitively expensive, and thus our intellectual property rights outside the United States are currently limited to selected countries in the EU, including China, including Hong Kong, and Japan. In addition, the laws of some foreign countries, especially developing countries, do not protect intellectual property rights to the same extent as federal and state laws in the United States. Also, it may not be possible to effectively enforce intellectual property rights in some countries at all or to the same extent as in the United States and other countries. Consequently, we are unable to prevent third parties from using our inventions in all countries, or from selling or importing products made using our inventions in the jurisdictions in which we do not have (or are unable to effectively enforce) patent protection. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop, market or otherwise commercialize their own products, and we may be unable to prevent those competitors from importing those infringing products into territories where we have patent protection, but enforcement is not as strong as in the United States. These products may compete with our products and our patents and other intellectual property rights may not be effective or sufficient to prevent them from competing in those jurisdictions. Moreover, competitors or others in the chain of commerce may raise legal challenges against our intellectual property rights or may infringe upon our intellectual property rights, including through means that may be difficult to prevent or detect.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. Proceedings to enforce our patent rights in the United States or foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and our patent applications at risk of not issuing, and could provoke third parties to assert patent infringement or other claims against us. We may not prevail in any lawsuits that we initiate, and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights in the United States and around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license from third parties.

We may be subject to patent infringement claims, which could result in substantial costs and liability and prevent us from commercializing our current and future products.

The medical device industry is characterized by competing intellectual property and a substantial amount of litigation over patent rights. In particular, our competitors in both the United States and abroad, many of which have substantially greater resources and have made substantial investments in competing technologies, have been issued patents and filed patent applications with respect to their products and processes and may apply for other patents in the future. The large number of patents, the rapid rate of new patent issuances, and the complexities of the technology involved increase the risk of patent litigation.

Determining whether a product infringes a patent involves complex legal and factual issues and the outcome of patent litigation is often uncertain. Even though we have conducted research of issued patents, no assurance can be given that patents containing claims covering our products, technology or methods do not exist, have not been filed or could not be filed or issued. In addition, because patent applications can take years to issue and because publication schedules for pending applications vary by jurisdiction, there may be applications now pending of which we are unaware and may result in issued patents which our current or future products infringe. Also, because the claims of published patent applications can change between publication and patent grant, published applications may issue with claims that potentially cover our products, technology or methods.

Infringement actions and other intellectual property claims brought against us, with or without merit, may cause us to incur substantial costs and could place a significant strain on our financial resources, divert the attention of management and harm our reputation. We cannot be certain that we will successfully defend against any allegations of infringement. If we are found to infringe another party's patents, we could be required to pay damages. We could also

be prevented from selling our products that infringe, unless we could obtain a license to use the technology covered by such patents or could redesign our products so that they do not infringe. A license may be available on commercially reasonable terms or none at all, and we may not be able to redesign our products to avoid infringement. Further, any modification to our products could require us to conduct clinical trials and revise our filings with the FDA and other regulatory bodies, which would be time consuming and expensive. In these circumstances, we may not be able to sell our products at competitive prices or at all, and our business and operating results could be harmed.

We rely on trademark protection to distinguish our products from the products of our competitors.

We rely on trademark protection to distinguish our products from the products of our competitors. We have registered the trademarks "MyoPro" (Registration No. 4,532,331), "MYOMO" (Registration No. 4,451,445), "MyoPal" (Registration No. 6,086,533) and "MyoCare" (Registration No. 6,579,736) in the United States. The MyoPro mark is registered in Canada and in selected EU countries with pending registration. In jurisdictions where we have not yet registered our trademark and are using it, and as permitted by applicable local law, we seek to rely on common law trademark protection where available. Third parties may oppose our trademark applications, or otherwise challenge our use of the trademarks, and may be able to use our trademarks in jurisdictions where they are not registered or otherwise protected by law. If our trademarks are successfully challenged or if a third-party is using confusingly similar or identical trademarks in particular jurisdictions before we do, we could be forced to rebrand our products, which could result in loss of brand recognition, and could require us to devote additional resources to marketing new brands. If others are able to use our trademarks, our ability to distinguish our products may be impaired, which could adversely affect our business. Further, we cannot assure you that competitors will not infringe upon our trademarks, or that we will have adequate resources to enforce our trademarks.

We may be subject to damages resulting from claims that our employees or we have wrongfully used or disclosed alleged trade secrets of their former employers.

Some of our employees were previously employed at other medical device companies, including our competitors or potential competitors, and we may hire employees in the future that are so employed. We could in the future be subject to claims that these employees, or we, have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. If we fail in defending against such claims, a court could order us to pay substantial damages and prohibit us from using technologies or features that are found to incorporate or be derived from the trade secrets or other proprietary information of the former employers. If any of these technologies or features are important to our products, this could prevent us from selling those products and could have a material adverse effect on our business. Even if we are successful in defending against these claims, such litigation could result in substantial costs and divert the attention of management.

Risks Related to our Securities

Risks Related to Ownership of Our Securities

Our stockholders will experience significant dilution upon the issuance of common stock if the shares of our common stock underlying our warrants are exercised or converted.

We have a significant number of securities convertible into, or allowing the purchase of, our common stock. Investors could be subject to increased dilution upon the conversion or exercise of these securities. For example, in conjunction with equity offerings in January 2024, August 2023 and January 2023, we issued 224,730, 1,920,000 and 6,830,926 pre-funded warrants, respectively. Each pre-funded warrant is exercisable for one share of common stock at the nominal exercise price of $0.0001 per share. As of December 31, 2024, we had 7,061,519 shares issuable upon the exercise of pre-funded warrants with an exercise price of $0.0001 per share, 668,250 shares issuable upon the exercise of other warrants, with a weighted-average exercise price of $7.50 per share and 1,218,792 unvested restricted stock units outstanding. In addition, we had 23,194 shares issuable upon the exercise of stock options under our equity incentive plans, with a weighted-average exercise price of $42.98 per share.

We may not be able to maintain a listing of our common stock on the NYSE American.

We must meet certain financial and liquidity criteria to maintain such listing. If we fail to meet any of the NYSE American's listing standards, our common stock may be delisted. In addition, our board may determine that the cost of maintaining our listing on a national securities exchange outweighs the benefits of such listing. A delisting of our common stock from the NYSE American may materially impair our stockholders' ability to buy and sell our common stock and could have an adverse effect on the market price of, and the efficiency of the trading market for, our common stock. A delisting of our common stock could significantly impair our ability to raise capital.

There is no public market for our warrants or pre-funded warrants to purchase common stock.

There is no established public trading market for our warrants or pre-funded warrants and we do not expect a market to develop. In addition, we do not intend to apply for listing of such warrants on any securities exchange. Without an active market, the liquidity of such warrants will be limited.

Holders of our warrants and pre-funded warrants have no rights as a common stockholder until such holders exercise their warrants and acquire our common stock.

Until holders of our warrants and pre-funded warrants exercise such warrants, they will have no rights with respect to the shares of our common stock underlying such warrants. Upon exercise of such warrants, the holders thereof will be entitled to exercise the rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

The market price of our common stock has been and may continue to be volatile.

The stock market in general, and the market price of our common stock in particular will likely be subject to fluctuation, whether due to, or irrespective of, our operating results, financial condition and prospects. For example, from December 31, 2023 to December 31, 2024, the high and low sales price of our common stock on the NYSE American has fluctuated from a low of $2.51 to a high of $6.74 per share. During the period from January 1, 2025 to the date of the filing of this report, our stock price has ranged from $4.21 to $7.17.

Our financial performance, our industry's overall performance, changing consumer preferences, technologies, government regulatory action, tax laws and market conditions in general could have a significant impact on the future market price of our common stock. Some of the other factors that could negatively affect our share price or result in fluctuations in our share price include:

- actual or anticipated variations in our periodic operating results;
- increases in market interest rates that lead purchasers of our common stock to demand a higher investment return;
- changes in earnings estimates;
- changes in market valuations of similar companies;
- actions or announcements by our competitors;
- adverse market reaction to any increased indebtedness we may incur in the future;
- additions or departures of key personnel;
- actions by stockholders;
- speculation in the media, online forums, or investment community; and
- our intentions and ability to maintain our common stock on the NYSE American.

We do not expect to declare or pay dividends in the foreseeable future.

We do not expect to declare or pay dividends in the foreseeable future, as we anticipate that we will invest future earnings in the development and growth of our business. In addition, pursuant to the terms of our Loan Agreement, we are prohibited from paying cash dividends without the prior written consent of Silicon Valley Bank. Therefore,

holders of our common stock will not receive any return on their investment unless they sell their securities, and holders may be unable to sell their securities on favorable terms or at all.

If securities industry analysts do not publish research reports on us, or publish unfavorable reports on us, then the market price and market trading volume of our common stock could be negatively affected.

Any trading market for our common stock will be influenced in part by any research reports that securities industry analysts publish about us. We do not have any control over these analysts. We currently have limited research coverage by securities industry analysts and we may be unable to maintain analyst coverage or have analysts initiate coverage on us. If securities industry analysts cease coverage of us, the market price and market trading volume of our common stock could be negatively affected. In the event we are covered by analysts, and one or more of such analysts downgrade our securities, or otherwise reports on us unfavorably, or discontinues coverage on us, the market price and market trading volume of our common stock could be negatively affected.

Future issuances of our common stock or equity-related securities could cause the market price of our common stock to decline and would result in the dilution of your holdings.

Future issuances of our common stock or securities convertible into our common stock could cause the market price of our common stock to decline. We cannot predict the effect, if any, of future issuances of our common stock or securities convertible into our common stock on the price of our common stock. In all events, future issuances of our common stock would result in the dilution of your holdings. In addition, the perception that new issuances of our common stock, or other securities convertible into our common stock, could occur, could adversely affect the market price of our common stock.

Future issuances of debt securities, which would rank senior to our common stock upon our bankruptcy or liquidation, and future issuances of preferred stock, which could rank senior to our common stock for the purposes of dividends and liquidating distributions, may adversely affect our common stock price.

In the future, we may attempt to increase our capital resources by offering debt securities. Upon bankruptcy or liquidation, holders of our debt securities, and lenders with respect to other borrowings we may make, would receive distributions of our available assets prior to any distributions being made to holders of our common stock. Moreover, if we issue preferred stock, the holders of such preferred stock could be entitled to preferences over holders of common stock in respect of the payment of dividends and the payment of liquidating distributions. Because our decision to issue debt or preferred securities in any future offering, or borrow money from lenders, will depend in part on market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of any such future offerings or borrowings. Holders of our common stock must bear the risk that any future offerings we conduct or borrowings we make may adversely affect the level of return they may be able to achieve from an investment in our common stock.

If our shares of common stock become subject to the penny stock rules, it would become more difficult to trade our shares.

The SEC has adopted rules that regulate broker-dealer practices in connection with transactions in penny stocks. Penny stocks are generally equity securities with a price of less than $5.00, other than securities registered on certain national securities exchanges or authorized for quotation on certain automated quotation systems, provided that current price and volume information with respect to transactions in such securities is provided by the exchange or system. If we do not retain a listing on the NYSE American or another national securities exchange and if the price of our common stock is less than $5.00, our common stock will be deemed a penny stock. The penny stock rules require a broker-dealer, before a transaction in a penny stock not otherwise exempt from those rules, to deliver a standardized risk disclosure document containing specified information. In addition, the penny stock rules require that before effecting any transaction in a penny stock not otherwise exempt from those rules, a broker-dealer must make a special written determination that the penny stock is a suitable investment for the purchaser and receive (i) the purchaser's written acknowledgment of the receipt of a risk disclosure statement; (ii) a written agreement to transactions involving penny stocks; and (iii) a signed and dated copy of a written suitability statement. These disclosure requirements may have the effect of reducing the trading activity in the secondary market for our common stock, and therefore stockholders may have difficulty selling their shares.

Anti-takeover provisions in our charter documents and under Delaware law could make an acquisition of us more difficult, limit attempts by our stockholders to replace or remove our current management and limit the market price of our common stock.

Provisions in our amended and restated certificate of incorporation and bylaws may have the effect of delaying or preventing a change in control or changes in our management. Our amended and restated certificate of incorporation and bylaws include provisions that:

- authorize our board of directors to issue preferred stock, without further stockholder action and with voting liquidation, dividend and other rights superior to our common stock;
- establish an advance notice procedure for stockholder proposals to be brought before an annual meeting, including proposed nominations of persons for director nominees;
- establish that our board of directors is divided into three classes, with directors in each class serving three-year staggered terms;
- require the approval of holders of two-thirds of the shares entitled to vote at an election of directors to adopt, amend or repeal our bylaws or amend or repeal the provisions of our certificate of incorporation regarding the election and removal of directors and the ability of stockholders to take action by written consent or call a special meeting;
- prohibit cumulative voting in the election of directors; and
- provide that vacancies on our board of directors may be filled only by the vote of a majority of directors then in office, even though less than a quorum or by the holders of at least sixty-six and two-thirds percent (66 2/3%) of the issued and outstanding shares of common stock.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law which generally prohibits a Delaware corporation from engaging in any of a broad range of business combinations with any "interested" stockholder for a period of three years following the date on which the stockholder became an "interested" stockholder. Any of the foregoing provisions could limit the price that investors might be willing to pay in the future for shares of our common stock, and they could deter potential acquirers of our company, thereby reducing the likelihood that you would receive a premium for your common stock in an acquisition.

Risks Related to Internal Controls

We are a "smaller reporting company" under the reporting rules set forth under the Exchange Act. For so long as we remain a "smaller reporting company," we may take advantage of certain exemptions from various reporting requirements that are applicable to other Exchange Act reporting companies that are not "smaller reporting companies".

We are a "smaller reporting company," for as long as we continue to be a smaller reporting company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not "smaller reporting companies," including exemption from compliance with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act (so long as we remain a non-accelerated filer) and reduced disclosure obligations regarding executive compensation in the Annual Report on Form 10-K and our periodic reports and proxy statements.

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 are obligated to develop and maintain a system of effective internal control over financial reporting. We may not complete our analysis of our internal control over financial reporting in a timely manner, or these internal

controls may not be determined to be effective, which may harm investor confidence in our company and, as a result, the value of our common stock.

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act ("Section 404") to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting in the annual and quarterly reports we file with the SEC. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal control over financial reporting. However, our auditors are not required to formally attest to the effectiveness of our internal control over financial reporting pursuant to Section 404 until we are no longer a "smaller reporting company" as set forth under the Exchange Act. As of December 31, 2024, management assessed that there was a material weakness in internal controls related to a lack of design and maintenance of effective information technology general controls due to privileged access rights for two individuals, lack of a formal reviews for user provisioning, periodic user access review, and change management for the financial reporting system, and lack of formal reviews of key third party service provider reports. We expect to implement measures during the first quarter of 2025 to remediate this material weakness.

We will need to continue to dedicate internal resources, engage outside consultants and adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented and implement a continuous reporting and improvement process for internal control over financial reporting. As we continue to grow, we may need to add additional finance staff. Despite our efforts, from time to time we may not be able to conclude that our internal control over financial reporting is effective as required by Section 404, as is the case in this Annual Report on Form 10-K, due to the material weakness identified and described above. Additionally, the material weakness in our internal control over financial reporting has resulted in our management being unable to conclude, and any additional material weakness in our internal control over financial reporting may in the future result, in our management being unable to conclude, that our disclosure controls and procedures were effective for the applicable period. If we are unable to assert that our internal control over financial reporting is effective, or if our auditors are unable to express an opinion on the effectiveness of our internal controls when they are required to issue such opinion, investors could lose confidence in the accuracy and completeness of our financial reports, which could harm our stock price.

The preparation of our financial statements involves the use of estimates, judgments and assumptions, and our financial statements may be materially affected if such estimates, judgments or assumptions prove to be inaccurate.

Financial statements prepared in accordance with accounting principles generally accepted in the United States typically require the use of estimates, judgments and assumptions that affect the reported amounts. Often, different estimates, judgments and assumptions could reasonably be used that would have a material effect on such financial statements, and changes in these estimates, judgments and assumptions may occur from period to period over time. Significant areas of accounting requiring the application of management's judgment include, but are not limited to, determining the fair value of assets and the timing and amount of cash flows from assets. These estimates, judgments and assumptions are inherently uncertain and, if our estimates were to prove to be wrong, we would face the risk that charges to income or other financial statement changes or adjustments would be required. Any such charges or changes could harm our business, including our financial condition and results of operations and the price of our securities. See "Management's Discussion and Analysis of Financial Condition and Results of Operations" for a discussion of the accounting estimates, judgments and assumptions that we believe are the most critical to an understanding of our financial statements and our business.

We are incurring increased costs as a public company and our management team is required to devote substantial time to new compliance initiatives and corporate governance practices.

As a public company, and particularly after we are no longer a "small reporting company," we will incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the NYSE American and other applicable securities rules and regulations impose various requirements on public companies. Our management and other personnel will need to devote a substantial amount of time to compliance with these requirements. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly.

Risks Related to Tax Laws

We may be subject to adverse legislative or regulatory changes in tax laws that could negatively impact our financial condition.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by persons involved in the legislative process and by the U.S. Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect our stockholders or us. In recent years, many such changes have been made and changes are likely to occur in the future. We cannot predict whether, when, in what form, or with what effective dates, tax laws, regulations and rulings may be enacted, promulgated or decided, which could result in an increase in our, or our stockholders' tax liability or require changes in the manner in which we operate in order to minimize increases in our tax liability.

Our ability to use net operating losses and research and development credits to offset future taxable income may be subject to certain limitations.

As of December 31, 2024, we had U.S. federal and state net operating loss ("NOL") carryforwards of approximately $79.1 million and $63.5 million, respectively available to offset future taxable income. The Federal NOLs incurred prior to 2018 of approximately $26.4 million, if not utilized, begin expiring in the year 2026. The Federal NOLs incurred after 2017 of approximately $52.6 million have an indefinite carryforward period. The state NOLs if not utilized begin to expire in 2025 through 2045. Additionally, the Company has U.S. federal and state research and development tax credits of $0.7 million and $0.4 million, respectively, which begin to expire in the year 2026 and 2033, respectively. These NOL and tax credit carryforwards could expire unused and be unavailable to offset future taxable income or tax liabilities, respectively. In addition, in general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended (the "Code"), and corresponding provisions of state law, a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change NOL carryforwards or tax credits, to offset future taxable income. For these purposes, an ownership change generally occurs where the aggregate stock ownership of one or more stockholders or groups of stockholders who owns at least 5% of a corporation's stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing period. We have determined that such ownership changes have occurred in prior years. The result of these ownership changes is that we have a $64,000 annual limitation on our ability to utilize pre-ownership change NOLs and approximately $20.0 million of our federal NOLs and $48.0 million of our state NOLs will expire unutilized. There may have been an ownership change associated with our equity offerings in August 2023, January 2024 and December 2024. We may undergo an ownership change in connection with future changes in our stock ownership (many of which are outside of our control), whereby our ability to utilize NOLs or credits could be further limited by Sections 382 and 383 of the Code or under corresponding provisions of state law. Furthermore, our ability to utilize our NOLs or tax credits is conditioned upon our attaining profitability and generating U.S. federal and state taxable income. As described above under "Risk factors— Risks Associated with Our Business," we have incurred net losses since our inception and anticipate that we will continue to incur losses for the foreseeable future; and therefore, we do not know whether or when we will generate the U.S. federal or state taxable income necessary to utilize our NOLs or tax credits that are subject to limitation by Sections 382 and 383 of the Code. Under current law, U.S. federal NOL carryforwards generated in taxable years beginning after December 31, 2017 will not be subject to expiration, but the amount of such NOL carryforwards that we are permitted to deduct in a taxable year beginning after December 31, 2020 will be limited to 80% of our taxable income in each such year to which the NOL carryforwards are applied.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

Some of the statements under "Business," "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations," "Business" and elsewhere in this Annual Report on Form 10-K constitute forward-looking statements. Forward-looking statements relate to expectations, beliefs, projections, future plans and strategies, anticipated events or trends and similar matters that are not historical facts. In some cases, you can identify forward-looking statements by terms such as "anticipate," "believe," "could," "estimate," "expect," "intend," "may," "plan," "potential," "should," "will" and "would" or the negatives of these terms or other comparable terminology. You should not place undue reliance on forward looking statements. The cautionary statements set forth in this Annual Report on Form 10-K, including in "Risk Factors" and elsewhere, identify important factors which you should consider in evaluating our forward-looking statements. These factors include, among other things:

- our ability to obtain sufficient reimbursement from third-party payers for our products;
- our ability to scale the business to return to positive cash flow from operations on a quarterly basis by the fourth quarter 2025;
- our revenue concentration with Medicare and with a particular insurance payer as a result of focusing our efforts on patients with insurers who have previously reimbursed for the MyoPro;
- our ability to continue normal operations and patient interactions without supply chain disruption in order to deliver and fit our custom-fabricated devices;
- our marketing and commercialization efforts;
- our dependence upon external sources for the financing of our operations, to the extent that we do not achieve or maintain cash flow breakeven;
- our ability to obtain and maintain our strategic collaborations and to realize the intended results of such collaborations;
- our ability to effectively execute our business plan and scale up our operations;
- our ability to remediate the material weakness in our internal control over financial reporting;
- our expectations as to our product development programs, including improving our existing products and developing new products;
- our ability to maintain and grow our reputation and to achieve and maintain the market acceptance of our products;
- our expectations as to our clinical research program and clinical results;
- our ability to maintain adequate protection of our intellectual property and to avoid violation of the intellectual property rights of others;
- our ability to gain and maintain regulatory approvals;
- our ability to compete and succeed in a highly competitive and evolving industry; and
- general market, economic, environmental and social factors that may affect the evaluation, fitting, delivery and sale of our products to patients; and
- other risks and uncertainties, including those listed under the captain "Risk Factors" in this Annual Report on Form 10-K.

Although the forward-looking statements in this Annual Report on Form 10-K are based on our beliefs, assumptions and expectations, taking into account all information currently available to us, we cannot guarantee future transactions, results, performance, achievements or outcomes. No assurance can be made to any investor by anyone that the expectations reflected in our forward-looking statements will be attained, or that deviations from them will not be

material and adverse. We undertake no obligation, other than as maybe be required by law, to re-issue this Annual Report on Form 10-K or otherwise make public statements updating our forward-looking statements.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 1C. Cybersecurity

Cyber Risk Management and Strategy

Our manager of information technology works in conjunction with our third-party managed security service provider to establish and maintain our cybersecurity risk management processes, which are informed by and incorporate elements of recognized industry standards, such as the National Institute of Standards and Technology Cybersecurity Framework. We also leverage our managed security services provider and other third-party consultants, providers, and technologies to support our internal information technology resources to monitor, identify, and address cybersecurity risks, including managing our monitoring and alerting tools and conducting periodic assessments of certain system applications.

Further, as part of our cybersecurity risk management, we have adopted an incident response plan that has been designed to identify and manage significant events that may impact our information technology infrastructure, including those arising from or related to cybersecurity threats.

We conduct periodic risk assessments of our information technology systems as part of our cybersecurity risk management processes and to evaluate the effectiveness of applicable security controls. Our efforts to address cybersecurity risks also include training employees, both from programs provided by our third-party managed security service provider and internal policies and training, which are designed to increase awareness of cybersecurity threats.

We have a process to assess and review the cybersecurity practices of certain third-party vendors and service providers, including through review of applicable certifications and security reports, where available, and contractual requirements, as appropriate.

Although risks from cybersecurity threats have to date not materially affected, and we do not believe they are reasonably likely to materially affect, us, our business strategy, results of operations or financial condition, we do, from time to time, experience threats and communicate security incidents relating to our and our third-party vendors' information systems. For more information please see the section entitled "Risks Related to Cybersecurity and Data Protection" in Item 1A- Risk Factors.

Governance Related to Cybersecurity Risks

Our cyber risk management program and related operations and processes are directed by our Chief Financial Officer, in consultation with internal information technology resources, other members of senior management and our third-party security managed service provider. The Chief Financial Officer is responsible for identifying, evaluating, and implementing risk management control and methodologies to address any identified risks, including risks from cybersecurity threats, with advice from our third-party managed security service provider as appropriate.

The Chief Financial Officer periodically provides reports to the technology, quality and regulatory committee of the board of directors regarding information technology and cybersecurity matters and associated risks. The technology, quality and regulatory committee is responsible for reviewing and overseeing the Company's risk management process and strategy, including risks from cybersecurity threats. The technology, quality and regulatory committee periodically reports on cybersecurity risk management to the full board of directors.

Item 2. Properties

Our primary offices are located at 45 Blue Sky Drive in Burlington, Massachusetts, where we have a lease expiring in October 2032 consisting of approximately 28,700 square feet of office, manufacturing and laboratory space, with an additional 7,500 square feet of manufacturing space committed to be leased in June 2025. Additionally, we have offices at 5601 Bridge St. in, Fort Worth, TX, where we have a lease expiring in December 2025 to operate a customer service call center consisting of approximately 2,800 square feet of office space. We believe our facilities are currently adequate for us to conduct our business. A number of our employees work remotely from home across the United States and Germany.

Item 3. Legal Proceedings

The Company may be involved in legal proceedings, claims and assessments arising from the ordinary course of business. Such matters are subject to many uncertainties, and outcomes are not predictable with assurance. There is no material litigation against the Company at this time that is required to be disclosed under Item 103 of Regulation S-K.

Item 4. Mine Safety Disclosures

Not applicable.

PART II

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

The information required to be disclosed by Item 201(d) of Regulation S-K, "Securities Authorized for Issuance Under Equity Compensation Plans," is incorporated herein by reference. Refer to Item 12 of Part III of this Annual Report on Form 10-K for additional information.

Market Information

Our common stock has been listed on NYSE American under the symbol "MYO" since June 12, 2017. Prior to that time, there was no public market for our common stock.

Holders of Record

On March 1, 2025, the closing price per share of our common stock was $5.07 as reported on The NYSE American, and we had approximately 121 stockholders of record (not including beneficial owners whose shares are held in street name).

Dividend Policy

We have never paid or declared any cash dividends on our common stock, and we do not anticipate paying any cash dividends on our common stock in the foreseeable future. In addition, the terms of our existing debt agreement precludes us from paying dividends. We intend to retain all available funds and any future earnings to fund the development and expansion of our business. Any future determination to pay dividends will be at the discretion of our board of directors and will depend upon a number of factors, including our results of operations, financial condition, future prospects, contractual restrictions, restrictions imposed by applicable law and other factors our board of directors deems relevant.

Recent Sales of Unregistered Securities
Not applicable

Use of Proceeds from Registered Securities
Not applicable

Issuer Purchases of Equity Securities
Not applicable.

Item 6. Reserved
Not applicable.

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

The following discussion should be read in conjunction with our financial statements and the related notes contained elsewhere in this Annual Report on Form 10-K and in our other Securities and Exchange Commission filings. The following discussion may contain predictions, estimates, and other forward-looking statements that involve a number of risks and uncertainties, including those discussed under "Risk Factors" and elsewhere in this Annual Report on Form 10-K. These risks could cause our actual results to differ materially from any future performance suggested below.

Overview

We are a wearable medical robotics company, specializing in myoelectric braces, or orthotics, for people with neuromuscular disorders. We develop and market the MyoPro product line, which is a myoelectric-controlled upper limb brace, or orthosis. The orthosis is a rigid brace used for the purpose of supporting a patient's weak or deformed arm to enable and improve functional activities of daily living, or ADLs, in the home and community. It is custom constructed by a trained professional during a custom fabrication process for each individual user to meet their specific needs. Our products are designed to help regain function in individuals with neuromuscular conditions due to brachial plexus injury, stroke, traumatic brain injury, spinal cord injury and other neurological disorders.

We utilize digital ads on various platforms as well as television ads to reach patients who are potential candidates for our product. Once the prospective patient contacts us or is referred to us, either our trained clinical staff or a trained O&P provider will evaluate the patient for their suitability as a candidate. Initial evaluations by our trained clinical staff are conducted using telehealth techniques, followed by an in-person clinical evaluation of the candidate. Prior to obtaining authorizations from commercial insurance companies or delivering to a patient with Medicare Part B, the patient's medical records are collected and reviewed to make sure the device is appropriate for their condition and a prescription is always obtained from a physician. Once these documents are obtained, if the patient has Medicare Advantage or other commercial insurance, a pre-authorization request is submitted to the patient's insurer. If we receive a pre-authorization, we proceed to measure the patient's arm a process we call shape capture. In many cases, shape capture is done using a remote measurement kit supplied to the patient. If the patient is covered by Medicare Part B, no pre-authorization is required and we can move directly to taking measurements of the patient's arm. We then use those measurements to 3D print orthotic parts, which are used to fabricate the MyoPro, and then deliver it to the patient. Since we are directly providing the device to the patient and then billing insurance ourselves, we refer to this process as direct billing. We also call on hospitals and O&P practices in the United States, Europe and Australia that provide our products to their patients as well as generate indirect sales. The MyoPro product line has been approved by the VA system for impaired veterans, and over 130 VA facilities have ordered devices for their patients.

Our myoelectric orthoses have been clinically shown in peer reviewed published research studies to help regain the ability to complete functional tasks by supporting the affected joint and enabling individuals to self-initiate and control movement of their partially paralyzed limbs by using their own muscle signals.

Our technology was originally developed at MIT in collaboration with medical experts affiliated with Harvard Medical School. Myomo was incorporated in 2004.

Other milestones in our history include:

- In 2012, we introduced the MyoPro, the primary business focus shifted during this time period, from devices which were designed for rehabilitation therapy and sold to hospitals, to providing an assistive device through O&P providers to patients who are otherwise impaired for use at home, work, and in the community that facilitates activities of daily living or ADLs.
- During 2015, we extended our basic MyoPro for the elbow with the introduction of the MyoPro Motion W, a multi-articulated non-powered wrist and the MyoPro Motion G, which includes a powered grasp. The MyoPro Motion W allows the user to use their sound arm to adjust the device and then, for instance, open a refrigerator door, carry a shopping bag, hold a cell phone, or stabilize themselves to avoid a fall and potential injury. The MyoPro Motion G model allows users with severely weakened or clenched hands, such as seen in certain stroke survivors, to open and close their hands and perform a large number of ADLs.

- On June 9, 2017, we completed our initial public offering, or IPO, and a private offering concurrent with the IPO, generating net proceeds of $6.9 million in the aggregate.
- On July 31, 2017, we met the criteria to apply the CE mark for the MyoPro under the EU MDD. The EU MDR repealed and replaced the EU MDD on May 26, 2021, and we therefore worked with our EU-Authorized Representative to ensure all EU MDR requirements were met, which enabled us to establish a new declaration of conformity under the EU MDR to allow continued to CE mark application. This has enabled us to sell the MyoPro to individuals in the EU.
- In November 2018, we announced that the CMS had published two new codes (L8701, L8702) that describe our products, pursuant to our application for HCPCS codes which become effective in early 2019. At that time, our products were classified as durable medical equipment rental at that time.
- In 2019 we transitioned our business to become a direct provider of the MyoPro to patients and bill insurance companies directly.
- In January 2021, we entered into a joint venture with Beijing Ryzur Medical Investment Co., Ltd. ("Ryzur Medical"), a medical device manufacturer based in Beijing, China to manufacture and sell our current and future products in greater China, including Hong Kong, Macau and Taiwan. Under the agreement with Ryzur Medical, we own 19.9% of the joint venture company, Jiangxi Myomo Medical Assistive Appliance Co. Ltd. (the "JV Company"), which is obligated to purchase $10.75 million of MyoPro control system units over the next 10 years, subject to receipt of regulatory approvals necessary to permit sales of the product in the greater China territory.
- In July 2021, we announced that we became accredited as a Medicare provider.
- In January 2022, we introduced the MyoPro 2+ and began in-house fabrication of the device.
- On November 1, 2023, CMS issued a final rule that resulted in a change in the benefit category associated with products billed under the HCPCS codes for our products from durable medical equipment rental to a brace, which would permit reimbursement of MyoPro sales on a lump sum basis. The rule became effective on January 1, 2024.
- On February 29, 2024, CMS published final payment determinations for the HCPCS codes describing our products which are L8701, for the MyoPro Motion W, and L8702, for the MyoPro Motion G, which became effective on April 1, 2024. These fees were subsequently updated to approximately $34,300 for the Motion W and approximately $67,500 for the Motion G, effective January 1, 2025. These fees are subject to annual inflationary adjustments.

Recent Developments

Equity Offerings

On December 6, 2024, we completed a public offering, selling 3,450,000 shares at $5.00 per share, generating net proceeds after fees and expenses of approximately $15.8 million. Net proceeds from the offering are expected to be used to grow revenues in our direct billing channel through additional advertising spending and the addition of clinical, reimbursement and manufacturing headcount to support expected increasing demand, to increase R&D spending in order to accelerate the completion of sustaining and new product development activities, to fund systems and headcount to support growth in the O&P channel, to fund associated working capital requirements and general corporate purposes. On January 19, 2024 we completed a registered direct equity offering, selling 1,354,218 shares of common stock and 224,730 pre-funded warrants at $3.80 per share, or $3,7999 per pre-funded warrant, generating net proceeds after fees and expenses of approximately $5.4 million. On August 29, 2023, we completed a public equity offering, selling 5,413,334 shares of common stock and 1,920,000 pre-funded warrants at $0.60 per share, or at $0.5999 per pre-funded warrant, generating net proceeds after fees and expenses of approximately $3.9 million. In January 2023, we completed a public equity offering, whereby we sold 13,169,074 shares of common stock and 6,830,926 pre-funded warrants at $0.325 per share, or $0.3249 per pre-funded warrant. Each pre-funded warrant in the above offerings entitles the holder to one share of common stock upon exercise at a nominal exercise price of $0.0001 per share. See section titled "Liquidity" for further discussion.

Results of Operations

We have been growing revenues while incurring net losses and negative cash flows from operations since inception and anticipate this to continue for most of 2025. Our financial performance in 2024 reflected our ability to be reimbursed by Medicare for providing the MyoPro to their beneficiaries. Our plan for 2025 is to invest in increasing demand and adding capacity to support our direct billing channel, while making investments to increase revenues in the U.S. O&P channel.

Comparison of the year ended December 31, 2024 to the year ended December 31, 2023

The following table sets forth our revenue, gross profit and gross margin for each of the years presented.

	Years Ended December 31,		Year-to-year change	
	2024	2023	$	%
Product revenue	$ 32,551,199	$ 17,476,238	$ 15,074,961	86%
License revenue	-	1,764,920	(1,764,920)	NM
Total revenue	32,551,199	19,241,158	13,310,041	69
Cost of revenue	9,365,856	6,058,775	3,307,081	55
Gross profit	$ 23,185,343	$ 13,182,383	$ 10,002,960	76
Gross margin	71.2%	68.5%		2.7%

Revenues

We derive revenue primarily from providing devices directly to patients and billing insurance companies directly. We also sell our products to O&P providers in the United States. Europe and Australia, to the VA and to rehabilitation hospitals. Though we increasingly provide devices directly to patients, we sometimes utilize the clinical services of O&P providers for which they are paid a fee.

We expect that our revenues will continue to grow, primarily as a result of investments to grow our direct billing channel and through expected higher revenue from O&P practices both inside and outside of the United States.

Product revenue in 2024 increased by approximately $15.1 million, or 86%, compared to 2023. The product revenue increase was driven primarily by higher direct billing revenues due to a higher average selling price, or ASP, as well as a higher number of revenue units as we were able to serve Medicare Part B beneficiaries in volume in 2024. Including the license revenue received from our joint venture partner in China in 2023, total revenue increased 69%. Revenues generated through the direct billing channel were approximately $25.3 million, or 78% of product revenue in 2024, compared to approximately $12.3 million, or 71%, of product revenue in 2023.

Cost of Revenue and Gross margin

Cost of revenue consists of direct costs for the manufacturing, casting/printing of orthotic parts, fabrication and fitting of our products, inventory reserves, warranty costs and overhead costs allocated to cost to revenue.

Gross margin increased to 71.2% in 2024 compared to 68.5% in 2023. The increase in gross margin was driven primarily by the increase in ASP discussed above and greater absorption of fixed costs into inventory. Excluding the license fees in 2023, gross margin on product sales was 65.3% for the year ended December 31, 2023. The increase in gross margin on product sales, was driven by the aforementioned factors.

We expect our gross margin to vary depending on the mix of channel revenues and timing of reimbursements from certain third-party payers, which impacts revenue recognition.

Operating expenses

The following table sets forth our operating expenses for each of the years presented.

	Years Ended December 31,		Year-to-year change	
	2024	2023	$	%
Research and development	$ 4,772,013	$ 2,636,487	$ 2,135,526	81%
Selling, clinical, and marketing	12,236,910	9,042,698	3,194,212	35%
General and administrative	12,383,118	9,734,747	2,648,371	27%
Total operating expenses	$ 29,392,041	$ 21,413,932	$ 7,978,109	37%

Research and development

R&D expenses consist of costs for our engineering and research personnel, including salaries, benefits, incentive and stock-based compensation, product development costs, clinical studies and the cost of certain third-party contractors and travel expense. R&D costs are expensed as they are incurred. We intend to accelerate our R&D efforts in 2025 and expect R&D costs to increase on an annual basis.

R&D expenses increased by approximately $2.1 million or 81% in 2024 compared to 2023. The increase during 2024 was driven primarily by higher payroll costs due to higher engineering headcount in 2024 as a result of a larger number of new product development and sustaining engineering projects.

Selling, clinical and marketing

Selling expenses consist of costs for our field clinical staff, clinical training organization, and marketing personnel, including salaries, benefits, stock-based compensation and sales commissions, costs of digital advertising, marketing and promotional events, corporate communications, product marketing and travel expenses. Variable compensation for personnel engaged in sales and marketing activities is generally earned and recorded as expense when the product is delivered. We expect sales and marketing expenses to increase in 2025 as we increase our advertising spending and clinical capacity to grow revenues in our direct billing channel.

Selling, clinical, and marketing expenses increased by approximately $3.2 million or 35% in 2024 compared to 2023. The increase during 2024 was driven primarily by higher advertising spending as well as an increases in clinical and customer service headcount in support of our direct billing channel.

General and administrative

General and administrative expenses consist primarily of costs for administrative, reimbursement, and finance personnel, including salaries, benefits, incentive and stock-based compensation, professional fees associated with legal matters, consulting expenses, costs for pursuing insurance reimbursements for our products and costs required to comply with the regulatory requirements of the SEC and Medicare accreditation, as well as costs associated with accounting systems, insurance premiums and other corporate expenses. We expect that general and administrative expenses will increase in 2025 as a result of increasing our reimbursement capacity in order to grow revenue in the direct billing channel.

General and administrative expenses increased by approximately $2.6 million or 27% in 2024 compared to 2023. The increase was primarily due to an increase in headcount in the human resource and reimbursement functions, as well as a higher bonus.

Other expense (income)

The following table sets forth our interest and other expense (income) for each of the years presented.

	Years Ended December 31,		Year-to-year change	
	2024	2023	$	%
Interest income, net	$ (388,586)	$ (410,274)	$ 21,688	(5)%
Other expense, net	-	785	(785)	(100)
Loss on equity investment	-	169,503	(169,503)	(100)
Total other income	$ (388,586)	$ (239,986)	$ (148,600)	62%

Interest income decreased primarily due to lower average investment balances in 2024. Loss on equity investment represents our share of the losses incurred by the JV Company, which began limited operations in 2023. Our investment in the JV Company was written off during the year ended December 31, 2023.

Income tax expense

Income tax expense recorded during the years ended December 31, 2024 and 2023 represents the provision for income taxes for our wholly-owned subsidiary, Myomo Europe GmbH. The increase in income tax expense relates to increased income from Myomo Europe GmbH in 2024 compared to 2023.

Adjusted EBITDA

We believe that the presentation of Adjusted EBITDA, a non-GAAP financial measure, provides investors with additional information about our financial results. Adjusted EBITDA is an important supplemental measure used by our board of directors and management to evaluate our operating performance from period-to-period on a consistent basis and as a measure for planning and forecasting overall expectations and for evaluating actual results against such expectations.

We define Adjusted EBITDA as earnings before interest and other income (expense), taxes, depreciation and amortization, adjusted for stock-based compensation and the loss on equity investment in the JV Company.

Adjusted EBITDA is not in accordance with, or an alternative to, measures prepared in accordance with U.S. GAAP. In addition, this non-GAAP measure is not based on any comprehensive set of accounting rules or principles. As a non-GAAP measure, Adjusted EBITDA has limitations in that it does not reflect all of the amounts associated with our results of operations as determined in accordance with U.S. GAAP. In particular:

- Adjusted EBITDA does not include interest income, net;
- Adjusted EBITDA does not reflect the amounts we paid in taxes or other components of our tax provision;
- Adjusted EBITDA does not include depreciation expense from fixed assets, or amortization of leasehold improvements;
- Adjusted EBITDA does not include the impact of stock-based compensation; and
- Adjusted EBITDA does not include the loss on equity investment in the JV Company.

Because of these limitations, you should consider Adjusted EBITDA alongside other financial performance measures including net income (loss) and our financial results presented in accordance with U.S. GAAP.

The following table provides a reconciliation of net loss to Adjusted EBITDA for each of the years indicated:

	2024	2023
GAAP net loss	$ (6,183,729)	$ (8,147,565)
Adjustments to reconcile to Adjusted EBITDA:		
Interest income, net	(388,586)	(410,274)
Loss on equity investment	—	169,503
Income taxes	365,617	156,002
Depreciation and amortization expense	205,910	164,306
Stock-based compensation	874,438	1,115,602
Adjusted EBITDA	$ (5,126,350)	$ (6,952,426)

Liquidity and Capital Resources

Liquidity

We measure our liquidity in a number of ways, including the following:

	December 31,	
	2024	2023
Cash and cash equivalents	$ 24,372,373	$6,871,306
Short-term investments	$ 492,990	$1,994,662
Working capital	22,618,158	8,173,925

We had working capital and stockholders' equity of approximately $22.6 million and $24.7 million respectively, as of December 31, 2024. We used $3.3 million in cash for operating activities during the year ended December 31, 2024. In the fourth quarter of 2024, the Company generated positive cash flow from operations of $3.4 million, as well as positive free cash flow of $2.5 million.

We have historically funded our operations through financing activities, including raising equity and debt capital. In December 2024, we completed a public equity offering, pursuant to which we sold 3,450,000 shares at $5.00 per share, generating net proceeds after fees and expenses of approximately $15.8 million. In January 2024, we completed a registered direct equity offering, pursuant to which we sold 1,354,218 shares of common stock and 224,730 pre-funded warrants at $3.80 per share, or $3.7999 per pre-funded warrant, generating net proceeds after fees and expenses of approximately $5.4 million. In August 2023, we completed a public equity offering pursuant to which we sold 5,413,334 shares of common stock and 1,920,000 pre-funded warrants at $0.60 per share or at $0.5999 per warrant, generating proceeds after fees and expenses of approximately $3.9 million. In January 2023, we completed an equity offering under which we sold 13,169,074 shares of common stock and 6,830,926 pre-funded warrants at $0.325 per share, generating proceeds after fees and expenses of approximately $5.7 million. In July 2024, we entered into a Loan and Security Agreement with Silicon Valley Bank, a division of First-Citizens Bank & Trust Company, which provides us the ability to borrow up to $4.0 million against eligible accounts receivable. The line of credit remains undrawn as of the issuance date of these financial statements. Availability under the line of credit is approximately $1.0 million based on eligible accounts receivable as of December 31, 2024. We amended the Loan and Security Agreement in February 2025 to provide for, among other changes, a $3 million term loan facility, which is available to be drawn at any time until February 28, 2026. Considering our cash balance and availability under our debt arrangements as of December 31, 2024 and our operating plans discussed below, we believe there will be sufficient cash to fund our operations and capital expenditures for the next 12 months from the date of this report.

Our operating plans are primarily focused on growing revenues in our direct billing channel in 2025, while we work concurrently on growing revenues in the O&P channel. This involves increasing our advertising spending and adding headcount to increase our clinical, reimbursement and manufacturing capacity in order to serve a higher volume of patients in 2025. These investments are expected to result in negative cash flows for at least the first three quarters of 2025.

Our business is dependent upon reimbursement of our products by insurance companies and government-controlled health care plans such as Medicare and Medicaid in the United States and by statutory health insurance plans in Germany, which could prevent our revenues from growing to the level necessary to return to ash flow breakeven on a

sustaining basis. We believe that we have access to capital resources, if necessary, through potential public or private equity offerings, debt financings, or other means. If we are unable to obtain adequate funds on reasonable terms, we may be required to significantly curtail or discontinue operations or obtain funds by entering into financing agreements on unattractive terms. We may also explore strategic alternatives for the purpose of maximizing stockholder value. There can be no assurance we will be successful in implementing our plans to sustain our operations and continue to conduct our business.

Cash Flows

	Year Ended December 31,	
	2024	2023
Net cash used in operating activities	$ (3,289,904)	$ (6,172,764)
Net cash provided by (used in) investing activities	259,981	(2,029,565)
Net cash provided by financing activities	20,932,429	9,713,457
Effect of foreign exchange rate changes on cash	(26,439)	14,211
Net increase in cash and cash equivalents	$ 17,876,067	$ 1,525,339

Operating Activities. The net cash used in operating activities for the year ended December 31, 2024 was primarily used to fund a net loss net approximately $6.2 million, adjusted for non-cash expenses in the aggregate amount of approximately $1.6 million of which approximately $0.9 million is related to non-cash adjustments related to stock-based compensation, and approximately $1.3 million of cash generated from changes in operating assets and liabilities, primarily related to an increase in accounts payable and accrued expenses and receipt of a tenant improvement allowance for our new headquarters facility in Burlington, MA., partially offset by increases in inventory and accounts receivable.

The net cash used in operating activities for the year ended December 31, 2023 was primarily used to fund a net loss net approximately $8.1 million, adjusted for non-cash expenses in the aggregate amount of approximately $1.7 million of which approximately $1.1 million is related to non-cash adjustments related to stock-based compensation, and approximately $0.3 million of cash generated from changes in operating assets and liabilities, primarily related to an increase in accounts payable and accrued expenses, offset by increases in inventory and accounts receivable.

Investing Activities. During the year ended December 31, 2024 our cash provided by investing activities of $0.3 million was primarily due to a greater amount of maturities compared to purchases of short-term investments, offset by purchases of furniture and fixtures related to the move to our new headquarters facility in December 2024 and demo units for O&P practices as we look to increase revenue from this channel in 2025. Cash used in investing activities in 2023 was primarily for our purchases of short-term investments and purchases of equipment.

Financing Activities. During the year ended December 31, 2024 cash provided by financing activities of approximately $20.9 million was due to net proceeds received from our equity offerings in January and December 2024.

During the year ended December 31, 2023 cash provided by financing activities of approximately $9.7 million was due to net proceeds received from the sale of common stock and pre-funded warrants, net of offering costs.

Critical Accounting Estimates

Our discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with U.S. GAAP. The preparation of these consolidated financial statements requires us to make estimates, judgments and assumptions that affect the reported amounts of assets, liabilities, revenue and expenses. We base our estimates on historical experience and on various other assumptions that we believe are reasonable under the circumstances. These estimates and assumptions are reviewed on an on-going basis and updated as appropriate. Materially different results can occur if circumstances change and

additional information becomes known. Actual results may differ from these estimates. Refer to *Note 2 - Summary of Significant Accounting Policies.* Our most critical accounting estimates include

- The timing and amount of revenue recognition based on assertions and estimates of payments from certain insurance payers
- The discount rate on leases

Timing and Amount of Revenue Recognition

The timing and amount of revenue recognized is determined based on certain estimates. For revenue derived from patients with Medicare Part B, we determined we had sufficient payment history in order to recognize revenue upon delivery of the device to the patient based on the published fees by CMS. With respect to patients with Medicare Advantage or other commercial insurance, except for a small number of payers, we do not have contracts to establish pricing or provide evidence of an arrangement. As a result, we rely on a history of payments after receiving an insurance authorization, delivery of the device and submission of a claim as evidence of an arrangement. Payment history is also used to estimate how much we expect to be paid upon delivery of our device and submission of an insurance claim, which determines how much revenue we recognize. For other Medicare Advantage and other commercial insurance payers, we have determined that we do not have sufficient collection history with the payer to assert evidence of an arrangement and collectibility. For these payers, revenue is recognized at payment, which is when we can determine how much we will be paid for the device.

Discount Rate on Leases

We estimate the discount rate applied to the lease payments under a lease. The discount rate is based on the interest rate on our line of credit or other inputs in the absence of a debt facility. The discount rate impacts the valuation of the lease asset and liability, as well as the periodic amortization of right of use assets in the statement of operations.

Recent Accounting Standards

In October 2023, the FASB issued ASU 2023-06, "Disclosure Improvements, Codification Amendments in Response to the SECs Disclosure Update and Simplification Initiative", that adds 14 of the 27 identified disclosure or presentation requirements to the Codification, each amendment in the ASU will only become effective if the SEC removes the related disclosure or presentatioTn from its existing regulations by June 30, 2027. We currently comply with these disclosure requirements as applicable under Regulation S-X or Regulation S-K and will adopt these new standards depending on timing of when they become effective, which is not expected to have a material impact on our financial position and results of operations.

In November 2023, the FASB issued ASU 2023-07 "Segmented Reporting - Improvements to Reportable Segment Disclosures". ASU 2023-07 focuses on the requirements to disclose its significant segment expense categories and amounts for each reportable segment. ASU 2023-07 became effective with the calendar year 2024 year-end financial statements. We have adopted these new standards, which did not have a material impact on our financial position and results of operations.

In December 2023, the FASB issued ASU 2023-09, "Accounting standards update, Income Taxes (Topic 740: Improvements to Income Tax Disclosures". ASU 2023-09 focuses on income tax disclosures around effective tax rates and cash income taxes paid. This amendment in the ASU will become effective for public companies as of December, 15 2024 and effective to all other companies one year later. We will adopt these standards when they become effective, which did not have a material impact on our financial position and results of operations.

Quantitative and Qualitative Disclosure about Market Risk

Our unrestricted cash, restricted cash, and cash equivalents, totaling approximately $24.7 million as of December 31, 2024, was deposited in bank accounts. The cash in these accounts is held for working capital purposes and invested by the bank in overnight money market funds that invest in short-term government or government backed securities. Any short-term investments are only in high-quality instruments with maturities of nine months or less. Our primary objective is to preserve our capital for purposes of funding our operations.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk

This item is not applicable to us as a smaller reporting company.

Item 8. Financial Statements and Supplementary Data

See the financial statements filed as part of this Annual Report on Form 10-K as listed under Item 15 below.

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

Not Applicable.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

The term "disclosure controls and procedures," as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), refers to controls and procedures that are designed to ensure that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported, within the time periods specified in the SEC's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that such information is accumulated and communicated to a company's management, including its principal executive and principal financial officers, as appropriate to allow timely decisions regarding required disclosure.
Our management, with the participation of our Chief Executive Officer, our principal executive officer, and our Chief Financial Officer, our principal financial officer, has evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2024, the end of the period covered by this Annual Report on Form 10-K.

Management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives, and management necessarily applies its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2024, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures were not effective as of such date at the reasonable assurance level due to the material weakness in the design of effective information technology general controls over our enterprise reporting system described below.

Material Weakness

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 company's annual or interim financial statements will not be prevented or detected on a timely basis.

We identified a material weakness related to a lack of design and maintenance of effective information technology general controls due to privileged access rights for two individuals, lack of formal processes for user provisioning, periodic user access review and change management for financial reporting system and lack of formal reviews of key third party service provider SOC reports. The deficiencies could allow for inappropriate financial transactions to be recorded that would not be detected by our other manual controls, rendering them ineffective. This material weakness did not result in any identified misstatements to our financial statements.

Notwithstanding the material weaknesses in our internal control over financial reporting, our management has concluded that our consolidated financial statements and related notes thereto included in this Annual Report on Form 10-K fairly present in all material respects the financial condition, results of operations and cash flows of the Company and have been prepared in accordance with generally accepted accounting principles. Our Chief Executive Officer and Chief Financial Officer have certified that, based on each such officer's knowledge, the financial statements, as well as the other financial information included in this Annual Report on Form 10-K, fairly present in all material respects the financial condition, results of operations and cash flows of the Company as of, and for, the periods presented in this

Annual Report on Form 10-K. Marcum LLP has issued an unqualified opinion on our financial statements, which is included in Part IV of this Annual Report on Form 10-K.

Management's Plan for Remediation of the Material Weakness

Management, with the oversight of the Audit Committee of the Board of Directors, is committed to maintaining a strong internal control environment. In response to the material weakness identified above, the Company intends to remediate the material weakness in internal control over financial reporting by formalizing our process and review of user provisioning to enable only the appropriate personnel to have access, including giving rights to provision access to our financial reporting system to an individual outside our finance organization, and formalizing change management processes and review of key third party service provider SOC reports.

We believe that these actions, when fully implemented, will remediate the material weakness. However, the material weakness will not be considered fully remediated until the design of these controls are determined to operate for a sufficient period of time and management has concluded, through testing, that these controls are effective. As we continue to evaluate operating effectiveness and monitor improvements to our internal control over financial reporting, we may take additional measures to address control deficiencies or modify the remediation plan described above.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2024. In making this assessment, we used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control - Integrated Framework (2013). Based on our assessment, and as a result of the material weakness described above, we believe that as of December 31, 2024, our internal control over financial reporting was not effective at the reasonable assurance level. However, after giving full consideration to this material weakness, our management has concluded that our consolidated financial statements present fairly, in all material respects, our financial position, results of operations and cash flows for the periods disclosed in conformity with generally accepted accounting principles.

Changes in Internal Control over Financial Reporting

Except for the material weakness discussed above, there was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act) identified in connection with the evaluation of our internal control that occurred during the fiscal quarter ended December 31, 2024 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Inherent Limitations of Internal Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal controls will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within the company have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty, and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people, or by management override of the control. The design of any system of controls also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions. Over time, control may become inadequate because of changes in conditions, or the degree of compliance with the policies or procedures may deteriorate. Because of the inherent limitations in a cost-effective control system, misstatements due to error or fraud may occur and not be detected.

Item 9B. Other Information

During the quarter ended December 31, 2024, no director or officer (as defined in Rule 16a-1(f) of the Exchange Act) of the Company adopted, modified or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408 of Regulation S-K.

Item 9C. Disclosure Regarding Foreign Jurisdiction That Prevent Inspections

Not Applicable

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this item is incorporated by reference to our Proxy Statement relating to our 2025 Annual Meeting of Shareholders. The Proxy Statement will be filed with the Securities and Exchange Commission within 120 days after our fiscal year ended December 31, 2024.

Our Board of Directors has adopted a Code of Business Conduct and Ethics, that applies to all directors, officers, and employees, which is available on our website at *www.myomo.com* . We intend to satisfy the disclosure requirements of Item 5.05 of Form 8-K by disclosing substantive amendments to or waivers (including implicit waivers) of any provision of the Code of Business Conduct and Ethics that apply to our principal executive officer, principal financial officer, principal accounting officer, or controller, or persons performing similar functions, by posting such information on our website available at *www.myomo.com.*

Item 11. Executive Compensation

The information required by this item is incorporated herein by reference to our Proxy Statement relating to our 2025 Annual Meeting of Shareholders. The Proxy Statement will be filed with the Securities and Exchange Commission within 120 days after our fiscal year ended December 31, 2024.

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

The information required by this item is incorporated herein by reference to our Proxy Statement relating to our 2025 Annual Meeting of Shareholders. The Proxy Statement will be filed with the Securities and Exchange Commission within 120 days after our fiscal year ended December 31, 2024.

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

The information required by this item is incorporated herein by reference to our Proxy Statement relating to our 2025 Annual Meeting of Shareholders. The Proxy Statement will be filed with the Securities and Exchange Commission within 120 days after our fiscal year ended December 31, 2024.

Item 14. Principal Accounting Fees and Services

The information required by this item is incorporated herein by reference to our Proxy Statement relating to our 2025 Annual Meeting of Shareholders. The Proxy Statement will be filed with the Securities and Exchange Commission within 120 days after our fiscal year ended December 31, 2024.

PART IV

Item 15. Exhibits and Financial Statement Schedules

a) The following documents are filed as part of this Annual Report on Form 10-K

(1) Financial Statements

See Index to Financial Statements on page F-1 of this Annual Report on Form 10-K

(2) Financial Statement Schedules

Schedules not listed above have been omitted because they are not required, not applicable, or the required information is otherwise included elsewhere in Annual Report on Form 10-K.

(3) Exhibits

Exhibit No.	Exhibit Description
3.1	Eighth Amended and Restated Certificate of Incorporation (Incorporated by reference to Exhibit 2.3 contained in the Registrant's Form 1-A filed on January 6, 2017).
3.2	Amended and Restated Bylaws (Incorporated by reference to Exhibit 2.4 contained in the Registrant's Form 1-A filed on January 6, 2017).
3.3	Certificate of Amendment to the Eighth Amended and Restated Certificate of Incorporation, as amended, of Myomo, Inc., filed with the Secretary of the State of Delaware on January 30, 2020 (Incorporated by reference to Exhibit 3.1 contained in the Registrant's Form 8-K filed on January 30, 2020).
3.4	Second certificate of Amendment to the Eighth Amended and Restated Certificate of Incorporation, as amended, of Myomo, Inc., filed with the Secretary of the State of Delaware on June 10, 2021 (Incorporated by reference to Exhibit 3.1 contained in the Registrant's Form 8-K filed on June 15, 2021).
4.1	Form of Investor Warrant in connection with the Company's February 2020 public offering (Incorporated by reference to Exhibit 4.1 contained in the Registrant's Form 8-K filed on February 12, 2020).
4.2	Form of Underwriter's Warrant (Incorporated by reference to Exhibit 4.1 in the Registrant's Form 8-K filed on February 8, 2019).
4.3	Form of pre-funded warrant. (Incorporated by reference to Exhibit 4.1 in the Registrant's Form 8-K filed on January 13, 2022).
4.4	Form of pre-funded warrant. (Incorporated by reference to Exhibit 4.1 in the Registrant's Form 8-K filed on August 28, 2023).
4.5	Form of pre-funded warrant. (Incorporated by reference to Exhibit 4.1 in the Registrant's Form 8-K filed on January 17, 2024).
4.6	Description of Registrant's Securities Registered Pursuant to Section 12 of the Securities Exchange Act of 1934 (Incorporated by reference to Exhibit 4.7 in the Registrant's Form 10-K filed on March 13, 2020).
10.1+	2004 Stock Option and Incentive Plan and form of award agreements (Incorporated by reference to Exhibit 6.1 contained in the Registrant's Form 1-A filed on January 6, 2017).
10.2+	2014 Stock Option and Grant Plan and form of award agreements (Incorporated by reference to Exhibit 6.2 contained in the Registrant's Form 1-A filed on January 6, 2017).
10.3+	2016 Equity Incentive Plan and form of award agreements (Incorporated by reference to Exhibit 6.3 contained in the Registrant's Form 10-K filed on March 12, 2018).
10.4+	Amendment No. 2 to the Myomo, Inc. 2018 Stock Option and Incentive Plan (incorporated by reference to Exhibit 99.3 contained in the Registrant's Form S-8 filed on June 28, 2023).

10.5+	Form of Indemnification Agreement (Incorporated by reference to Exhibit 6.21 contained in the Registrant's Form 1-A filed on January 6, 2017).
10.6+	Executive Employment Agreement, dated April 22, 2021, by and between the Company and David Henry (Incorporated by reference to Exhibit 10.2 contained in the Registrant's Form 8-K filed on April 28, 2021).
10.7+	Executive Employment Agreement, dated April 22, 2021, by and between the Company and Micah Mitchell (Incorporated by reference to Exhibit 10.3 contained in the Registrant's Form 8-K filed on April 28, 2021).
10.8+*	Employment Agreement dated December 13, 2023 by and between the Company and Paul R Gudonis.
10.9+	Amendment to Employment Agreement dated February 21, 2024 by and between Myomo, Inc. and David Henry (Incorporated by reference to Exhibit 10.1 contained in the Registrant's Form 8-K filed on February 22, 2024).
10.10+*	Amendment to Employment Agreement dated February 21, 2024 by and between Myomo, Inc. and Micah Mitchell.
10.11+	Amended and Restated Change of Control and Severance Agreement dated February 21, 2024 by and between Myomo, Inc. and Harry Kovelman (Incorporated by reference to Exhibit 10.2 contained in the Registrant's Form 8-K filed on February 22, 2024).
10.12**	Equity Joint Venture Contract, by and between Myomo, Inc. and Beijing Ryzur Medical Investment Co., Ltd., dated as of January 21, 2021 (Incorporated by reference to Exhibit 10.1 contained in the Registrant's Form 8-K filed on January 26, 2021).
10.13**	Amended and Restated Equity Joint Venture Contract by and between Myomo, Inc., Anhui Ryzur Medical Equipment Manufacturing Co. Ltd., Wuxi Chinaleaf Rehabilitation Industry Equity Investment Fund (Limited Partnership) and Beijing Ryzur Medical Investment Company Ltd., dated December 29, 2021. (Incorporated by reference to Exhibit 10.27 contained in the Registrant's Annual Report on Form 10-K dated March 11, 2022).
10.14**	Technology License Agreement by and between Myomo, Inc, and Jiangxi Myomo Medical Assistive Appliance Co., Ltd., dated December 29, 2021. (Incorporated by reference to Exhibit 10.28 contained in the Registrant's Annual Report on Form 10-K dated March 11, 2022).
10.15	Trademark License Agreement by and between Myomo, Inc. and Jiangxi Myomo Medical Assistive Appliance Co., Ltd., dated December 29, 2021. (Incorporated by reference to Exhibit 10.29 contained in the Registrant's Annual Report on Form 10-K dated March 11, 2022).
10.16	Form of Securities Purchase Agreement between Myomo, Inc. and investors identified on the signatures thereto dated January 13, 2023. (Incorporated by reference to Exhibit 10.1 in the Registrant's From 8-K filed on January 13, 2023).
10.17	Form of Securities Purchase Agreement between Myomo, Inc, and investors identified on the signatures thereto dated January 16, 2024. (Incorporated by reference to Exhibit 10.1 in the Registrant's Form 8-K filed on January 17, 2024).
10.18	Placement Agency Agreement by and between Myomo, Inc. and AGP Alliance Global Partners dated January 11, 2023. (Incorporated by reference to Exhibit 10.2 contained in the Registrant's Form 8-K filed on January 13, 2023).
10.19	Placement Agency Agreement by and between Myomo, Inc. and AGP Alliance Global Partners dated August 24, 2023. (Incorporated by reference to Exhibit 10.1 contained in the Registrant's Form 8-K filed on August 28, 2023).
10.20	Placement Agency Agreement by and between Myomo, Inc. and AGP Alliance Global Partners dated January 16, 2024. (Incorporated by reference to Exhibit 10.2 contained in the Registrant's Form 8-K filed on January 17, 2024).

10.21	Loan and Security Agreement, dated July 11, 2024, between the Registrant and Silicon Valley Bank, a division of First-Citizens Bank & Trust Company (Incorporated by reference to Exhibit 10.1 contained in the Registrant's Form 8-K filed on July 15, 2024)
10.22	Lease Agreement, dated August 9, 2024, by and between the Registrant and NDB Property Owner 1. L.P. (Incorporated by reference to Exhibit 10.1 contained in the Registrant's Form 8-K filed on August 13, 2024)
10.23	First Amendment to Loan and Security Agreement, dated February 18, 2025, between the Registrant and Silicon Valley Bank, a division of First-Citizens Bank & Trust Company (Incorporated by reference to Exhibit 10.1 contained in the Registrant's Form 8-K filed on February 20, 2025).
19.1*	Insider Trading Policy
21.1*	List of Subsidiaries
23.1*	Consent of Marcum LLP
31.1*	Certification of Chief Principal Officer, pursuant to Rule 13a-14(a) or 15(d)-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2*	Certification of Chief Principal Officer, pursuant to Rule 13a-14(a) or 15(d)-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1*	Certification of Chief Principal Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2*	Certification of Chief Principal Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97.1+*	Compensation Recovery Policy (Incorporated by reference to Exhibit 97.1 contained in the Registrant's Form 10-K filed on March 8, 2024).
101*	The following financial information from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2024 formatted in Inline eXtensible Business Reporting Language (XBRL): (i) Balance Sheets, (ii) Statements of Operations, (iii) Statements of Changes in Stockholders' Equity, (iv) Statements of Cash Flows and (v) Notes to Financial Statements.
104*	The cover page from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2024, formatted in Inline XBRL

+ Management contract or compensatory arrangement.
* Filed herewith
** Portions of this exhibit filed herewith containing confidential information have been omitted pursuant to a confidential treatment order granted by the SEC pursuant to Rule 406 under the Securities Act. Confidential information has been omitted from the exhibit in places marked "[*]" and has been filed separately with the SEC.

Item 16. Form 10-K Summary

Not applicable.

SIGNATURES

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

Myomo, Inc.,

By: /s/ Paul R. Gudonis

Date: March 10, 2025

Paul R. Gudonis
Chairman, Chief Executive Officer and President
(Principal Executive Officer)

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

Signature	Title	Date
/s/ Paul R. Gudonis **Paul R. Gudonis**	Chief Executive Officer and Chairman of the Board (*Principal Executive Officer)*	March 10, 2025
/s/ David A. Henry **David A. Henry**	Chief Financial Officer (*Principal Financial and Accounting Officer)*	March 10, 2025
/s/ Amy Knapp **Amy Knapp**	Director	March 10, 2025
/s/ Thomas A. Crowley, Jr. **Thomas A. Crowley, Jr.**	Director	March 10, 2025
/s/ Thomas F. Kirk **Thomas F. Kirk**	Director	March 10, 2025
/s/ Milton M. Morris **Milton M. Morris**	Director	March 10, 2025
/s/ Heather Getz **Heather Getz**	Director	March 10, 2025
/s/ Yitzchak Jacobovitz **Yitzchak Jacobovitz**	Director	March 10, 2025

INDEX TO FINANCIAL STATEMENTS

Myomo, Inc.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Stockholders and Board of Directors of
Myomo, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Myomo, Inc. and subsidiaries (the "Company") as of December 31, 2024 and 2023, the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity and cash flows for each of the two years in the period ended December 31, 2024, and 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, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

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

Our audits included performing procedures to assess the risks of material misstatement of the 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.

Critical Audit Matters

Critical audit matters are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. We determined that there are no critical audit matters.

/s/ Marcum LLP

Marcum LLP

We have served as the Company's auditor since 2016.

New York, NY
March 10, 2025

MYOMO, INC.
CONSOLIDATED BALANCE SHEETS

December 31,	2024	2023
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 24,372,373	$ 6,871,306
Short-term investments	492,990	1,994,662
Accounts receivable, net	3,825,291	2,382,658
Inventories, net	3,165,965	1,803,507
Prepaid expenses and other current assets	933,377	598,850
Total Current Assets	32,789,996	13,650,983
Restricted Cash	375,000	—
Equipment, net	1,330,008	175,794
Operating lease assets with right-of-use, net	7,584,663	663,554
Other Assets	164,412	91,237
Total Assets	$ 42,244,079	$ 14,581,568
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	9,021,817	4,885,944
Current operating lease liability	748,021	486,143
Income taxes payable	318,885	96,461
Deferred revenue	83,115	8,510
Total Current Liabilities	10,171,838	5,477,058
Non-current operating lease liability, net of current portion	7,358,184	115,160
Total Liabilities	17,530,022	5,592,218
Commitments and Contingencies - Note 10	—	—
Stockholders' Equity:		
Preferred stock, $0.0001 par value; 10,000,000 shares authorized; no shares issued or outstanding	—	—
Common stock par value $0.0001 per share 65,000,000 shares authorized; 34,378,297 and 27,135,061 shares issued as of December 31, 2024 and 2023, respectively, and 34,378,270 and 27,135,034 shares outstanding as of December 31, 2024 and 2023, respectively.	3,439	2,715
Additional paid-in capital	127,846,026	105,840,239
Accumulated other comprehensive (loss) income	(14,406)	83,669
Accumulated deficit	(103,114,538)	(96,930,809)
Treasury stock, at cost; 27 shares of common stock	(6,464)	(6,464)
Total Stockholders' Equity	24,714,057	8,989,350
Total Liabilities and Stockholders' Equity	$ 42,244,079	$ 14,581,568

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

MYOMO, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

For the years ended December 31,	2024	2023
Revenue		
Product Revenue	$ 32,551,199	$ 17,476,238
License Revenue	-	1,764,920
	32,551,199	19,241,158
Cost of revenue	9,365,856	6,058,775
Gross profit	23,185,343	13,182,383
Operating expenses:		
Research and development	4,772,013	2,636,487
Selling, clinical, and marketing	12,236,910	9,042,698
General and administrative	12,383,118	9,734,747
	29,392,041	21,413,932
Loss from operations	(6,206,698)	(8,231,549)
Other expense (income)		
Interest income, net	(388,586)	(410,274)
Other expense, net	—	785
Loss on equity investment	—	169,503
	(388,586)	(239,986)
Loss before income taxes	(5,818,112)	(7,991,563)
Income tax expense	365,617	156,002
Net loss	$ (6,183,729)	$ (8,147,565)
Weighted average number of common shares outstanding:		
Basic and diluted	37,758,837	29,499,341
Net loss per share available to common stockholders:		
Basic and diluted	$ (0.16)	$ (0.28)

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

MYOMO, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

For the years ended December 31,	2024	2023
Net loss	$ (6,183,729)	$ (8,147,565)
Other comprehensive (loss) income, net of tax:		
Foreign currency translation (loss) gain	(97,910)	41,199
Unrealized loss on short-term investments	(165)	(757)
Total other comprehensive (loss) income	(98,075)	40,442
Comprehensive loss	$ (6,281,804)	$ (8,107,123)

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

MYOMO, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
For the years ended December 31, 2024 and 2023

	Common stock		Additional paid-in	Comprehensive	Accumulated	Treasury stock		Total Stockholders'
	Shares	Amount	capital	(loss) income	deficit	Shares	Amount	Equity
Balance, January 1, 2022	7,750,635	775	95,105,071	43,227	(88,783,244)	27	(6,464)	6,359,365
Common stock issued in public offerings (net of offering costs $996,269)	18,582,408	1,858	6,529,824	—	—	—	—	6,531,682
Proceeds from sale of 8,750,926 pre-funded warrants (net of offering costs $273,236)			3,097,940	—	—	—	—	3,097,940
Common stock issued upon vesting of restricted stock units, net of 16,744 shares withheld for taxes	322,611	34	(8,150)	—	—	—	—	(8,116)
Exercise of prefunded warrants	479,407	48	(48)	—	—	—	—	—
Stock-based compensation	—	—	1,115,602	—	—	—	—	1,115,602
Unrealized gain on foreign currency	—	—	—	41,199	—	—	—	41,199
Unrealized loss on short-term investments	—	—	—	(757)	—	—	—	(757)
Net Loss	—	—	—	—	(8,147,565)	—	—	(8,147,565)
Balance, December 31, 2023	27,135,061	2,715	105,840,239	83,669	(96,930,809)	27	(6,464)	8,989,350
Common stock issued in registered direct equity offering January 2024 and public offering December 2024 (net of offering costs of $2,027,237)	4,804,218	480	20,368,311	—	—	—	—	20,368,791
Issuance of pre-funded warrants in registered direct equity offering January 2024 (net of offering costs of $90,814)			763,138	—	—	—	—	763,138
Common stock issued upon vesting of restricted stock units	1,004,288	100	(100)	—	—	—	—	—
Exercise of prefunded warrants	1,434,730	143	-	—	—	—	—	143
Stock-based compensation	—	—	874,438	—	—	—	—	874,438
Unrealized loss on foreign currency	—	—	—	(97,910)	—	—	—	(97,910)
Unrealized loss on short-term investments	—	—	—	(165)	—	—	—	(165)
Net Loss	—	—	—	—	(6,183,729)	—	—	(6,183,729)
Balance, December 31, 2024	34,378,297	$ 3,439	$ 127,846,026	$ (14,406)	$ (103,114,538)	27	$ (6,464)	$ 24,714,057

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

MYOMO, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

For the years ended December 31,	2024	2023
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (6,183,729)	$ (8,147,565)
Adjustments to reconcile net loss to net cash used in operations:		
Depreciation	205,910	164,306
Stock-based compensation	874,438	1,115,602
Accretion of discount on short-term investments	(118,598)	(110,788)
Credit losses	43,657	28,401
Loss on equity investment	—	169,503
Amortization of deferred debt origination cost	41,552	—
Amortization of right-of-use assets	571,061	353,375
Other non-cash changes	16,020	(38,809)
Changes in operating assets and liabilities:		
Accounts receivable	(1,559,604)	(495,599)
Inventories	(1,395,042)	(384,781)
Prepaid expenses and other current assets	(887,525)	(115,523)
Other assets	84,773	19,797
Accounts payable and accrued expenses	4,693,127	1,790,133
Operating lease liabilities	(503,543)	(460,790)
Deferred revenue	74,604	(12,642)
Income tax payable	236,721	(47,384)
Tenant improvement allowance	516,274	—
Net cash used in operating activities	(3,289,904)	(6,172,764)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of equipment	(1,360,125)	(145,816)
Maturities of short-term investments	7,595,673	4,000,000
Purchases of short-term investments	(5,975,567)	(5,883,749)
Net cash provided by (used in) investing activities	259,981	(2,029,565)
CASH FLOWS FROM FINANCING ACTIVITIES		
Deferred debt origination costs	(199,500)	—
Net settlement of vested restricted stock units to fund related employee statutory tax withholding	—	(8,116)
Proceeds from sale of pre-funded warrants, net of offering costs	763,138	—
Proceeds from sale of common stock and pre-funded warrants, net of offering costs	20,368,791	9,721,573
Net cash provided by financing activities	20,932,429	9,713,457
Effect of foreign exchange rate changes on cash	(26,439)	14,211
Net increase in cash and cash equivalents	17,876,067	1,525,339
Cash and cash equivalents beginning of year	6,871,306	5,345,967
Cash, cash equivalents and restricted cash end of year	$ 24,747,373	$ 6,871,306
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Cash paid during the period for income taxes	$ —	$ —
Non-cash financing and investing activities		
Right of use assets obtained in exchange for lease obligations	$ 7,492,170	$ 508,186
Deferred offering costs incurred in a prior period to additional paid in capital	$ —	$ (91,952)

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

Note 1 — Description of Business

Myomo Inc. ("Myomo" or the Company") is a wearable medical robotics company that develops, designs, and produces myoelectric orthotics for people with neuromuscular disorders. The MyoPro ® myoelectric upper limb orthosis product is registered with the Food and Drug Administration as a Class II medical device. The Company provides the device to patients and bills their insurance companies directly, sometimes utilizing the clinical services of orthotics and prosthetics ("O&P") providers for which they are paid a fee. The Company sells the product to O&P providers around the world and the Veterans Health Administration ("VA"). The Company was incorporated in the State of Delaware on September 1, 2004 and is headquartered in Burlington, Massachusetts.

Pursuant to an amended and restated certificate of incorporation, the Company is authorized to issue up to 75,000,000 shares of stock, consisting of 65,000,000 shares of common stock, par value $0.0001, and 10,000,000 shares of undesignated Preferred Stock, par value of $0.0001.

Liquidity

The Company incurred net losses of approximately $6.2 million and $8.1 million during the years ended December 31, 2024 and 2023, respectively, and has an accumulated deficit of approximately $103.1 million and $96.9 million at December 31, 2024 and 2023, respectively. Cash used in operating activities was approximately $3.3 million and $6.2 million for the years ended December 31, 2024 and 2023, respectively.

The Company has historically funded its operations through financing activities, including raising equity and debt capital. On January 19, 2024, the Company completed a registered direct equity offering, pursuant to which it sold 1,354,218 shares of common stock and 224,730 pre-funded warrants at $3.80 per share, or $3.7999 per pre-funded warrant, generating net proceeds after fees and expenses of approximately $5.4 million. On August 29, 2023, The Company completed a public equity offering, selling 5,413,334 shares of common stock and 1,920,000 pre-funded warrants at $0.60 per share, or at $0.5999 per pre-funded warrant, generating proceeds after fees and expenses of approximately $3.9 million. In January 2023, the Company completed a public equity offering pursuant to which it sold 13,169,074 shares of common stock and 6,830,926 pre-funded warrants at $0.325 per share, or $0.3249 per pre-funded warrant, generating proceeds after fees and expenses of approximately $5.7 million. (See Note 8 - Common Stock for further discussion regarding the equity offerings.) These financing activities have enabled the Company to sustain its operations.

The Company's balance of cash, cash equivalents and short-term investments was $24.9 million as of December 31, 2024. On December 6, 2024, we completed a public equity offering, selling 3,450,000 shares at $5.00 per share, generating net proceeds after fees and expenses of approximately $15.8 million. On July 11, 2024, we entered into a Loan and Security Agreement with Silicon Valley Bank, a division of First-Citizens Bank & Trust Company, which provides us the ability to borrow up to $4.0 million against eligible accounts receivable. The line of credit remains undrawn as of the issuance date of these financial statements. Availability under the line of credit is approximately $1.0 million based on eligible accounts receivable as of December 31, 2024. In February 2025, the Company entered into an amendment to the Loan and Security Agreement, which among other changes, provides for a $3 million term loan facility which is available to be drawn at any time before February 28, 2026. See Note 14- *Subsequent Events* for further discussion.

Management's operating plans are primarily focused on growing revenues in its direct billing channel, while working to grow revenues in its O&P channel. These plans include increasing advertising spending and adding headcount to support growth in its clinical, reimbursement and manufacturing capacity in order to serve a higher volume of patients in 2025. These investments are expected to result in negative cash flows for at least the first three quarters of 2025. In addition, the Company believes that it has access to capital resources through possible public or private equity offerings, debt financings, or other means. Debt financing may contain other terms that are not favorable to the Company or its stockholders.

Note 2 — Summary of Significant Accounting Policies

Basis of Consolidation

The consolidated financial statements include the accounts of the Company and its wholly-owned subsidiary Myomo Europe GmbH. All significant intercompany balances and transactions are eliminated.

Comprehensive Loss

Comprehensive loss includes all changes in equity during a period, except those resulting from investments by stockholders and distributions to stockholders, if any. The Company's comprehensive loss includes changes in foreign currency translation adjustments and unrealized gains and losses on short term investments. There was a reclassification which management does not consider to be material out of accumulated other comprehensive income (loss) to other (income) expense related to realized gains or losses on short-term investments in the year ending December 31, 2024. There were no reclassifications in the year ending December 31, 2023.

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America require management to make estimates and assumptions that affect certain reported amounts and disclosures. These estimates and assumptions are reviewed on an on-going basis and updated as appropriate. Actual results could differ from those estimates. The Company's estimates include assertion of collectability with payers where we have no contracts as it relates to timing of revenue recognition and discount rate of leases.

Cash, Cash Equivalents and Short-Term Investments

The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents. Cash and cash equivalents consist principally of deposit accounts and money market accounts at December 31, 2024 and 2023.

The Company considers all investments with an original maturity of greater than three months to be short-term investments. Short-term investments primarily consists of commercial paper and U.S. Treasury Bills and are carried on the consolidated balance sheets at fair value. Short-term investments as of December 31, 2024 and 2023 consist of U.S. Treasury Bills, which are classified as held-maturity, agency bonds and commercial paper totaling approximately $493,000 and $1,994,700 respectively. The Company determines the appropriate balance sheet classification of its investments at the time of purchases and evaluates the classification at the date of purchase. Unrealized gains and losses on short-term investments are recorded to accumulated other comprehensive (loss) income on the consolidated balance sheets and other gain (loss) on the consolidated statements of comprehensive loss. Once unrealized gains and losses become realized, they are reclassified from other comprehensive gains and losses to cost of goods sold.

Our cash balances as of December 31, 2024 and 2023 consist of the following:

	2024	2023
Cash and cash equivalents	$ 24,372,373	$ 6,871,306
Restricted cash	375,000	—
Total cash, cash equivalents, and restricted cash	$ 24,747,373	$ 6,871,306

Accounts Receivable and Allowance for Credit Losses

The Company reports accounts receivable at invoiced amounts less an allowance for credit losses accounts. The Company evaluates its accounts receivable on a continuous basis, and if necessary, establishes an allowance for credit losses accounts based on a number of factors, including current credit conditions and customer payment history. The Company does not require collateral or accrue interest on accounts receivable and credit terms are generally 30 days. At December 31, 2024 and 2023, the Company recorded an allowance for credit losses of approximately $43,700 and approximately $28,400, respectively.

Inventories

Inventories are recorded at the lower of average cost or net realizable value. Average cost approximates valuation on a first-in, first-out basis. The Company reduces the carrying value of inventory for those items that are potentially excess, obsolete or slow-moving based on changes in customer demand, technology developments or other economic factors. In addition, the carrying value of units used by patients on a trial basis only includes the value of motor units that can be re-used. Orthotic components on trial units are expensed to cost of goods sold once consumed.

Equipment

Equipment is stated at historical cost, net of accumulated depreciation and is depreciated using the straight-line method over the estimated useful lives of the related assets, generally three years. Leasehold improvements are amortized using the straight-line method over the shorter of the lease term or the estimated useful life. Expenditures for maintenance and repairs, which do not extend the economic useful life of the related assets, are charged to operations as incurred, and expenditures, which extend the economic life, are capitalized. When assets are retired, or otherwise disposed of, the costs and related accumulated depreciation or amortization are removed from the accounts and any gain or loss on disposal is recognized.

Demonstration units are provided by the Company to certain O&P providers, certain VA hospitals and to its internal clinical and sales personnel for marketing and patient evaluation purposes. These units are manufactured by the Company and are capitalized as equipment on the Company's consolidated balance sheet.

Prototype and validation units are provided to research and development staff to use in their development process and to end users who are provided units to act as testers so that research and development staff can evaluate and understand their use by patients. A primary objective of these units is to determine when and under what conditions they fail, at which time they are analyzed for cause of failure and then scrapped. These units are expensed in the statements of operations as part of research and development expense. During the year ended December 31, 2023 the Company charged to operations approximately $36,700 for these units.

Impairment of Long-Lived Assets

The Company assesses the recoverability of its long-lived assets, including equipment when there are indications that the assets might be impaired. When evaluating assets for potential impairment, the Company compares the carrying value of the asset to its estimated undiscounted future cash flows. If an asset's carrying value exceeds such estimated undiscounted cash flows, the Company records an impairment charge for the difference. Based on its assessments, the Company did not record any impairment charges for the years ended December 31, 2024 and 2023.

Leases

The Company accounts for leases under Accounting Standards Topic 842 ("ASC 842"). The Company assesses whether a contract is or contains a lease at inception of the contract and leases, recognizes right-of-use assets and corresponding lease liabilities at the lease commencement date, except for short-term leases, which are under one year, and leases of low value. For these leases, the Company recognizes the lease payments as an operating expense on a straight-line basis over the term of the lease.

Joint Venture

On March 28, 2022, the Company invested cash consideration of $199,000 for a 19.9% ownership stake in Jiangxi Myomo Medical Assistive Appliance Co., Ltd. (the "JV Company"), a company headquartered in China that is majority-owned by Beijing Ryzur Medical Investment Co., Ltd. ("Ryzur Medical"). In addition, the Company and the JV Company entered into a ten-year agreement to license the Company's intellectual property, including recently issued patents in China and Hong Kong, and purchase MyoPro Control System units from us. The JV Company will manufacture and sell the Company's current and future products in greater China, including Hong Kong, Macau and Taiwan, and has begun limited operations. The Company accounts for its investment in the JV Company under the

equity method because the Company exerts significant influence over its management. The investment was included in total assets on the consolidated balance sheet. As a result of recording its share of losses in the JV Company, the investment was written off as of December 31, 2023. The Company records its share of the JV Company's earnings in its consolidated statement of operations in other expense (income). The Company will resume recording its share of losses of the JV Company to the extent there are other assets on the consolidated balance sheet from the JV Company. The Company recorded a loss on equity investment of approximately $169,500 for the year ended December 31, 2023.

Revenue Recognition

The Company accounts for revenue under ASC 606, "Revenue from Contracts with Customers" and all the related amendments (Topic 606). Revenues under Topic 606 are required to be recognized either at a "point in time" or "over time," depending on the facts and circumstances of the arrangement and are evaluated using a five-step model. Generally, the Company recognizes revenue at a point in time.

The Company recognizes revenue after applying the following five steps:

1) Identification of the contract, or contracts, with a customer,
2) Identification of the performance obligations in the contract, including whether they are distinct within the context of the contract
3) Determination of the transaction price, including the constraint on variable consideration
4) Allocation of the transaction price to the performance obligations in the contract; and
5) Recognition of revenue when, or as, performance obligations are satisfied.

Revenue is recognized when control of these services is transferred to its customers, in an amount that reflects the consideration the Company expects to be entitled to in exchange for those services.

Product Revenue

The Company derives the majority of its revenue from direct billing. The Company also derives revenue from the sale of its products to clinical consulting services of orthotics and prosthetics or "O&P" providers in the United States and internationally and the VA. Under direct billing, the Company recognizes revenue when all of the following criteria are met:

(i) The product has been delivered to the patient, including completion of initial instruction on its use.

(ii) Collection is deemed probable and it has been determined that a significant reversal of the revenue to be recognized is not deemed probable when the uncertainty associated with the variable consideration is resolved; and

(iii) The amount to be collected is estimable using the "expected value" estimation techniques, or the "most likely amount" as defined in ASC 606.

For revenue derived from patients with Medicare Part B, the Company recognizes revenue upon delivery of the device to the patient based on the published fees by the Centers for Medicare & Medicaid Services ("CMS"). With respect to patients with Medicare Advantage or other commercial insurance, for payers where the Company either has a contract or in the absence of a contract, has demonstrated sufficient payment history, the Company will recognize revenue when it receives a pre-authorization from the insurance company and control passes to the patient upon delivery of the device in an amount that reflects the consideration the Company expects to receive in exchange for the device. During 2024 and 2023, the Company made such a determination for certain insurers. These insurers represented approximately 25% and 66% of direct billing channel revenue in 2024 and 2023, respectively. In cases where the Company is the direct provider and it does not have sufficient collection history with the payer, the Company recognizes revenue when payment is received, as then all of the revenue recognition criteria have been met.

Depending on the timing of product deliveries to customers, which is when cost of revenue must be recorded, and when the Company meets the criteria to record revenue, there may be fluctuations in gross margin on an ongoing basis. During the years ended December 31, 2024 and 2023, the Company recognized revenue of approximately $1,140,800 and $1,554,800, respectively, from third-party payers for which costs related to the completion of the Company's performance obligations were recorded in a prior period.

For revenues derived from O&P providers in the U.S. and internationally and the VA, the Company recognizes revenue when control passes to the customer in an amount that reflects the consideration the Company expects to receive in exchange for those services, which may be recognized upon shipment or upon delivery, depending on the terms of the arrangement, provided that persuasive evidence of an arrangement exists, there are no uncertainties regarding customer acceptance and collectability is deemed probable.

The Company has elected to record taxes collected from customers on a net basis and does not include tax amounts in revenue or cost of revenue.

License Revenue

If a license to the Company's intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenue allocated to the license when the license is transferred to the customer, the customer is able to use and benefit from the license, and collectability is deemed probable.

On January 21, 2021, the Company entered into a Technology License Agreement (the "Agreement") with the JV Company. Under the Agreement, the Company is entitled to receive an upfront license fee of $2.7 million, which has been paid in full, with the final payment amount recognized as licensee revenue during the year ended December 31, 2023. In addition, the Company is entitled to receive a guaranteed minimum payment for purchase of MyoPro Control Units for a period of ten years from the effective date of the Agreement. The Company will recognize revenue on these amounts upon invoicing to the JV Company so long as collectability is deemed to be assured.

Contract Balances

The timing of revenue recognition may differ from the timing of payment by customers. The Company records a receivable when revenue is recognized prior to payment and there is an unconditional right to payment. Alternatively, when payment precedes the provision of the related services, the Company records deferred revenue until the performance obligations are satisfied. The Company had approximately $83,100 and $8,500 of deferred revenue as of December 31, 2024 and 2023, respectively.

Disaggregated Revenue from Contracts with Customers

The following table presents revenue by major source:

	2024	2023
Clinical/medical providers	$ 7,224,243	$ 5,128,864
Direct-to-patient	25,326,956	12,347,374
License revenue	-	1,764,920
Total revenue from contracts with customers	$ 32,551,199	$ 19,241,158

Geographic Data

The Company generated 86% of its revenue from the United States, 13% from Germany and 1% from other international locations for the year ended December 31, 2024. The Company generated 73% of its revenue from the United States, 16% from Germany, 10% from China and 1% from other international locations for the year ended December 31, 2023.

Cost of Revenue

In conjunction with the adoption of ASC 606, there are certain cases in which the Company will expense costs when incurred as required by ASC 340-40-25, such as when the Company ships the MyoPro device to O&P providers, or provides the device directly to patients, pending reimbursement from certain third-party payers, which triggers revenue recognition. For the years ended December 31, 2024 and December 31, 2023, the Company recorded cost of goods sold of approximately $216,400 and $65,200, respectively, without corresponding revenue. The cost of clinical services by O&P providers for which they are paid a fee in conjunction with devices being sold directly to patients and billing their insurance companies directly are expensed as incurred as required by ASC 340-40-25, as a cost of obtaining a contract. These costs are recorded as sales and marketing expense, with the remaining costs associated with the patient being expensed to cost of revenue.

Shipping and Handling Costs

Shipping and handling costs paid by customers are netted against the related shipping costs we incur. The net cost is recorded in cost of revenues. Historically, such costs have not been material.

Income Taxes

The Company accounts for income taxes under Accounting Standards Codification ASC 740, "Income Taxes" ("ASC 740"). Under ASC 740, deferred tax assets and liabilities are determined based on the difference between the financial reporting and tax bases of assets and liabilities and net operating loss and credit carryforwards using enacted tax rates in effect for the year in which the differences are expected to impact taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amounts expected to be realized.

ASC 740 requires that the tax effects of changes in tax laws or rates be recognized in the financial statements in the period in which the law is enacted.

ASC 740 also clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements and prescribes a recognition threshold and measurement process for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return.

Tax benefits claimed or expected to be claimed on a tax return are recorded in the Company's financial statements. A tax benefit from an uncertain tax position is only recognized if it is more likely than not that the tax position will be sustained on examination by the taxing authorities, based on the technical merits of the position. The tax benefits recognized in the financial statements from such a position are measured based on the largest benefit that has a greater than fifty percent likelihood of being realized upon ultimate resolution.

The Company files income tax returns in federal, state and foreign jurisdictions and is no longer subject to examinations by tax authorities for years prior to 2021. Currently, there are no income tax audits in process. To the extent the Company has tax attribute carryforwards the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service, or state of foreign tax authorities to the extent utilized in a future period.

Stock-Based Compensation

The Company accounts for stock awards to employees by measuring the cost of services received in exchange for the award of equity instruments based upon the fair value of the award on the date of grant. The fair value of that award is then ratably recognized as expense over the period during which the recipient is required to provide services in exchange for that award.

Foreign Currency Translation

The functional currency of the Company's foreign subsidiary, Myomo Europe GmbH, is the Euro. Foreign exchange translation gains and losses from the Euro to U.S. dollars are included in other comprehensive (loss)/gain. The Company recorded a comprehensive loss of approximately $98,000 and comprehensive income of approximately $41,200 during the years ended December 31, 2024 and 2023, respectively, which are included in accumulated other comprehensive (loss) income in the consolidated balance sheets. Transactional foreign exchange

gains and losses from a foreign currency to the functional currency are included in cost of sales, in the consolidated statement of operations. Such amounts were immaterial for the years ended December 31, 2024 and 2023. The balance sheet is translated using the spot date on the day of reporting and the income statement is translated monthly using the average rate for the month.

Net Loss per Share

Basic loss per common share is computed by dividing net loss attributable to common stockholders by the weighted average number of common shares outstanding during the period. Diluted net loss per common share is computed by dividing net loss attributable to common stockholders by the weighted average number of common shares outstanding, plus potentially dilutive common shares. Restricted stock units, stock options and warrants are excluded from the diluted net loss per share calculation when their impact is antidilutive. The Company reported a net loss for the years ended December 31, 2024 and 2023, respectively, and as a result, all potentially dilutive common shares are considered antidilutive for these periods.

Potentially common shares issuable at December 31, 2024 and 2023 consist of:

	2024	2023
Options	23,194	24,529
Warrants	668,250	668,250
Restricted stock units	1,218,792	1,501,659
Total	1,910,236	2,194,438

Due to their nominal exercise price of $0.0001 per share, a total of 7,061,519 and 8,271,519 outstanding pre-funded warrants as of December 31, 2024 and 2023, respectively are considered common stock equivalents and are included in weighted average shares outstanding in the accompanying consolidated statements of operations as of the closing dates of the Company's public equity offerings in January 2023 and August 2023, respectively.

Advertising

The Company charges the costs of advertising to operating expenses as incurred. Advertising expense amounted to approximately $3,484,800 and $3,216,100 in 2024 and 2023, respectively.

Research and Development Costs

The Company expenses research and development costs as incurred. Research and development costs primarily consist of salaries and benefits, prototyping materials, facility and overhead costs, and outsourced research activities.

Recent Accounting Standards

In October 2023, the FASB issued ASU 2023-06, , "Disclosure Improvements, Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative", that adds 14 of the 27 identified disclosure or presentation requirements to the Codification, each amendment in the ASU will only become effective if the SEC removes the related disclosure or presentation from its existing regulations by June 30, 2027. The Company currently complies with these disclosure requirements as applicable under Regulation S-X or Regulation S-K and will adopt these new standards depending on timing of when they become effective, which is not expected to have a material impact on its financial position and results of operations.

In November 2023, the FASB issued ASU 2023-07 "Segmented Reporting - Improvements to Reportable Segment Disclosures". ASU 2023-07 focuses on the requirements to disclose its significant segment expense categories and amounts for each reportable segment. ASU 2023-07 and became effective for the calendar year 2024 year-end financial statements. The Company has adopted these new standards, which did not have a material impact on its financial position and results of operations.

In December 2023, the FASB issued ASU 2023-09, "Accounting standards update, Income Taxes (Topic 740: Improvements to Income Tax Disclosures". ASU 2023-09 focuses on income tax disclosures around effective tax rates and cash income taxes paid. This amendment in the ASU became effective for public companies as of

December, 15 2024 and will be effective for all other companies one year later. The Company will adopt these new standards when they become effective, which we do not believe will have a material impact on its financial position and results of operations.

Subsequent Events

The Company evaluates whether there have been subsequent events through the date the financial statements were issued and determines whether subsequent events exist that would require recognition in the financial statements or disclosure in the notes of the financial statements.

Note 3 — Inventories

Inventories consist of the following at December 31:

	2024	2023
Finished goods	$1,289,368	$ 321,484
Work in Process	60,731	6,589
Parts and subassemblies	1,815,866	1,475,434
Inventories, net	$3,165,965	$1,803,507

Note 4 — Equipment, net

Equipment consists of the following at December 31:

	2024	2023
Computer equipment	$ 541,047	$ 318,559
Sales demonstration units	708,351	278,710
R&D tools and molds	141,484	52,644
Leasehold improvements	362,687	254,043
Furniture and fixtures	571,348	60,837
	2,324,917	964,793
Less: accumulated depreciation	(994,909)	(788,999)
Equipment, net	$ 1,330,008	$ 175,794

Depreciation expense was approximately $205,900 and $164,300 for the years ended December 31, 2024 and 2023, respectively.

Note 5 — Fair Value of Financial Instruments

The Company measures the fair value of financial assets and liabilities based on the guidance of ASC 820 "Fair Value Measurements" ("ASC 820"), which defines fair value, establishes a framework for measuring fair value, and establishes disclosures about fair value measurements.

ASC 820 defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. ASC 820 also establishes a fair value hierarchy, which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. ASC 820 describes three levels of inputs that may be used to measure fair value:

- Level 1 — Quoted prices available in active markets for identical assets or liabilities.
- Level 2 — Observable inputs other than quoted prices included in Level 1, such as quotable prices for similar assets and liabilities in active markets; quoted prices for identical or similar assets and liabilities in markets that are not active; or other inputs that are observable or can be corroborated by observable market data.

- Level 3 — Unobservable inputs that are supported by little or no market activity and that are significant to the fair value of the assets or liabilities. This includes certain pricing models, discounted cash flow methodologies and similar valuation techniques that use significant unobservable inputs.

The carrying amounts of the Company's financial instruments such as cash and cash equivalents, accounts receivable and accounts payable, approximate fair value due to the short-term nature of these instruments. Cash equivalents consists of a money market fund that limits its investments to only short-term U.S. Treasury securities and repurchase agreements related to these securities.

The Company considers all investments with an original maturity of greater than three months to be short-term investments. Short-term investments primarily consists of commercial paper and U.S. Treasury Bills and are carried on the consolidated balance sheets at fair value. Short-term investments as of December 31, 2024 and 2023 consisted of U.S. Treasury Bills, which are classified as held-maturity, agency bonds and commercial paper totaling approximately $493,000 and $1,994,700, respectively. The Company determines the appropriate balance sheet classification of its investments at the time of purchase and evaluates the classification at the date of purchase. Unrealized gains and losses on short-term investments are recorded to accumulated other comprehensive income on the consolidated balance sheets and other gain (loss) on the consolidated statements of comprehensive loss. Once unrealized gains and losses become realized, they are reclassified from other comprehensive gains and losses to cost of goods sold.

Cash equivalents, which are measured at fair value, were as follows At December 31, 2024:

	In Active Markets for Identical Assets or Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	December 31, 2024 Total
Money market funds	$23,334,374	—	—	$23,334,374
Commercial paper	—	—	—	—
Short-term investments	—	$ 492,990	—	$ 492,990

Cash equivalents and short-term investments, which are measured at fair value, were as follows at December 31, 2023:

	In Active Markets for Identical Assets or Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	December 31, 2023 Total
Money market funds	$ 4,893,387	—	—	$ 4,893,387
Commercial paper	—	$ 746,762	—	$ 746,762
Short-term investments	—	$ 1,994,662	—	$ 1,994,662

Note 6 – Accounts Payable and Other Accrued Expenses

Accounts Payable and Other Accrued Expenses consists of the following at December 31:

	2024	2023
Trade payables	$1,169,901	$1,073,405
Accrued compensation and benefits	5,009,385	1,964,487
Accrued professional services	54,257	52,202
Warranty reserve	129,615	231,108
Customer deposits	2,194,804	1,114,979
Accrued insurance	128,556	—
Other	335,299	449,763
	$9,021,817	$4,885,944

Note 7 — Line of Credit

On July 11, 2024 (the "Effective Date"), the Company, entered into a Loan and Security Agreement (the "Loan Agreement") with Silicon Valley Bank.

The Loan Agreement provides for a revolving line of credit whereby the Company may borrow up to $4,000,000 (the "Revolving Line"), which Revolving Line may be increased to $5,500,000 at Silicon Valley Bank's sole discretion upon the occurrence of certain events. Amounts advanced by Silicon Valley Bank are based on 80% of "eligible accounts", which includes all receivables in the United States, reduced by aged amounts and customers and insurance payers with concentrations in excess of defined limits, among other deductions. The outstanding principal amount of any advance shall accrue interest at a floating rate per annum equal to the greater of (i) 8.50% and (ii) the "prime rate" as published in The Wall Street Journal for the relevant period plus one-half percent (0.50%). The Revolving Line is secured on a first priority basis by all of Company's assets other than intellectual property and certain customary exceptions. Any newly formed or acquired subsidiary of the Company or any guarantor under the Loan Agreement, will either join the Loan Agreement as a co-borrower or become a guarantor under the Loan Agreement, as determined by Silicon Valley Bank in its sole discretion. The Company intends to use the Revolving Line for working capital and general business purposes.

The Revolving Line terminates, and any outstanding principal amount of all advances made thereunder, and any accrued and unpaid interest thereon, become immediately due and payable on the two year anniversary of the Effective Date. The Company must also pay Bank (i) a commitment fee of $20,000, (ii) an "Anniversary Fee" of 0.50% of the Revolving Line and (iii) an "Unused Revolving Line Facility Fee" of 0.50% per annum of the average unused portion of the Revolving Line. In addition, upon termination of the Loan Agreement or the Revolving Line prior to the two year anniversary of the Effective Date, the Company must pay a termination fee of 1.00% of the Revolving Line, subject to certain exceptions.

The Company recorded approximately $199,500 in debt origination costs during the year ended December 31, 2024 in conjunction with entering into the Loan Agreement, which includes the commitment fee and the Anniversary Fee. The Company capitalized the debt origination costs and is amortizing them into interest expense using the interest rate method, which approximates straight-line amortization over the term of the Loan Agreement. As of December 31, 2024, the balance of debt origination costs was approximately $158,000, which is included in other long-term assets on the consolidated balance sheet. The Company amortized $41,600 of debt origination costs to interest expense during the year ended December 31, 2024.

Approximately $1.0 million was available to be drawn under the Loan Agreement based on eligible accounts receivable as of December 31, 2024. No amounts were drawn under the Loan Agreement as of December 31, 2024.

On February 18, 2025, the Company entered into an amendment to the Loan Agreement. See Note 14 - *Subsequent Events.*

Note 8 — Common Stock

On December 6, 2024, the Company completed a public equity offering, selling 3,450,000 shares at $5.00 per share, generating net proceeds after fees and expenses of approximately $15.8 million.

On January 19, 2024, the Company completed a registered direct equity offering, pursuant to which it sold 1,354,218 shares of common stock and 224,730 pre-funded warrants at $3.80 per share, or $3.7999 per pre-funded warrant, generating net proceeds after fees and expenses of approximately $5.4 million.

On August 29, 2023, the Company completed a public equity offering, selling 5,413,334 shares of common stock and 1,920,000 pre-funded warrants at $0.60 per share, or at $0.5999 per warrant, generating proceeds after fees and expenses of approximately $3.9 million. Each pre-funded warrant is exercisable for one share of the Company's common stock at a nominal exercise price of $0.0001 per share.

On January 17, 2023, the Company completed a public equity offering, selling 13,169,074 shares of common stock and 6,830,926 pre-funded warrants at $0.325 per share or at $0.3249 per warrant, generating proceeds after fees and expenses of approximately $5.7 million. Each pre-funded warrant is exercisable for one share of the Company's common stock at a nominal exercise price of $0.0001 per share.

No shares of common stock were issued through the exercise of stock options during the years ended December 31, 2024 and 2023.

During the years ended December 31, 2024 and 2023, the Company issued 1,004,288 and 339,355 shares of common stock, respectively, upon the vesting of restricted stock units.

Note 9 — Stock Award Plans and Stock-Based Compensation

Equity Incentive Plan

On June 19, 2018, the Company's Shareholders and Board of Directors (the "Board of Directors") approved the Myomo, Inc. 2018 Stock Options and Incentive Plan (the "2018 Plan"). On January 1 of each year, the number of shares of common stock reserved and available for issuance under the 2018 Plan will cumulatively increase by 4% of the number shares of common stock outstanding on the immediately preceding December 31 or such lesser number of shares of common stock determined by management in consultation with members of the Board of Directors, including the compensation committee of the Board of Directors.

On January 1, 2024 and 2023, the number of shares reserved and available for issuance under the 2018 Plan increased by 1,085,401 and 310,024 shares, respectively. At December 31, 2024, there were 484,470 shares available for future grant under the 2018 Plan.

Under the terms of the 2018 Plan, incentive stock options ("ISOs") may be granted to officers and employees and non-qualified stock options and awards may be granted to directors, consultants, officers and employees of the Company. The exercise price of ISOs cannot be less than the fair market value of the Company's Common Stock on the date of grant. The options vest over a period determined by the Board of Directors, ranging from immediate to four years, and expire not more than ten years from the date of grant.

Stock Option Awards

Stock option activity under the Stock Option Plans during the years ended December 31, 2024 and 2023 is as follows:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Life (years)	Intrinsic Value
Balance at January 1, 2023	29,605	$ 40.58	6.52	$ 587
Forfeited or cancelled	(3,139)	$ 17.58		
Exercised	(1,937)	$ 69.61		
Balance at December 31, 2023	24,529	$ 41.79	5.53	$ 7,468
Forfeited or cancelled	(1,283)	$ 11.94		
Expired	(52)	$ (0.05)		
Balance at December 31, 2024	23,194	$ 42.98	4.41	$ 15,660
Options exercisable at December 31, 2023	20,229	$ 54.96	5.67	$ 587
Options exercisable at December 31, 2024	21,758	$ 45.13	4.26	$ 15,660

The Company uses the Black-Scholes option pricing model to estimate the grant date fair value of its stock options. There was no income tax benefit recognized in the financial statements for share-based compensation arrangements for the years ended December 31, 2024 and 2023, respectively. There were no stock options granted during the years ended December 31, 2024 and 2023, respectively.

Restricted Stock Units

Restricted stock unit "RSU" activity for the years ended December 31, 2024 and 2023 is summarized below:

	Number of Shares	Weighted average grant date fair value	Weighted average remaining contractual life (in years)
Outstanding as of January 1, 2023	454,447	$ 5.06	2.27
Awarded	1,450,445	0.57	
Vested	(339,409)	2.37	
Canceled	(63,824)	4.51	
Outstanding as of December 31, 2023	1,501,659	5.06	1.44
Awarded	780,390	3.41	
Vested	(1,004,204)	1.41	
Canceled	(59,053)	12.66	
Outstanding as of December 31, 2024	1,218,792	$ 2.29	2.34

In 2024 and 2023, the Company granted an aggregate of 780,390 and 1,450,445 RSUs to employees, respectively, of which 303,000 and 608,000 RSUs were granted to executive officers, respectively, which vest over a period of three years and two years, respectively. In 2024 and 2023, the Company granted 60,170 and 239,952 RSUs respectively, to independent members of the board of directors, which vest in four equal quarterly installments.

The Company determined the fair value of these grants based on the closing price of the Company's common stock on the respective grant dates. The compensation expense is being amortized over the respective vesting periods.

Awards of RSUs may be net share settled upon vesting to cover the required employee statutory withholding taxes and the remaining amount is converted into shares based upon their share-value on the date the award vests. These payments of employee withholding taxes, if made, are presented in the statements of cash flows as a financing activity.

Share-Based Compensation Expense

The Company recognized stock-based compensation expense related to the issuance of stock option awards to employees and non-employees and time-based and performance-based restricted stock units to employees and directors, and restricted stock units to employees in the consolidated statements of operations as follows:

	2024	2023
Cost of goods sold	$ 60,103	$ 91,604
Research and development	94,088	(4,488)
Selling, clinical, and marketing	149,049	194,540
General and administrative	571,198	833,946
Total	$ 874,438	$ 1,115,602

As of December 31, 2024, there was approximately $5,800 of unrecognized compensation cost related to unvested stock options which is expected to be recognized over a weighted-average period of 0.6 years.

As of December 31, 2024, there was approximately $2,226,000 of unrecognized compensation cost related to unvested restricted stock unit awards which is expected to be recognized over a weighted-average period of 2.3 years.

Note 10 — Warrants

The following table presents the Company's common stock warrant activity for the years ended December 31, 2024 and 2023:

	Warrants		Weighted Average Exercise Price	
	Outstanding	Exercisable	Outstanding	Exercisable
Balance, Jan 1, 2023	680,363	680,363	8.30	8.30
Issued	8,750,926	8,750,926	—	—
Expired	(12,113)	(12,113)	0.53	0.53
Exercised	(479,407)	(479,407)	—	—
Balance, Dec 31, 2023	8,939,769	8,939,769	0.56	0.56
Issued	224,730	224,730	—	—
Expired	—	—	—	—
Exercised	(1,434,730)	(1,434,730)	—	—
Balance, Dec 31, 2024	7,729,769	7,729,769	$ 0.65	$ 0.65

Due to their nominal exercise price of $0.0001 per share, a total of 7,061,519 and 8,271,519 outstanding pre-funded warrants as of December 31, 2024 and 2023, respectively are considered common stock equivalents and are included in weighted average shares outstanding in the accompanying consolidated statements of operations as of the closing dates of the Company's public equity offerings in January 2024, August 2023 and January 2023, respectively. A total of 1,434,730 and 479,407 pre-funded warrants were exercised during the years ended December 31, 2024 and 2023, respectively. The pre-funded warrants have no maturity date. The weighted average remaining contractual life of warrants outstanding and exercisable, excluding pre-funded warrants at December 31, 2024 was 0.1 years.

Note 11 — Commitments and Contingencies

Litigation

The Company may be involved in legal proceedings, claims and assessments arising from the ordinary course of business. Such matters are subject to many uncertainties, and outcomes are not predictable with assurance. During 2022, a former employee that was terminated in 2021 brought an age discrimination claim against the Company. During the fourth quarter of 2023, the Company settled the claim with its former employee. At that time, the Company deemed it probable that its insurance company will pay its share of the claim. As a result of this assumed gain contingency, the Company reduced its accrual to an amount that is not expected to be covered by insurance, and recorded a liability of approximately $55,000 for severance and legal expenses as of December 31, 2023. The Company and its insurer paid their respective amounts due under the settlement during the year ended December 31, 2024. There is no other material litigation against the Company at this time.

Operating Leases

The Company had a lease agreement for its corporate headquarters in Boston, Massachusetts, which expired in January 2025 and has a lease agreement for office space in Fort Worth, TX. which expires in December 2025. In August 2024, the Company entered into a lease agreement for a new corporate headquarters and manufacturing facility in Burlington, Massachusetts. The Company began relocating operations in December 2024 and completed the move in January 2025. The term of the lease is 88 months following the rent commencement date, which will be May 11, 2025. The Company has the option to extend the new lease for an additional five years, subject to certain conditions being satisfied. Under the new lease, the Company provided a security deposit to the landlord in the form of a letter of credit for $375,000. The Company has collateralized the letter of credit with cash in a separate bank account, which is accounted for as long-term restricted cash on the consolidated balance sheet. Termination options are either not included, or have expired, for the Company's other existing operating leases. Certain arrangements have discounted rent periods or escalating rent payment provisions. Leases with an initial term of twelve months or less are not recorded on the consolidated balance sheets. We recognize rent expense on a straight-line basis over the lease term.

As of December 31, 2024, operating lease assets were approximately $7,584,700 and operating lease liabilities were approximately $8,106,200, which includes a liability for a tenant improvement allowance paid to the Company by the landlord for approximately $516,300 as of December 31, 2024, which will be amortized on a straight-line basis and recorded as a reduction to rental expense over the term of the rental payments. The maturity of the Company's operating lease liabilities as of December 31, 2024, were as follows:

	As of December 31, 2024
2025	680,341
2026	1,168,752
2027	1,522,500
2028	1,584,678
Thereafter	6,511,404
Total future minimum lease payments	11,467,675
Less imputed interest	3,361,470
Total operating lease liabilities	$ 8,106,205
Included in the consolidated balance sheet:	
Current operating lease liabilities	$ 748,021
Non-current operating lease liabilities	7,358,184
Total operating lease liabilities	$ 8,106,205

For the twelve months ended December 31, 2024, the total lease cost comprised of the following amounts:

	Years ended December 31,	
	2024	2023
Operating lease expense	639,829	454,040
Short-term lease expense	6,420	3,989
Total lease expense	$ 646,249	$ 458,029

The Company paid cash of approximately $582,700 and $550,600 for its operating leases for the years ended December 31, 2024 and 2023, respectively.

The following summarizes additional information related to operating leases:

	As of December 31	
	2024	2023
Weighted-average remaining lease term	7.8	1.2
Weighted-average discount rate	8.6%	23.3%

If the rate implicit in the lease is not readily determinable, the Company uses its incremental borrowing rate as the discount rate. The Company uses its best judgment when determining the incremental borrowing rate, which is the rate of interest that the Company would have to pay to borrow on a collateralized basis over a similar term to the lease payments in a similar currency.

Licensing Agreement

During 2006, the Company entered into an exclusive licensing agreement (the "MIT License") with Massachusetts Institute of Technology ("MIT") for access to certain patent rights that require the payment of royalties, which vary based on the level of the Company's net sales and whether the customer is located in the United.States, or in an international location. As part of the agreement, the Company was required to pay to MIT a nonrefundable annual license maintenance fee which could have been credited to any royalty amounts due in that same year. The MIT license expired in November 2023. The royalty charge for the year ended December 31, 2023 was approximately $244,900, and is included as a component of cost of revenue in the consolidated statement of operations.

Warranty Liability

The Company accrues an estimate of their exposure to warranty claims based on historical warranty costs incurred and the number units under warranty to estimate future warranty costs to be insured. Most of the Company's current product sales include a three-year warranty. The Company assesses the adequacy of their recorded warranty liability annually and adjusts the amount as necessary.

Changes in warranty liability were as follows:

	2024	2023
Accrued warranty liability, beginning of year	$ 231,108	$ 234,647
Accrual provided for warranties issued during the period	25,244	71,797
Adjustments to prior accruals	—	—
Actual warranty expenditures	(126,737)	(75,337)
Accrued warranty liability, end of year	$ 129,615	$ 231,108

Credit Risk

Financial instruments that potentially expose the Company to a concentration of credit risk consist primarily of cash, cash equivalents, short-term investments and accounts receivable. The Company attempts to maintain its operating cash within federally insured limits. Its cash equivalents, including money market funds, are invested in instruments

that are off the balance sheets of its operating banks. Its short term investments are held in high quality instruments issued by large companies, government agencies and U.S. Treasury Bills. Its cash equivalents and short-term investments, to the extent that there are balances in excess of federally insured limits, are with major financial institutions that management believes are financially sound and have minimum credit risk. The Company has not experienced any losses in such accounts and believes credit risks related to its cash, cash equivalents and short-term investments are limited based upon the creditworthiness of the financial institutions holding these funds.

Supplier Finance Program Obligations

The Company finances its directors and officers insurance policy, which requires the Company to make a down payment, followed by equal payments over a defined term. During the year ended December 31, 2023, the Company completed its payment obligation associated with its 2022-2023 policy and entered into a new policy covering the twelve-month period ending June 2024. Under this financing arrangement, the Company made a down payment of approximately $29,000 during the three months ended June 30, 2023 and made nine equal monthly payments of approximately $27,000, starting in July 2023. During the year ended December 31, 2024, the Company completed its payment obligation associated with its 2023-2024 policy and entered into a new policy covering the twelve-month period ending June 2025. Under this new financing arrangement, the Company made a down payment of approximately $39,000 during the three months ended June 30, 2024, and is making nine equal monthly payments of approximately $39,000, starting in July 2024. Changes in the Company's supplier finance obligations were as follows:

For the Twelve Months Ended December 31,	2024	2023
Balance January 1	$ 142,217	$ 56,603
Increase	417,763	534,325
Expensed	(378,724)	(448,711)
Balance December 31,	$ 181,256	$ 142,217

Note 12 — Income Taxes

Income (loss) before provision for income taxes was as follows:

	2024	2023
United States	$ (6,824,771)	$ (8,716,750)
Foreign	$ 1,006,659	$ 725,187
Loss before income taxes	$ (5,818,112)	$ (7,991,563)

The income tax provision (benefit) for the years ended December 31, 2024 and 2023 consists of the following:

	2024	2023
U.S. federal		
Current	$ —	$ —
Deferred	(1,901,754)	2,762,774
State and local		
Current	—	—
Deferred	(635,744)	3,278,803
Foreign		
Current	365,616	156,002
Deferred	—	—
	(2,171,882)	6,197,579
Change in valuation allowance	2,537,499	(6,041,578)
Income tax provision	$ 365,617	$ 156,002

The reconciliation between the U.S statutory federal income tax rate and the Company's effective rate for the years ended December 31, 2024 and 2023 is as follows:

	2024	2023
U.S. federal statutory rate	21.00%	21.00%
State income taxes, net of federal benefit	5.96%	(38.19)%
State rate change and other	1.89%	(2.16)%
NOLs' to expire unutilized due to 382 limitation	0.00%	(51.74)%
Foreign tax rate differential	(1.57)%	(0.82)%
Other permanent items	10.04%	(5.63)%
Prior year taxes	0.00%	(0.02)%
Change in valuation allowance	(43.61)%	75.60%
Effective rate	(6.28)%	(1.95)%

The significant components of the Company's deferred tax assets are as follows:

	2024	2023
Net operating loss carryover	$ 12,300,344	$ 11,744,294
Tax credits	534,876	130,722
Research and Experimental cost capitalization	1,850,075	1,027,243
Stock-based compensation	793,031	890,334
Other	3,335,205	610,069
Total deferred tax asset	18,813,531	14,402,661
Less: valuation allowance	(16,940,159)	(14,402,661)
Deferred tax asset, net of valuation allowance	$ 1,873,372	$ —
Right of Use Asset	(1,873,372)	$ —
Total deferred tax liablitiies	(1,873,372)	$ —
Net deferred tax asset (liability)	$ —	$ —

As of December 31, 2024 and 2023, the Company had approximately $79,060,000 and $77,360,000 of Federal NOLs and $63,502,000 and $61,239,000 of state NOLs, respectively, available to offset future taxable income. The Federal NOLs incurred prior to 2018 of approximately $6,425,000, if not utilized, begin expiring in the year 2026. The Federal NOLs incurred after 2017 of approximately $52,635,000 have an indefinite carryforward period. The state NOL's if not utilized begin to expire in to expire in 2025 through 2045.

Additionally, the Company has U.S. federal and state research and development tax credits of $662,000 and $263,000, respectively, which will begin to expire in the year 2026 and 2033, respectively.

NOL carryforwards may face limitations caused by changes in ownership under Section 382 of the Internal Revenue Code. During 2023, the Company experienced an ownership change within the meaning of Section 382 of the Internal Revenue Code of 1986. The ownership change has and will continue to subject the Company's pre-ownership change net operating loss carryforwards to an annual limitation, which will significantly restrict its ability to use them to offset taxable income in periods following the ownership change. The annual use limitation equals the aggregate value of the Company's stock at the time of the ownership change multiplied by a specified tax-exempt interest rate. As a result of these ownership changes, the Company is limited to an approximately $64,000 annual limitation on its ability to utilize pre-change NOLs during the carryforward period and has determined that approximately $20,000,000 and $48,000,000 of the Company's pre-change Federal and State NOLs, respectively, will expire unutilized. As of the issuance date of these financials, the Company has not undertaken a study to determine if its equity offerings in August 2023, January 2024 and December 2024 constituted ownership changes under Section 382.

ASC 740 , "Income Taxes" requires that a valuation allowance be established when it is "more likely than not" that all, or a portion of, deferred tax assets will not be realized. A review of all available positive and negative evidence needs to be considered, including the scheduled reversal of deferred tax liabilities, projected future taxable income, and tax planning strategies. After consideration of all the information available, management believes that uncertainty exists with respect to future realization of its deferred tax assets and has, therefore, established a full valuation allowance as of December 31, 2024 and 2023. For the years ended December 31, 2024 and 2023, the change in valuation allowance was a increase of approximately $2,540,000 and a decrease of ($6,042,000), respectively.

The Company recognizes interest and penalties relating to unrecognized tax benefits on the income tax expense line in the statement of operations. There are no tax penalties and interest on the consolidated statement of operations as of December 31, 2024 and 2023, respectively. The Company operates in multiple tax jurisdictions and, in the normal course of business, its tax returns are subject to examination by various taxing authorities. Such examinations may result in future assessments by these taxing authorities. The Company is subject to examination by U.S. tax authorities beginning with the year ended December 31, 2021. To the extent the Company has tax attribute carryforwards the tax years in which the attribute was generated may still be adjusted upon examination by the Internal Revenue Service, or state of foreign tax authorities to the extent utilized in a future period.

There were no accrued interest and penalties at December 31, 2024 and 2023, respectively.

Note 13 — Segment Reporting and Major Customers

Segment Reporting

ACS 280, "Segment Reporting" establishes standards for reporting information about operating segments on a basis consistent with the Company's internal organization structure as well as information about products, business segments, and major customers in financial statements. The Company conducts its business in one operating segment, and sells products in one family, which are versions of the MyoPro. While the Company has several sales channels and operates in different geographies, the Chief Executive Officer, who is the Company's chief operating decision-maker, and is responsible for allocating resources and assessing the performance of the Company, manages the Company's business on a consolidated basis, focusing on revenue, gross margin, certain operating expenses, loss from operations, other expenses (income), Income Tax, and Net loss. The Chief Executive Officer reviews the consolidated balance sheet with relation to consolidated Assets. The Chief Executive Officer does not review any additional or more disaggregated level.

For the years ended December 31,	2024	2023
Revenue		
Product Revenue	$ 32,551,199	$ 17,476,238
License Revenue	—	1,764,920
	32,551,199	19,241,158
Cost of revenue	9,365,856	6,058,775
Gross profit	23,185,343	13,182,383
Gross margin	71.2%	68.5%
Operating expenses:		
Payroll and benefits expense	22,945,239	14,455,812
Advertising	3,484,824	3,216,081
All other segment operating expenses	7,348,273	5,882,623
Payroll and benefits expense in cost of revenue	(4,386,295)	(2,140,584)
	29,392,041	21,413,932
Loss from operations	$ (6,206,698)	$ (8,231,549)
Other expense (income)	(388,586)	(239,986)
Income Tax Expense	365,617	156,002
Net Loss	$ (6,183,729)	$ (8,147,565)

All other segment operating expenses include: Product Development, Software Expense, Travel and Entertainment, Outside Services, Consultants, and Legal Fees.

Major Customers

For the years ended December 31, 2024 and 2023, there were no customers which accounted for more than 10% of revenues. For the year ended December 31, 2024, CMS and a U.S. commercial insurance payer represented 49% and 18%, respectively, of product revenues. For the year ended December 31, 2023, a U.S insurance payer represented 38% of product revenues.

For the year ended December 31, 2024. CMS and a U.S. commercial insurer and its affiliates, accounted for approximately 36% and 19% of accounts receivable, respectively. For the year ended December 31, 2023, a U.S. commercial insurer and its affiliates, accounted for approximately 71% of accounts receivable.

For the year ended December 31, 2024 and 2023, approximately 25% and 57% of the Company's product revenues were derived from patients with Medicare Advantage insurance plans, respectively.

Note 14 — Subsequent Events

On February 18, 2025, the Company entered into a First Amendment (the "Amendment") to the Loan and Security Agreement (the "Loan Agreement"), dated July 11, 2024, by and between the Company and Silicon Valley Bank. The Amendment provides for, among other things, a new term loan facility (the "Term Loan") to the Company of up to $3,000,000, available to the Company until February 28, 2026. Advances under the Term Loan (collectively, the "Term Loan Advances") will be payable in 36 equal monthly installments of principal plus interest, commencing on March 1, 2026, and to the extent not paid, all remaining obligations will become due and payable on February 1, 2029. Term Loan Advances shall accrue interest at a floating rate per annum equal to the greater of (a) 5.0% or (b) the "prime rate," as published from time to time in the money rates section of the Wall Street Journal, minus 1.0%. At the Company's option, the Company may prepay all outstanding borrowings under the Term Loan, plus accrued and unpaid interest thereon, subject to a prepayment premium ranging from 1.0% to 3.0%, depending on the year of prepayment. The Term Loan also provides for an end of term charge equal to 2.50% of the aggregate principal amount of any loans prepaid or repaid, as applicable.

The Amendment also makes certain changes to the Company's revolving line of credit under the Loan Agreement, including (i) increasing the defined limit for concentration of Medicare receivables that may be included as "eligible accounts" under the Loan Agreement, and (ii) increasing the permitted aggregate maximum balance that may be maintained in the Company's German subsidiary.

Myomo Corporate Information

Executive Officers

Paul R. Gudonis
Chairman, President and Chief Executive Officer

David Henry
Chief Financial Officer

Dr. Harry Kovelman
Chief Medical Officer

Micah Mitchell
Chief Commercial Officer

Virtual Annual Meeting of Stockholders
Date: June 11, 2025
Time: 9:00 am
Link: www.proxydocs.com/myo

Form 10-K
A copy of the Company's Form 10-K filed with the Securities and Exchange Commission is available on the company's website www.myomo.com and also available without charge upon written request to: Myomo, Inc., Investor Relations, 45 Blue Sky Dr., Suite 101, Burlington, MA. 01803; by calling 877.736.9666; or by emailing ir@myomo.com

Board of Directors

Paul R. Gudonis
Chairman, President and Chief Executive Officer

Thomas A. Crowley, Jr.
Chief Executive Officer, Vertical Spine

Thomas Kirk, Lead Independent Director
Former Chairman and Chief Executive Officer American Surgical Professionals

Amy Knapp
Chief Growth Officer
Harbor Health

Milton Morris
Former President and Chief Executive Officer
Neuspera, Inc.

Yitzchak Jacobovitz
Partner and Lead Healthcare Analyst
AIGH Capital Management

Heather Getz
Chief Financial and Operations Officer
Butterfly Network, Inc.

Corporate Headquarters
Myomo, Inc.,
45 Blue Sky Dr., Suite 101,
Burlington, MA. 01803
Phone: 877.736.9666

Website
www.myomo.com

Ticker Symbol
NYSE-American: MYO

Transfer Agent
Vstock Transfer, LLC
18 Lafayette Place
Woodmere, NY 11598
Phone: 212.838.8436

Independent Registered Public Accounting Firm
CBIZ CPA's P.C.
730 3rd Avenue, 11th Floor
New York, NY 10017
Phone: 212.485.5500

Outside Legal Counsel
Goodwin Procter LLP
100 Northern Avenue
Boston, MA 02210
Phone: 617.570.1000

Investor Relations
Alliance Advisors IR
800 Third Avenue, 17th Floor
New York, NY 10022
Phone: 212.838.3777

Myomo, Inc.
45 Blue Sky Dr., Suite 101
Burlington, MA. 01803

www.myomo.com I NYSE-American Ticker: MYO