myomo®

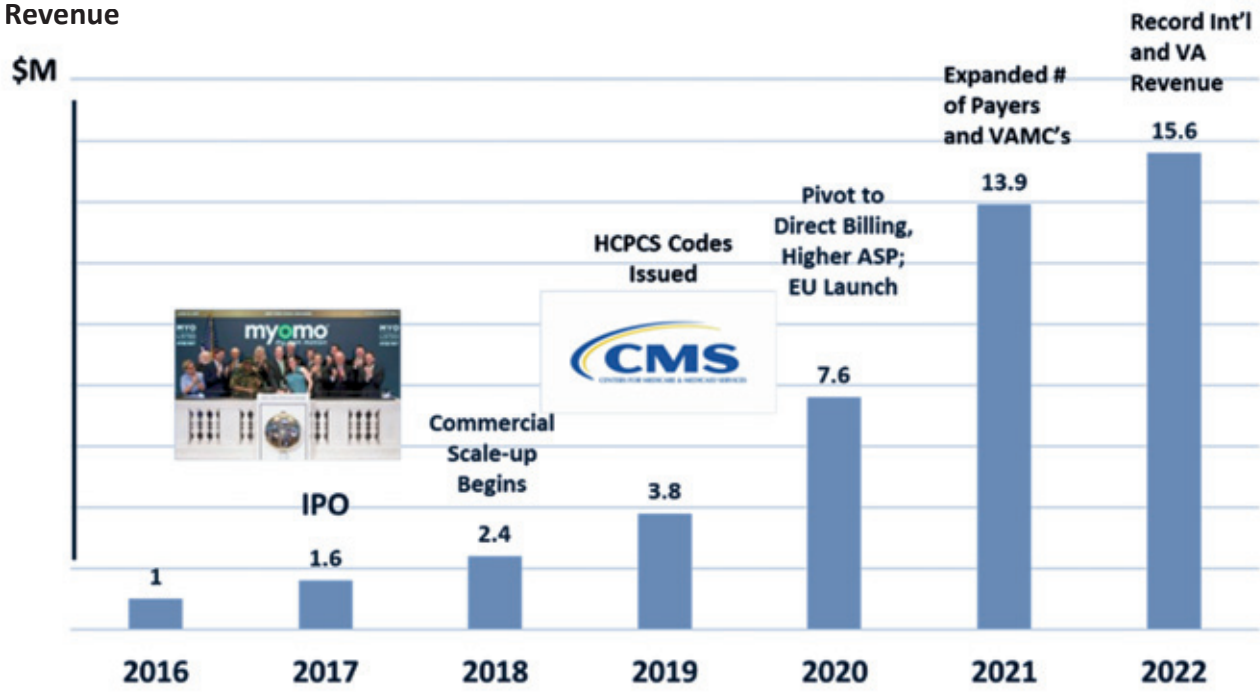
my own motion

2022 Annual Report

To My Fellow Stockholders:

I'm very proud to be writing you as Myomo marks a decade of revenue growth by helping a growing number of patients to improve their lives with a MyoPro® powered arm brace. Most importantly, this is just the beginning. While our growth in 2022 reflected prior-year challenges in growing our patient pipeline, we reversed this trend and began 2023 with a record number of candidates in the process of obtaining a MyoPro. Notably, we have significantly improved the quality of this pipeline by focusing on prospective patients with health insurance plans that have a track record of reimbursing the device. I'll provide more details about our approach below.

Revenue



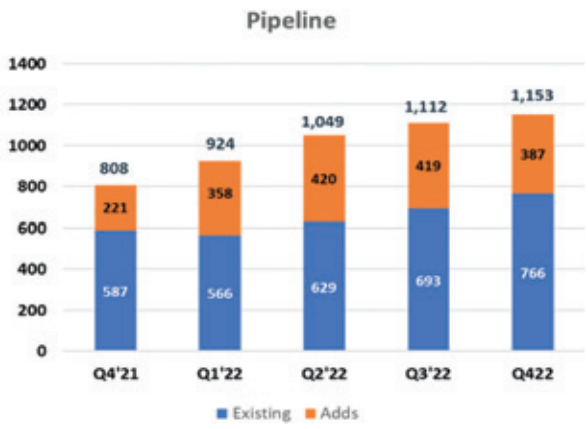
A year ago in my annual shareholder letter, I laid out a set of goals for 2022 and today I am pleased to report on our progress in achieving these objectives:

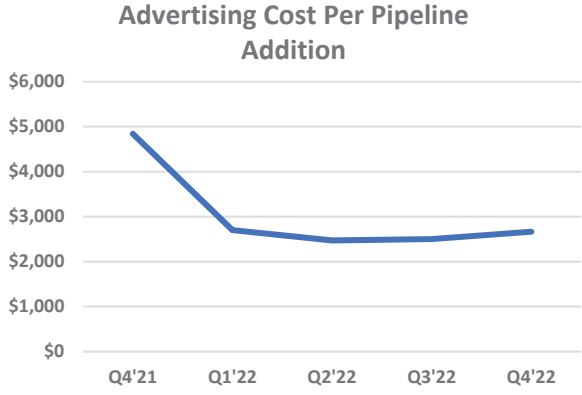
- Accelerating the growth of our patient pipeline;
- Broadening the number of insurance plans that cover MyoPro for their members;
- Conducting additional research on patient outcomes to further support payer decisions;
- Utilizing digital technologies to reduce the cost of marketing, manufacturing and delivery;
- Expanding our international distribution channels and launching the China joint venture; and,
- Resuming development of the MyoPal product to address this unmet market need among children with paralyzed arms.

Accelerating the growth of our patient pipeline

Throughout 2021 our ability to expand the number of patients in our candidate pipeline was impacted by Apple's decision to limit Facebook's ability to target individuals who are seeking information about stroke and related healthcare issues, along with the rising cost of social media advertising as consumer-facing companies emerged from the pandemic and increased their ad spending. As a result, our patient pipeline grew only 5% during the year, and our product revenues in 2022 reflected this modest pipeline growth as the size of the candidate pipeline is a leading indicator of future revenue.

To remedy this situation, in 2022 we began to use TV advertising as a means to educate patients and family members about the benefits of the MyoPro brace. We also revised our approach to social media and moved the handling of inbound prospect calls to our call center in Fort Worth, Texas. As a result, our patient pipeline grew by more than 40% while our cost per pipeline addition – defined as marketing spend leading to new, medically-qualified candidates who are interested in obtaining a MyoPro – was reduced by nearly 50% from the peak cost in the fourth quarter of 2021. These results should enable us to increase our revenue growth rate in 2023.





Broadening the number of insurance plans that cover the cost of MyoPro for their members

One of our business objectives is to expand the number of health insurance plans that reimburse the cost of the MyoPro, and we succeeded in adding nearly 30 new payers. These include Medicare Advantage plans operated by Blue Cross Blue Shield of Arizona, Minnesota and Vermont as well as CareFirst Blue Cross Blue Shield; Blue Cross Blue Shield plans in

Mississippi, Idaho, Nebraska; and various smaller regional insurance carriers such as Sanford Health and HealthNet. Obtaining coverage for the first MyoPro by these payers is an important milestone in seeking pre-authorization approval for subsequent devices. Our Chief Medical Officer and Department of Patient Advocacy work with the candidate's physician to submit the patient's clinical documentation of chronic arm paralysis and doctor's order to payers, highlighting the MyoPro brace as a medical necessity along with its safety and effectiveness for patients. After the insurance plan authorizes the device, our Myomo clinical team or O&P partners then provide a custom MyoPro to the patient.

We made excellent and meaningful progress in advancing the important topic of providing the MyoPro to Medicare Part B beneficiaries. In June 2022, we were invited to testify at the Centers for Medicare and Medicaid Services (CMS) public hearing and present our case that because the MyoPro is customized for each patient and designed for long-term use in the home (similar to a custom prosthetic limb for an amputee), it should be included in the benefit category for arm braces, rather than its current classification as Durable Medical Equipment (DME), which is reimbursed as a monthly rental.

In follow up with CMS staff, we were advised to begin filing claims for patients with Part B coverage and to meet with DME MAC medical directors to seek approval of these claims. We recently filed several Part B claims and have an upcoming meeting with these medical directors to present new compelling research about the patient outcomes for Medicare-age users of a MyoPro as part of the rationale for achieving greater healthcare equity and access to treatments for Part B beneficiaries.

As I mentioned above, at the end of 2022 we made the decision to focus our clinical and reimbursement resources on patients with insurance plans that have reliably covered the cost of the MyoPro while we engage with CMS staff about Medicare Part B coverage. In turn, in early 2023 we reduced our headcount by about 12%. Assuming guidelines from CMS that expand coverage beyond individual consideration, we expect that a greater number of insurance plans will reimburse for the MyoPro in the future, thus expanding access for patients that can benefit from our technology.

Conducting additional research on patient outcomes with the MyoPro to further support payer decisions

The year 2022 was also active on the research front, with a number of clinical studies supporting the value of a MyoPro underway and papers published or submitted. Dr. Svetlana Pundik of the Louis Stokes Cleveland VA Medical Center published a study on the use of the MyoPro in the clinic and in the home, which documented the improvements in clinical measures by veterans under her care. Our in-house Patient Registry produced two studies on using a MyoPro for activities of daily living in the home over an extended period of time, and

of Medicare-age patients improving their DASH (Disabilities of the Arm, Shoulder, and Hand) scores through use of the MyoPro brace at home.

Other well-regarded institutions are also conducting research on the MyoPro, including the Kessler Institute, the University of Utah, and the University of Strathclyde in the UK. We look forward to these studies adding to the body of evidence to support clinical adoption of the MyoPro and reimbursement by a growing number of payers.

Utilizing digital technologies to reduce the cost of marketing, manufacturing and delivery of our products

In early 2022, we introduced the new MyoPro 2+ version of our powered arm brace, which utilizes 3D printing of the custom orthotic components in the manufacturing process. Along with this product roll-out, we began using our innovative Remote Measurement System (RMS) to obtain the dimensions of the patient's arm and hand to produce the custom parts of the patient's brace. There are multiple advantages to this approach. By sending the RMS to the patient's home, our clinicians can use telehealth to measure the patient's arm, which is more convenient for the patient and avoids the time and cost associated with a trip to the home. In addition, it accelerates our revenue cycle and provides a more accurate digital file for the device production and, if necessary, subsequent repairs.

At the front end of the patient journey to obtain a MyoPro, we have continued to fine-tune the use of digital marketing platforms to grow our patient pipeline and to reduce our cost of customer acquisition. We also began using a new "online waiting room" for interested patients to immediately meet with one of our licensed clinicians to conduct a telehealth screening and to discuss the merits of our device for their condition. We have also implemented a number of digital aids and videos for patients and therapists to use for more efficient MyoPro delivery sessions and follow-on treatments.

Expanding our international distribution channels and launching the China joint venture

Our international revenues grew 30% in 2022 with much of that growth in Germany, where our European operations are based. We have invested in expanding our German staff of Business Development Managers and Clinical Trainers, and this team has established relationships with 52 Orthotics and Prosthetics (O&P) practices across Germany. In markets outside the U.S., we partner with local O&P providers who are in-network with the insurance companies and have relationships with patients and medical professionals.

MyoPro – Certified O&P Locations in Germany

Due to several positive decisions from the German Social Court system, more payers are reimbursing for the MyoPro including major Statutory Health Insurance companies such as BARMER, TK, IKK Classic and DAK. As in the U.S., in Germany we are using social media and medical conferences to educate patients, family members and clinicians about the benefits of the MyoPro to build our candidate pipeline. Here is an example of favorable press we received as this young mother is able to hug her son for the first time after her stroke, thanks to her MyoPro brace.


GESUNDHEIT

Nadine Czarnetzki (33) hatte einen Schlaganfall

Mit der Orthese kann ich endlich meinen Sohn umarmen

Das sagt der Experte:

Source: BILD der FRAU, Autorin Sabine Hoffmann, Heft 11/2023, Seite 56-57; Fotos: Georg Lukas

Our German operations also handle sales in other international markets where we have distribution agreements such as the UK, Italy and Australia. We achieved an important milestone in Australia with the first authorization of a MyoPro by the National Disability Insurance Scheme (NDIS), which covers approximately 500,000 residents. We expect growing sales in Australia in the future with this new approved path to reimbursement.

As the COVID-19 pandemic has receded in China, we have finally kicked off the joint venture to bring the MyoPro to this large population of an estimated 14.0 million cases of upper extremity paralysis, which increases every year due to 2.5 million new strokes in the country. We have now received the full $2.7 million upfront license payment, and our agreement calls for over $10.0 million in future payments over the next 10 years as the operation ramps up.

Our Chinese partners, Beijing Ryzur Medical Device Co. and Wuxi Chinaleaf Rehabilitation Industry Equity Investment Fund, are providing all of the capital to set up local manufacturing and distribution of our product line, and Myomo shareholders have a 19.9% equity interest in the joint venture company - Jiangxi Myomo Medical Assistive Appliance Company. Sales will begin after obtaining approval from the National Medical Products Administration regulatory body (similar to the U.S. Food and Drug Administration) in China, setting up the manufacturing

facility, establishing the local supply chain, and receiving the necessary training from Myomo's staff.

Restarting development of the pediatric MyoPal product to address this unmet market need among children with paralyzed arms

Until vaccines were available to protect against the SARS-CoV-2 virus, we had to put development of the MyoPal pediatric version on hold since we did not want to have exposure to young patients during the design and testing phase. In the time since pausing product development, improvements in motors, electronics and batteries enabled us to create a smaller, lightweight prototype for patient testing on several children with arm paralysis due to stroke, cerebral palsy and birth brachial plexus injuries.

To the right is a photo of a child born with upper extremity impairment trying on a MyoPal and moving her arm for the first time in her life.

The initial year of sales of the MyoPro2+ in 2022 revealed some improvements to the device that our engineering team is prioritizing during 2023. As this work is completed, we intend to continue MyoPal development work this year in conjunction with several leading children's hospitals in Boston and Cleveland, and we have designed a clinical trial to begin testing the device's safely and efficacy for this younger patient population. Our current projection is that we will be able to commercialize this new product line in 2024.

Looking Ahead

Based on the size of the patient pipeline as we entered 2023, we believe we have the opportunity to grow product revenues by 20-30%, provided insurance coverage continues by the payers with a history of reimbursing for the MyoPro.

Our major goal this year is to expand access to the MyoPro for Medicare Part B patients, and we believe we have a good case based on both medical necessity and scientific evidence. Because the timing of any decision by CMS staff or contractors is uncertain, we raised additional capital in January 2023 and intend to reduce operating expenses by approximately $2 million in order to sustain operations to the point of a CMS decision. The capital raise was led by AIGH, a fundamental investor in healthcare technology, and in January we welcomed Yitzchak Jacobovitz of the firm to our board of directors.

With increased efficiencies in our marketing programs and operations, we expect to grow MyoPro deliveries and revenues with just a small increase in headcount, which reflects our drive to increase productivity across the company. Our long-term objective remains to become a much larger, profitable company and be the market leader in using neuroscience, brain-computer interfaces, robotics technology and clinical expertise to improve the lives of numerous patients worldwide.

On behalf of my colleagues at Myomo and our board of directors, I thank you for your continued support.

Sincerely,

Paul R. Gudonis
Chairman and CEO
April 28, 2023

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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2022

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.)**
137 Portland St., 4th Floor, Boston, Massachusetts	**02114**
(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 30, 2022 was $10,010,976. 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, 2023, the registrant had 20,921,712 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, 2022.

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

MYOMO, INC

2021 FORM 10-K ANNUAL REPORT
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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 and our financial statements for the year ended December 31, 2022 include disclosures regarding there being substantial doubt about our ability to continue as a going concern.
- If CMS does not allow coverage for the MyoPro, insurers offering Medicare Advantage insurance plans may no longer reimburse for the MyoPro, which could have an adverse effect on our business.
- Our strategy to maximize revenues by focusing our efforts on patients whose insurance has reimbursed for the MyoPro in the past has resulted in a concentration of revenues with patients covered by a particular insurer. Adverse changes in that insurer's reimbursement policy regarding the MyoPro could have an adverse effect on our business.
- The outbreak of the novel strain of coronavirus, SARS-CoV-2, which causes COVID-19, could adversely impact 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 may not be able to obtain third-party payer reimbursement, including reimbursement by Medicare, for our products.
- 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.
- We sell to orthotics and prosthetics providers and distributors who are free to market products that compete with the MyoPro, and we rely on these distributors to market and promote our products in accordance with their 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 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 in value, 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 may evaluate, measure and fit the MyoPro devices using our own clinical staff or 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, the Veterans Administration, or VA, and to our distributors in certain accounts and geographic markets outside the United States.

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 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 current device able to help neuromuscular-impaired people 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, and a lightweight battery unit. The product is worn to support the dysfunctional joint 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 non-invasive 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 our MyoPal device for pediatric use during calendar year 2024. The addressable market in the United States for products directed at all individuals with upper extremity paralysis, such as our MyoPro, is substantial, based on an estimated prevalence population of 3 million existing cases of upper extremity paralysis and our estimate that up to 10% of such individuals may be medically qualified candidates for a MyoPro whose insurance may reimburse for the device. In addition, 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, although not all of these new chronic patients are suitable for a MyoPro.

To assess whether an individual is a medically-qualified candidate for a MyoPro, we and our distribution partners utilize a variety of techniques to evaluate patients, including tele-health video conference sessions, in-person 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 receive referrals from O&P providers and hospitals such as the Mayo Clinic, Cleveland Clinic, and VA Medical Centers.

In most cases, private health insurance companies pay for the MyoPro device, either to us directly or to an O&P provider depending on the patient's insurance plan. If we are serving the patient directly, then we bill the payer, and 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, the Centers for Medicare and Medicaid Services, or CMS, issued two codes for the MyoPro, L8701 and L8702. We continue to be in discussions with CMS regarding reimbursement for the MyoPro, with those discussions centering on the appropriate benefit category for the device. We believe the MyoPro should be covered as a custom-fabricated orthosis, or brace, while CMS is currently listing the device as durable medical equipment, or DME. This distinction is relevant for how the device would be reimbursed. It is reimbursed on a lump sum basis if the benefit category is an orthosis, or as a rental over thirteen months under a capped rental program if it is determined that DME is the appropriate benefit category. The current determination of CMS differs from the lump-sum reimbursement currently received from commercial payers, VA hospitals, worker's compensation, and state Medicaid plans. A new rule has been published by CMS covering the process to request a benefit category change. In conjunction with the publication of this new rule, CMS invited us to present our request to change the benefit category for our MyoPro device to a brace at its public meeting in June 2022. In September 2022, CMS published its determination, deferring its decision on our request, and further stating that coverage and payment for the MyoPro would be at the discretion of its regional Medicare billing contractors, known as the DME MAC's. We intend to submit additional research for publication before the end of the first quarter of 2023, that is expected to add to existing evidence that the MyoPro is effective, reasonable, necessary and appropriate for Medicare beneficiaries. Once submitted for publication, we intend to meet with the medical directors of the DME MAC's to discuss coverage and payment for the MyoPro and begin submitting claims for Medicare Part B beneficiaries. In January 2023, CMS published a notice stating that it intends to publish a proposed rule in the coming months regarding the scope of the Medicare Part B benefit for leg, arm, back and neck braces and newer technology devices. We expect this rule to clarify whether CMS considers the MyoPro to be a brace or DME. There is no timetable for CMS to make any coverage or payment decisions, nor is there any guarantee that any such decisions will actually increase access to the MyoPro or result in reimbursement from payers, including Medicare. In addition, we cannot predict the impact of any such decision on the amounts that we may be reimbursed by private insurance companies, if any.

We are the exclusive licensee of 2 U.S. patents for the myoelectric limb orthosis device based on technology originally developed at MIT in collaboration with medical experts affiliated with Harvard Medical School, which will expire by December 2023. We also hold 20 issued patents in the U.S. and various countries and have multiple pending patent applications in the US and international markets. These patents expand upon the MIT patents and extend the life of our patent portfolio to the year 2039. 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 Boston, 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 U.S. affecting approximately 800,000 people per year. We have working relationships with rehabilitation facilities in the U.S., 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 hemi-paresis, 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 6-12 months of therapy, many patients plateau and continued therapy will not likely result in further improvement. These chronic patients then

enter the prevalence population and become potential candidates for the MyoPro, which we believe is the most cost-effective alternative for regaining function for these individuals.

Vehicular and Workplace Accidents

One of the most straightforward applications 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 in some cases their 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. One of the leading medical facilities in the U.S. for treating brachial plexus injuries is the Mayo Clinic. We have been working with surgeons at the Mayo Clinic who have incorporated the MyoPro into their surgical post-operative treatment protocol to help improve function in upper limbs.

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 during calendar year 2024.

Progressive Conditions

The MyoPro has been prescribed in a few cases for individuals with progressive conditions such as multiple sclerosis and ALS. 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 known in the medical community as a custom fabricated limb orthosis. It is created

individually for each patient from a cast, just like a prosthetic, except the MyoPro is appropriate for someone who still has a limb that is non-functional. Beginning in 2022, we enabled the use of remote measurement and 3D printing techniques in order to create the orthotic parts for the device, which has reduced the number of in-person visits by our clinical field staff.

Orthotic devices are provided by clinical professionals who custom fabricate and fit these devices. According to the American Orthotics and Prosthetics Association, there are more than 2,000 member O&P facilities located in the U.S. 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, a paralyzed individual, such as one who has suffered 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 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, either through in-person measurement or utilizing telehealth and remote measurement equipment in order to obtain the patient's measurements. Once the patient's arm measurements are captured, the orthotic parts are 3D printed 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 or by an O&P practice, 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 minor adjustments to the brace can be made to optimize comfort.
- The patient will be provided with initial training and a set of take-home tasks to practice with the brace donned. We now 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 then 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. Finally, under our MyoCare program, a coach is assigned to each patient 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.

In a cost-conscious healthcare environment, we believe that the use of the MyoPro is compelling since it enables functional improvement that can help users improve their ability to perform ADL's, which may allow them to return to work or improve their ability to be independent and remain at home. In the U.S., 7% of adults aged 65 and over require daily help with ADLs, with such long term support services consuming almost 10% of all healthcare spending. We believe that helping regain upper limb function to these individuals may result in fewer emergency room visits

related to falls, increase their level of activity, and avoid the need for institutionalization. With approximately 70 million baby boomers 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, and material science 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, software enhancements and a new design that facilitates easier donning and doffing of the device.

We plan, depending on available resources, to continually improve our system architecture and develop new product innovations that increase the value and breadth of our product offerings. During calendar year 2024, we expect to launch MyoPal, a pediatric version of the MyoPro which is designed to meet the needs of younger patients suffering from arm and hand paralysis.

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. A study was published in January 2017 that demonstrated the instantaneous reduction in upper limb impairment and increase in ability to complete functional tasks for chronic stroke patients. In addition to the previous published 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 recently funded study of the device for patients with spinal cord injury, or SCI at Kessler Rehabilitation Center in New Jersey. These studies focused on the ability of MyoPro users to initiate movement of their affected limbs and perform ADLs such as picking up objects so that they may feed themselves and live more independently. In 2021, we launched an internal outcomes patient registry to collect data on a number of patient outcomes from use of the MyoPro in their homes. This is an ongoing study that will provide valuable insight into long term outcomes and will also drive future development of the MyoPro. Before the end of the first quarter of 2023, we expect to submit research for publication regarding the ability of MyoPro users to perform activities of daily living from data obtained from our outcomes registry. In addition to the studies Myomo is directly involved in, various clinical facilities are undertaking their own research projects on the outcomes of MyoPro users, including a recent publication detailing outcomes for patients with brachial plexus injuries, or BPI, by the Mayo Clinic. In non-clinical based research, the University of Utah has been awarded grant funding to study and improve the control systems that communicate muscle intention for better control of the motors on the MyoPro brace. This could lead to future collaboration between Myomo and the University of Utah if new intellectual property is developed.

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. In addition to our recent

geographic expansion to serve more areas in the United States, we are entering international markets via local partnerships and distribution arrangements to meet the large global need that we believe exists for individuals with upper limb paralysis.

We utilize digital ads on various platforms as well as television ads to educate and inform 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. In instances where we are the provider, the initial evaluation is typically conducted using a telehealth platform. Prior to obtaining authorizations from commercial insurance companies, the patient's medical records are collected and reviewed to make sure the device is appropriate for their condition and a prescription and letter of medical necessity are typically obtained from the patient's physician. Once these documents are obtained, our patient advocacy team submits a pre-authorization request to the patient's insurer. If we receive a pre-authorization, we will proceed to measure the patient's arm and hand, print orthotic parts using 3D printing techniques, then fabricate the MyoPro and deliver it 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 distributors in Europe and Australia. The MyoPro product line has been approved by the VA system for impaired veterans, and approximately 70 VA facilities have already 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, 2022, 1,153 patients were in our reimbursement pipeline, a 43% increase compared to 808 patients in the pipeline at December 31, 2021. As of December 31, 2022, 164 MyoPro units were in backlog, which we define as patients for whom we received insurance authorization, but revenue has not been recognized, with an estimated revenue value of $7.6 million, which is a 9% increase over 154 patients in backlog at December 31, 2021. As a cost savings measure, during 2023 we intend to focus our efforts only on those patients in our pipeline with payers who have reimbursed for our products. We have suspended activities and reduced expenditures directed to growing the number of payers reimbursing for our product until CMS begins to reimburse or states that it intends to reimburse for the MyoPro. Excluding patients with payers who have not previously reimbursed for our products, our patient pipeline was 794 patients as of December 31, 2022, a 50% increase over the comparable pipeline of 528 patients as of December 31, 2021. We refer to this measure of the pipeline as our Adjusted Pipeline. In conjunction with our intention to only focus on those patients in our Adjusted Pipeline, we reduced our workforce by 12% in January 2023. This action and other intended costs reductions are expected to save approximately $2 million in 2023. While we intend to focus only on patients in our Adjusted Pipeline in 2023, the impact on backlog and revenues is expected to be deminimus, as approximately 98% of our direct billing revenues in 2022 came from patients with payers that comprise our Adjusted Pipeline.

To bring the MyoPro to what we believe is the large number of potential patients outside of the U.S., in July 2017 we met the criteria to apply the CE Mark, which is a manufacturer's declaration that the product complies with the essential requirements of the relevant European Union health, safety and environmental protection legislation for the MyoPro so that it can be marketed in Europe. 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 distribution 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 2022.

Competition

An individual with difficulty walking has a wide range of technology 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.

Experimental Surgery: Battelle and Thomas Jefferson University — Brain Implants

An array of experimental interventions currently is being researched at universities and non-profit research facilities around the world. One such innovation recently announced by Battelle Memorial Institute in Ohio and Thomas Jefferson University in Philadelphia involves a craniotomy, which is a surgical opening into the skull performed to implant a sensor chip in the brain. An electrical cable is connected to the top of the head connecting to a system that sends pulses of electrical stimulation to activate muscles in the forearm or to control the MyoPro brace. The procedure is experimental, invasive, and costly, but may be offered as an alternative to a myoelectric orthosis.

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 ReWalk, Ekso Bionics, and Cyberdyne. It is possible that companies may begin to compete with solutions such as ours for the upper extremity. Ekso Bionics has recently announced a product to be used only for rehab therapy at a hospital, and we can provide no assurance that these or other companies are not currently developing competing products for the home market.

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 Vincent Systems and HKK in Germany.

Intellectual Property

The MyoPro is protected by two core patents exclusively licensed from MIT for the life of the patents. The first patent (U.S. Pat. No. 7,396,337) covers a powered orthotic device, worn over a patient's elbow or other joint that senses relatively low-level muscle signals in the vicinity of the joint generated by a patient. In response to the relatively low-level signals, the powered orthotic device moves, causing the patient's body part to move about the joint accordingly with adjustable force and assistance settings. The patent expires on December 1, 2023. The second patent (U.S. Pat. No. 7,367,958) covers a method of providing rehabilitation movement training for a person suffering from nerve damage, stroke, spinal cord injury, neurological trauma or neuromuscular disorder by moving a body part about a joint using a powered orthotic device. The patent claims methods that include moving the body part about the joint in two directions based on an EMG signal from a muscle associated with that body part or moving the body part about the joint in one direction based on the EMG signal and in another direction based on a return force in the absence of a sensed EMG signal. This patent expires on November 21, 2023, which represents the earliest patent expiration among Myomo's intellectual property portfolio.

The two patent licenses discussed above were granted pursuant to the MIT License. Under the MIT License, we have been granted access to those certain patent rights in exchange for the payment of royalties, which vary based on the level of our net sales. As part of the MIT License, we must pay a nonrefundable annual license maintenance fee which may be credited to any royalty amounts due in that same year. The license agreement can be terminated if certain sales

targets are not achieved. The future minimum amounts due under this agreement is $25,000 for the final year of the agreement in 2023.

Under the MIT License, we issued 6,172 shares of our common stock to MIT. They have the right to purchase additional shares of our common stock to maintain their pro rata ownership.

Myomo has 20 of its own issued patents as well. 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 licensed from MIT. The Motion G generated 97% of our product revenue for the year ended December 31, 2022. 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 two U.S. patents 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). 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 4 pending U.S. patent applications and 11 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 2039.

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. Within the first ten years from the registration dates shown above, we will be required to complete two (2) "maintenance" filings, one between the 5th and 6th years and the second between the 9th and 10th years. Each successive 10-year period thereafter we will be required to complete a "maintenance" filing between every 9th and 10th year.

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 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 European Union, or EU, medical devices are regulated under the European Medical Devices Regulation, or the EU MDR, which was effective in May 2020. An authorized third-party, also called a Notified Body, must approve products for CE marking and conducts periodic inspections to ensure applicable regulatory requirements are met. The CE mark is contingent upon continued compliance to the applicable regulations and the quality system requirements of the ISO 13485 standard.

Under the new EU MDR requirements, CE certificates issued under the previous directives prior to May 2020 will remain valid in accordance with their term, beyond the expiration of the transition period, however certain limitations set forth in the EU MDR, such as the need to use classifications that are different from the previous directives, would apply.

We, together with Cogmedix, our primary contract manufacturer, actively maintain FDA 21 CFR Part 820 QSR and ISO 13485 Quality Management Systems for product design and development, manufacturing, distribution, and customer feedback processes. 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.

We have declared conformity to European Directives and apply the CE Mark for distribution of the MyoPro product line in Europe, and we have a Medical Device License for Canada. In addition, Myomo has recently 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, the Office of Inspector General and Office for Civil Rights, other divisions of the Department of Health and Human Services, or HHS, 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 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 federal civil False Claims Act, 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, biologicals 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;
- federal price reporting laws, which require manufacturers to calculate and report complex pricing metrics to government programs, where such reported prices may be used in the calculation of reimbursement and/or discounts on approved products; 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, including compensation of physicians with stock or stock options to serve on our Scientific Advisory Board 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 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 and O&P providers 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. The process usually requires obtaining a pre-authorization of the MyoPro for the patient, and if the authorization request is initially denied by the payer, we support 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, where we believe providers are typically paid monthly over a period of thirteen months. We are continuing to work with CMS on publishing reimbursement guidelines for our product. . In June 2022, we presented our request to CMS to change our benefit category to a brace. In September 2022, CMS published its determination that it needed more time to determine how to proceed to resolve what it referred to as a "complex issue", further stating that coverage and payment for the MyoPro would be at the discretion of the DME MAC's. We intend to meet with the medical directors of the DME MAC's to discuss coverage and payment for the MyoPro and begin submitting claims for Medicare Part B beneficiaries in early 2023.

There is no guarantee that the future level of reimbursement payments for the MyoPro directly to us or to our O&P distributors will be 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. Further, reimbursement levels may

affect the number of O&P providers who wish to supply the MyoPro and may limit patient access to the technology depending on the policies of their health insurance plans.

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 through 2030 unless additional Congressional action is taken. 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 vendor creates the orthotic parts from these measurements and the fabrication of the device is done in our facility in Boston, MA.

If the volume and geographic reach of our sales expand, we may seek additional sources for manufacturing and custom fabrication of the devices as our needs may require.

Employees and Human Capital

As of December 31, 2022, we employed a total of 100 full time employees and 6 part time employees. In January 2023 we reduced our headcount by 12%. 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 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 137 Portland St., 4thFloor, Boston, Massachusetts 02114, 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 Securities and Exchange Commission may be accessed through the Securities and Exchange Commission'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, Compensation Lead Independent Director and Nominating and Corporate Governance Committees 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 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

If CMS does not allow coverage for the MyoPro, insurers offering Medicare Advantage insurance plans may no longer reimburse for the MyoPro, which would have an adverse effect on our business.

Revenues from patients who are covered by Medicare Advantage insurance plans are becoming an increasingly significant portion of our overall revenues. For the year ended December 31, 2022, approximately 60% of our product revenues were derived from patients with Medicare Advantage insurance plans. If CMS does not allow coverage for the MyoPro, or if such coverage is obtained and is subsequently retracted, insurers offering Medicare Advantage insurance plans may no longer reimburse for the MyoPro. As a result, our 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.

Our strategy to maximize revenues by focusing our efforts on patients whose insurance has reimbursed for the MyoPro in the past has resulted in a concentration of revenues with patients covered by a single insurer. Adverse changes in that insurer's reimbursement policy regarding the MyoPro could have an adverse effect on our business.

In order to maximize revenues and minimize cash used for operations, we focus our lead generation efforts in geographical areas of the country where insurers who have previously reimbursed for the MyoPro operate their businesses. Beginning in September 2021, a large 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 30% of total revenues during the year ended December 31, 2022. With a small number of exceptions, appeals filed with the payer requesting payment have been successful and these claims have ultimately been paid. This payer also continues to provide us with pre-authorizations to serve new patients. If this payer were to start regularly denying appeals on filed claims, reduce the number of MyoPro's that it will authorize for its insured patients, or delays payments pending resolution of the denial and appeals process, 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 carry-forwards;
- increased product and price competition, due to 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.

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 currently rely, and in the future will rely, on sales of our MyoPro products for our revenue. MyoPro products are relatively new products, and market acceptance and adoption 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. MyoPro 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, we believe that healthcare providers tend to be slow to change their medical treatment practices because of perceived liability risks arising from the use of new products and the uncertainty 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.

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

- 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;
- 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.

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 will be 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." Third-party payers are increasingly challenging the prices charged, examining the medical necessity, 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. As a result, the coverage determination process is often a time-consuming and costly process that will require 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. Currently, we are almost entirely dependent on third parties to cover the cost of our products to patients and rely on our distributors' ability to obtain reimbursement for the cost of our products. If the U.S. Department of Veterans Affairs, or 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, through the year ended December 31, 2022, fewer than 30 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. Starting in 2023, we no longer pursue sales to patients whose insurance payers have not previously reimbursed for the MyoPro. In the event we are unsuccessful in obtaining 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. See section title *"Business Section – Government Regulation – Health Insurance Reimbursement."*

In connection with Medicare reimbursement, the Centers for Medicare and Medicaid Services, or CMS, had published two new codes pursuant to our application for HCPCS codes, which became effective on January 1, 2019. CMS placed the Myopro device in a DME rental benefit category instead of lump sum, which is standard practice for other custom-fabricated orthotics and prosthetics. We submitted an appeal to change our benefit category to an orthotic, or brace, which was presented at a public meeting in June 2022. In September 2022, CMS announced that it elected not to make a determination on our application at this time. In January 2023, CMS provided notice that it intends to publish a proposed rule covering the scope of the Medicare Part B benefit for leg, arm, back and neck braces as well as newer technology devices. We cannot give any assurance that CMS will change our benefit category determination, that the DME MAC's will cover the device on a case by case basis, or at all, or that the amount of reimbursement, if any, to be approved will be sufficient to provide a reasonable profit to us, that the receipt of these codes would result in appropriate coverage and payment terms or otherwise lead to any greater access to our products or reimbursement for such products.

While we announced that we became accredited as a Medicare provider in July 2021, enabling us to bill Medicare directly when we deliver our MyoPro powered orthosis to patients in 39 states and the District of Columbia, since we continue to await a decision by CMS on our benefit category change request, coverage policy and allowable fee for the MyoPro, we are currently not serving Medicare Part B patients, though we intend to start submitting claims on behalf of Medicare Part B beneficiaries in early 2023. There is no specific timetable or guarantee that CMS will in fact issue such coverage and payment guidelines, or agree to change our benefit category. There is no guarantee that we will receive those terms in a timely manner or at all. In addition, decisions by CMS or other governmental payers on whether and to what extent they would cover our products, as well as decisions on what basis they would cover our products, whether as outright purchases by patients or on a rental basis, may impact similar coverage decisions by private payers that may follow the decisions by governmental payers.

Reimbursement amounts, whether on a case-by-case basis or pursuant to broader coverage policies, which may be established in the future, may be insufficient to permit us to generate sufficient gross margins to allow us to operate on a profitable basis. Third-party payers also may deny 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 receive such approvals would negatively impact market acceptance of MyoPro. Further, due to the COVID-19 pandemic, millions of individuals have lost employer-based coverage, which may adversely affect our sales to our patients relying on such coverage.

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, or the FDA, for the MyoPro device we sell, we have contracted with Cogmedix, Inc., or Cogmedix, a contract manufacturer with expertise in the medical device industry, for the contract manufacture of all of our products and the sourcing of all of our components and raw materials. Pursuant to this contract, Cogmedix manufactures 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 products 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 products 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 and International Organization for Standardization, or ISO, standard 13485.

We also rely on third-party suppliers, some of which 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 agreement 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 the batteries used by the MyoPro and do not maintain any long-term supply agreement with respect to batteries. If we fail to obtain sufficient quantities of batteries 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 resulting from the coronavirus outbreak, or other factors, our supply chain may be disrupted and our ability to manufacture and ship our products may be limited. While many companies are experiencing 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. In addition, as a result of shelter-in-place orders, workplace capacity restrictions, or other mandated travel restrictions, our on-site staff conducting sales and marketing and engineering activities may not be able to access our office or laboratory space, and these restrictions may adversely impact our contract manufacturing partners as well. Further, these core activities may be significantly limited or curtailed, possibly for an extended period of time.

Risks Related to Limited Operating History and Capital Requirements

We have a history of operating losses and our financial statements for the year ended December 31, 2022 include disclosures regarding there being substantial doubt about our ability to continue as a going concern.

We have a history of losses since inception. For the years ended December 31, 2022 and 2021, we incurred net losses of $10.7 million and $10.4 million, respectively. At December 31, 2022, we had an accumulated deficit of approximately $88.8 million. We expect to continue to incur operating and net losses for the foreseeable future, though we have implemented measures to reduce our operating expenses through eliminating costs associated with activities to broaden the number of payers reimbursing for MyoPro. However, there can be no assurance that our cost reduction measures will be effective in reducing our operating expenses, or that these measures would not adversely affect our revenue-generating activities.

Our cash and cash equivalents at December 31, 2022 was approximately $5.3 million. In January 2023, we completed a follow-on offering of our common stock and pre-funded warrants, raising net proceeds of approximately $5.7 million. In addition, we entered into a Common Stock Purchase Agreement (the "Purchase Agreement") with Keystone Capital Partners ("Keystone") on August 2, 2022 to establish an equity line facility permitting the sale of up to $5.0 million of shares of common stock, subject to an exchange cap that limits the number of shares that we may sell to 1,349,334, unless stockholder approval were obtained to remove such cap. We also have an at-the-market facility with Alliance Global Partners (the “ATM Facility”), that permits us to sell up to $0.3 million of shares of common stock from time to time. Because the shares of common stock to be sold under the Purchase Agreement and the ATM Facility are registered under our registration statement on Form S-3, we are subject to the limitations imposed by General Instruction I.B.6 of Form S-3, which limits the amount of securities that we may issue under our registration statement on Form S-3 to one-third of our public float in any 12-month period. We have also agreed with the purchasers in our January 2023 financing not to sell shares under our Purchase Agreement and ATM Facility for a period of one year.

We believe that there is substantial doubt that our cash and cash equivalents at December 31, 2022, together with the net proceeds from our January 2023 financing will be sufficient to fund our operations for the twelve months from the date of this report. Disclosure of this substantial doubt about our ability to continue operations in the future as a going concern, is disclosed in the notes to the audited financial statements for the year ended December 31, 2022. Because our financial statements raise substantial doubt about our ability to continue as a going concern, they do not reflect any adjustments that might result if we are unable to continue our business. If we cannot continue as a viable entity, our stockholders may lose some or all of their investment in our company.

Our limited operating history makes it difficult for us to evaluate our future business prospects and make decisions based on those estimates of our future performance.

Since inception through December 31, 2022, we have delivered nearly 2,000 units for use by patients at home and at clinical facilities. Our latest product line, the MyoPro, was introduced to the market in fiscal year 2012 and we have delivered more than 1,600 units since such time. As a result, we have a limited operating history. It is difficult to forecast our future results based upon our historical data. Because of the uncertainties related to our limited historical operations, we may be hindered in our ability to anticipate and timely adapt to increases or decreases in revenues or expenses.

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

Our cash and cash equivalents at December 31, 2022 was approximately $5.3 million. In January 2023, we completed a follow-on offering of our common stock and pre-funded warrants, raising net proceeds of approximately $5.7 million. In addition, we entered into a Purchase Agreement with Keystone to establish an equity line facility permitting the sale of up to $5.0 million of shares of common stock, subject to an exchange cap that limits the number of shares that we may sell to 1,349,334, unless stockholder approval were obtained to remove such cap. We also have an ATM Facility , that permits us to sell up to $0.3 million of shares of common stock from time to time. Because the shares of common stock to be sold under the Purchase Agreement and the ATM Facility are registered under our registration statement on Form S-3, we are subject to the limitations imposed by General Instruction I.B.6 of Form S-3, which limits the amount of securities that we may issue under our registration statement on Form S-3 to one-third of our public float in any 12-month period. We have also agreed with the purchasers in our January 2023 financing not to sell shares under our ATM Facility for a period of one year. However, there can be no assurance that we will be able to sell any or all of the shares under the Purchase Agreement or the ATM Facility, or raise significant amounts of capital even if we do. If we cannot use these facilities to raise sufficient capital to operate our business, we may be required to utilize more costly and time-consuming means of accessing the capital markets.

Our financial statements for the year ended December 31, 2022 contain a qualification regarding substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern is dependent on our ability to generate sufficient cash flows from operations or to raise additional capital to meet our obligations. Based on our historical cash burn, we do not anticipate that our existing cash and cash equivalents will be sufficient to enable us to maintain our currently planned operations for the next twelve months from the date of this report. 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. The incurrence of indebtedness could require us to meet financial and operating covenants, which could place limits on our operations and ability to raise additional capital, 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.

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

Inflation has increased during the period covered by this Annual Report on Form 10-K, 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.

Risks Related to COVID-19

The outbreak of the novel strain of coronavirus, SARS-CoV-2, which causes COVID-19, could adversely impact our business.

The outbreak of the novel coronavirus, SARS-CoV-2, which causes coronavirus disease 2019 ("COVID-19"), has evolved into a global pandemic. The coronavirus has spread to many regions of the world, including the United States and Europe. As a result of the coronavirus pandemic, we have experienced and may continue to experience disruptions that could materially impact our business. The extent to which the coronavirus impacts our business and operating results will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning the coronavirus and the actions taken to contain the coronavirus or treat its impact, among others.

As a result of COVID-19, various aspects of our business operations have been, and could continue to be, disrupted. For example, because we provide a custom-fabricated device to each patient, the in-person contact required as part of the fabrication and delivery process has been impacted and likely will continue to be impacted if COVID-19-related public health restrictions on travel and personal interaction are broadly reinstated. Similarly, the impairment in the ability for patient consultation and fittings has caused us to delay and re-prioritize in our launch of MyoPal, our product for pediatric patients. While we continued in-person interactions with, and deliveries to, patients during the fourth quarter of 2022, incidences of the virus and its variants remain prevalent in the United States and the world. The spread of the current variants has resulted in more incidences of infection involving employees of the Company and its vendors and subcontractors as compared to earlier in the pandemic, which has impacted the Company in terms of lost productivity and temporary reductions in capacity. While current variants do not appear to be as virulent as previous variants, it is possible that future variants will be more transmissible and virulent. As a result, public health restrictions may be reinstated in various areas in the future. While insurance reimbursement practices of government and third-party payers were largely unaffected by the pandemic, we can provide no assurance that will continue in the future. While we currently believe we have sufficient inventory in our supply chain and currently expect to have sufficient fabrication capacity available to manufacture and deliver devices to patients, there can be no assurance that we will be able to continue to do so. If we, or any third parties in our supply chain for materials which are used in the manufacture of our products are adversely impacted by infections or restrictions resulting from the coronavirus outbreak, our supply chain may be disrupted and our ability to manufacture and ship our products may be limited. Further, these core activities may be significantly limited or curtailed, possibly for an extended period of time. In addition, the company through which we have a joint venture in China for our MyoPro product has advised us that effects of COVID lockdowns in China are delaying the banking and government approvals necessary to pay the remaining amounts owed to us under our technology license for the joint venture. We cannot be certain as to if or when the remaining license fee will be paid. If uncured, failure to pay us the required fees contemplated by the Agreements may entitle us to terminate such our agreements related to the joint venture and withdraw from the joint venture.

In response to COVID-19, we have implemented a work from home policy, with many of our employees continuing their work outside of our offices. The increase in working remotely could increase our cyber security risk, create data accessibility concerns, and make us more susceptible to communication disruptions, any of which could adversely impact our business operations or delay necessary interactions with local and federal regulators and manufacturing sites.

In addition, the trading prices for our common stock and other companies in the life sciences industry have been highly volatile as a result of the COVID-19 pandemic. As a result, if we needed to raise additional capital, we may face difficulties raising capital through equity or debt financings, or such financing transactions may be on unfavorable terms. While the potential economic impact brought by and the duration of the pandemic may be difficult to assess or predict, it has already caused, and is likely to result in further, significant disruption of global financial markets, which

may reduce our ability to access capital either at all or on favorable terms. In addition, a recession, depression or other sustained adverse market event resulting from the spread of COVID-19 could materially and adversely affect our business and the value of our common stock.

The ultimate impact of the current pandemic, or any other health epidemic, is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our commercialization, sales and marketing, research, manufacturing, and regulatory activities, healthcare systems or the global economy as a whole. However, these effects could have a material adverse impact on our operations, and we will continue to monitor the situation closely

Risks Related to Competitors and Our Market

The industries in which we operate are highly competitive and subject to rapid technological change. 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. 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 achieve 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 and distributors who are free to market products that compete with the MyoPro, and we rely on these parties to market and promote our products in accordance with their FDA listings, select appropriate patients and provide adequate follow-on care.

We rely on our relationships with qualified O&P providers and our distribution arrangements to market and sell our products. We believe that a meaningful percentage of our sales will continue to 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 other independent providers or our direct field representatives, which may not prevent our sales from being adversely affected. Additionally, to the extent that we enter into additional arrangements with independent distributors to perform sales, marketing, or distribution services, the terms of the arrangements could cause our profit margins to be lower than if we directly marketed and sold our products.

If these independent O&P providers or distributors 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 distributors have arisen in the past, we have supplied additional training and documentation and/or ended the distributor 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 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 new and the rate of adoption is uncertain. Our estimates of market size are derived from statistics regarding the number of individuals with paralysis, but not necessarily limited to their upper extremities. 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. Our agreement with GRE does not contain a similar limitation of liability; however, 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 (the "JV") with Beijing Ryzur Medical Investment Co., Ltd. ("Ryzur Medical"), to manufacture and sell the products containing our technology in China, 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 will be 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. As of December 31, 2022, we received $1.0 million partial payment of the license fee. The joint venture has advised us that effects of COVID-19 lockdowns in China are delaying the banking and government approvals necessary to pay the remaining amounts owed to us under our technology license. We cannot be certain as to if or when the remaining license fee will be paid. If uncured, failure to pay us the required fees contemplated by the Agreements may entitle us to terminate such our agreements related to the joint venture and withdraw from the joint venture. 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 competitive 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 international markets, our business could suffer.

As we expand the number of locations which provide the MyoPro products, including 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 misallocate 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 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, in January 2021, we announced that we had entered into a joint venture with Beijing Ryzur Medical Investment Co., Ltd., to manufacture and sell the products containing the Company's technology in China, 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 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 international expansion, and it 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 expanding into international markets because of limited brand recognition, leading to delayed or limited acceptance of our products by patients in these markets. Accordingly, if we are unable to 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.

Our recent organizational changes and cost cutting measures may not be successful.

In January 2023, we implemented reduction-in-force affecting approximately 12% of our workforce. The objective of this workforce reduction was to realign our workforce to meet our needs and to improve operating efficiency in our direct billing channel and reduce our cash burn. However, these restructuring and cost cutting activities may yield unintended consequences and costs, such as attrition beyond our intended reduction-in-force, a reduction in morale among our remaining employees, and the risk we may not achieve the anticipated benefits of such reduction-in-force measure, all of which may have an adverse effect on our results of operations or financial condition. In addition, while positions have been eliminated, certain functions necessary to our reduced operations remain, and we may be unsuccessful in distributing the duties and obligations of departed employees among our remaining employees. We may also discover the reductions in workforce and cost cutting measures will make it difficult for us to resume development activities we have suspended or pursue new initiatives, requiring us to hire qualified replacement personnel, which may require us to incur additional and unanticipated costs and expenses. As a result of the loss of services of substantially all of our personnel, including several of our executive officers, we may be unable to continue our operations and meet our ongoing obligations. Any of these unintended consequences may have a material adverse impact on our business, financial condition, and results of operations.

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 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 Federal Food, Drug, and Cosmetic Act, or 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. See "Business — Government Regulation" in our Annual Report on Form 10-K.

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, or PMA, 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 U.S. 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 pre-clinical (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, or 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 US or other countries. 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. 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 entitled "*Business – Government Regulation – Healthcare Privacy Laws and Regulations."*

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 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. 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;
- 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 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 Section – Government Regulations – Current and Future Legislation*.".

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 in 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 or security breaches, which could result in a material disruption of our product development programs.

Despite the implementation of security measures, our internal computer systems and those of our customers, collaborators and other contractors are vulnerable to damage from computer viruses and unauthorized access. 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, social engineering and other means to affect service reliability and threaten the confidentiality, integrity and availability of information. Cyber-attacks also could include phishing attempts or e-mail fraud to cause payments or information to be transmitted to an unintended recipient. A material cyber-attack or security breach 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 sensitive data, including, among other things, personally identifiable information about our employees and patients, intellectual property, and proprietary business information. Any cyber-attack or security breach that leads to unauthorized access, use or disclosure of personal or proprietary 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 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 systems and networks of our company and our vendors, including personal information of our employees, and company and vendor confidential data. In addition, outside parties may attempt to penetrate our systems 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 a material breach of our information technology systems 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 respond to these threats or breaches and to repair or replace information systems or networks and could suffer financial loss or the loss of valuable confidential information. In addition, we could be subject to regulatory actions and/or claims made by individuals and groups in private litigation involving privacy issues related to data collection and use practices and other data privacy 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 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, the possibility of these events occurring cannot be eliminated entirely and there can be no assurance that any measures we take will prevent cyber-attacks or security breaches that could adversely affect our business.

In the United States, states have recently become to be rather active in privacy. Leading efforts has been California which has recently enacted the California Consumer Privacy Act, or CCPA, a comprehensive measure 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. 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, also in California, as of January 1, 2023, the California Privacy Rights Act (CPRA), will create additional obligations with respect to processing and storing personal information that are scheduled to take effect on January 1, 2023. We will continue to monitor developments related to the CPRA and anticipate additional costs and expenses associated with CPRA compliance. While the CCPA and CPRA contain an exception for certain activities involving PHI under HIPAA, we cannot yet determine the impact the CCPA, CPRA or other such future laws, regulations and standards may have on our business.

Certain other state laws impose similar privacy obligations and we also anticipate that more states will increasingly enact legislation similar to the CCPA and the CPRA. For example, on March 2, 2021, Virginia enacted the Consumer Data Protection Act, or CDPA. The CDPA became effective January 1, 2023. The CDPA regulates how businesses (which the CDPA refers to as "controllers") collect and share personal information. While the CDPA incorporates many similar concepts of the CCPA and CPRA, there are also several key differences in the scope, application, and enforcement of the law that will change the operational practices of controllers. The new law will impact how controllers collect and process personal sensitive data, conduct data protection assessments, transfer personal data to affiliates, and respond to consumer rights requests.

Also, on July 8, 2021, Colorado's governor signed the Colorado Privacy Act, or CPA, into law. The CPA is rather similar to Virginia's CDPA, but also contains additional requirements. The new measure applies to companies conducting business in Colorado or who produce or deliver commercial products or services intentionally targeted to residents of the state that either: (1) control or process the personal data of at least 100,000 consumers during a calendar year; or (2) derive revenue or receive a discount on the price of goods or services from the sale of personal data and process or control the personal data of at least 25,000 consumers.

With the CPA, Colorado became the third state to enact a comprehensive privacy law. A number of additional other states have proposed bills for comprehensive consumer privacy laws and it is quite possible that certain of these bills will pass. The existence of comprehensive privacy laws in different states in the country, if enacted, will add additional complexity, variation in requirements, restrictions and potential legal risk, may require additional investment of resources in compliance programs, impact strategies and the availability of previously useful data, and has resulted in and may result in further increased compliance costs and/or changes in business practices and policies.

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 health data in the European Union is governed by the provisions of the General Data Protection Regulation, or GDPR and applicable data protection laws in effect in the member states of the European Union. The GDPR imposes a broad range of strict requirements on companies subject to the GDPR, such as including requirements relating to having legal bases for processing personal data relating to identifiable individuals and transferring such information outside the European Economic Area, or EEA, including to the U.S., 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, 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. The GDPR substantially increases the penalties to which we could be subject in the event of any non-compliance, including fines of up to €20,000,000 or 4% of total annual global revenue, whichever is greater. In addition, further to the UK's exit from the EU on January 31, 2020, the GDPR ceased to apply in the UK at the end of the transition period on December 31, 2020. However, as of January 1, 2021, the UK's European Union (Withdrawal) Act 2018 incorporated the GDPR (as it existed on December 31, 2020 but subject to certain UK specific amendments) into UK law, referred to as the UK GDPR. The UK GDPR and the UK Data Protection Act 2018 set out the UK's data protection regime, which is independent from but aligned to the EU's data protection regime. Non-compliance with the UK GDPR may result in monetary penalties of up to £17.5 million or 4% of worldwide revenue, whichever is higher. Although the UK is regarded as a third country under the EU's 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 EU 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.

To enable the transfer of personal data outside of the EEA or the UK, adequate safeguards must be implemented in compliance with European and UK data protection laws. On June 4, 2021, the EC issued new forms of standard contractual clauses for data transfers from controllers or processors in the EU/EEA (or otherwise subject to the GDPR) to controllers or processors established outside the EU/EEA (and not subject to the GDPR). The new standard contractual clauses replace the standard contractual clauses that were adopted previously under the EU Data Protection Directive. The UK is not subject to the EC's new standard contractual clauses but has published a draft version of a UK-specific transfer mechanism, which, once finalized, will enable transfers from the UK. We will be required to implement these new safeguards when conducting restricted data transfers under the EU and UK GDPR and doing so may require significant effort and additional cost.

Risks Related to Our Intellectual Property

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.

We rely on licenses to two core patents that are material to our business, including the development of the MyoPro, which expire in November 2023 and December 2023, respectively. We have entered into the MIT License for those certain patents that cover (i) a powered orthotic device worn on a patient's elbow or other joint, that senses relatively low level signals in the vicinity of the joint generated by a patient having spinal cord or other nerve damage and (ii) a method of providing rehabilitation movement training for a person suffering from nerve damage, stroke, spinal cord injury, neurological trauma or neuromuscular disorder in attempt to move a body part with a powered orthotic device. Our rights to use these patents will be subject to the continuation of and our compliance with the terms of those licenses.

We have certain revenue obligations, or Revenue Obligations under the MIT License. Our revenue exceeded $750,000 for the fiscal years ended December 31, 2022 and 2021, which satisfied the Revenue Obligations for each of those fiscal years. The Revenue Obligations are a continuing requirement of the MIT License. While we expect to exceed the required revenue and satisfy the Revenue Obligations in 2023, the final year of the MIT License, we cannot make any assurance that we will continue to comply with these obligations. Additionally, MIT has the right to terminate the MIT License upon any future uncured material breach of the agreement or if we fail to make any payments due under the agreement. If the MIT License is terminated for any reason, our business will be harmed. Specifically, if we were to lose access to these licenses, we would be unable to manufacture the MyoPro or develop new products until we obtained access to a comparable technology.

We may not control the prosecution, maintenance or filing of the patents to which we now hold or in the future intend to acquire licenses. Enforcement of our licensed patents or defense of any claims asserting the invalidity of these patents may be subject to the control or cooperation of our licensors. We cannot be certain that our licensors will prosecute, maintain, enforce and defend the licensed patent rights in a manner consistent with the best interests of our business. We also cannot be certain that drafting or prosecution of the licensed patents and patent applications by the relevant licensors have been or will be conducted in compliance with applicable law.

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 European Union, China, 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 European Union, or 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, as of December 31, 2022, we had 680,363 shares issuable upon the exercise of warrants, with a weighted-average exercise price of $8.30 per share, and 29,605 shares issuable upon the exercise of stock options under our equity incentive plans, with a weighted-average exercise price of $40.50 per share. In addition, we have 454,447 restricted stock units outstanding. In January 2023, we issued 6,830,926 pre-funded warrants in conjunction with our follow-on equity offering. Each pre-funded warrant is exercisable for one share of common stock at the nominal exercise price of $0.0001 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 June 9, 2017 to December 31, 2022, the high and low sales price of our common stock on the NYSE American has fluctuated from a low of $0.37 to a split adjusted high of $695.88 per share. During the period from January 1, 2023 to the date of the filing of this report, our stock price has ranged from $0.37 to $0.84.

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. 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, or DGCL, 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.

As a result of sales of shares of our Common Stock pursuant to our equity line of credit, our existing stockholders will experience immediate dilution and our stock price may decrease.

Pursuant to the Purchase Agreement, we may sell up to $5,000,000 of shares of our common stock at our discretion to Keystone, subject to satisfaction of certain conditions and limitations contained in the equity line facility. Because the purchase price under the facility includes a discount to prevailing market prices, the sale of shares of our common stock pursuant to the Purchase Agreement will have a dilutive impact on our existing stockholders. Keystone may resell some or all of the shares we issue to it under the Purchase Agreement and such sales could cause the market price of our common stock to decline, and such decline could be significant.

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, or 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.

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 as a public company, we may need to add additional finance staff. We may not be able to remediate any future material weaknesses, or to complete our evaluation, testing and any required remediation in a timely fashion. During the evaluation and testing process, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal controls are effective. 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, or IRS 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, 2022, we had U.S. federal and state net operating loss, or NOL, carryforwards of $72.7 million and $64.7 million, respectively, which begin to expire in the year 2028 and 2023 through 2043, respectively. Additionally, we had U.S. federal and state research and development tax credits, or tax credits, of $0.3 million and $0.1 million, respectively, which begin to expire in the year 2027 and 2036, 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, or 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, or NOLs or 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 $281,000 annual limitation on our ability to utilize pre-ownership change NOL's and that approximately $437,000 of our NOL's will expire unutilized. We believe that we may have experienced an ownership change as a result of our follow-on equity offering in January 2023. As of the date of this report, we have not determined the extent of any further limitations on our ability to utilize our NOL's. 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:

- We have a history of operating losses and our financial statements for the year ended December 31, 2022 include disclosures regarding there being substantial doubt about our ability to continue as a going concern.
- our ability to achieve reimbursement from third-party payers for our products, including the establishment of reimbursement codes from third-party payers for our products;
- our dependence upon external sources for the financing of our operations;
- our ability to operate our business during the COVID-19 pandemic, including manufacturing and delivery, sales, patient consultations, supply chain insurance reimbursement and employees;
- our ability to obtain and maintain our strategic collaborations and to realize the intended of such collaborations;
- our ability to effectively execute our business plan;
- 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 improve our products and develop new products;
- our ability to manage the growth of our operations over time;
- 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 maintain relationships with existing customers and develop relationships with new customers;
- our ability to compete and succeed in a highly competitive and evolving industry; 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 2. Properties

Our primary offices are located at 137 Portland St. in Boston, Massachusetts, where we have a sublease expiring in August 2023 consisting of 9,094 square feet of office and laboratory space, which has been extended as a result of a lease in the same building for 3,859 square feet of space to be used for manufacturing which expires in January 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 U.S.

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, 2023, the closing price per share of our common stock was $0.63 as reported on The NYSE American, and we had approximately 282 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 any future indebtedness that we may incur could preclude 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, 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, 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. Beginning in 2022, this is being done in some cases using a remote measurement kit supplied to the patient. 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 U.S., 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 70 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 and completed licensing of its technology from MIT in 2006.

Other milestones 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 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 ("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. This has enabled us to sell the MyoPro to individuals in the European Union (the "EU").
- In November 2018, we announced that the CMS had published two new codes (L8701, L8702) pursuant to our application for HCPCS codes which become effective in early 2019. The assignment of unique L-Codes, if followed by appropriate payment terms (which are still pending), would offer greater access to the MyoPro for Medicare beneficiaries.
- In 2019 we transitioned our business to become a direct provider of the MyoPro to patients and bill insurance companies directly.
- 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.

Recent Developments

China Joint Venture

On January 21, 2021, we entered into a definitive agreement with Beijing Ryzur Medical Investment Co., Ltd. ("Ryzur Medical"), a medical device manufacturer based in Beijing, to form a joint venture (the "JV") to manufacture and sell our current and future products in greater China, including Hong Kong, Macau and Taiwan (the "JV Agreement").

Majority ownership in the JV, named Jiangxi Myomo Medical Assistive Appliance Co., Ltd. (the "JV Company"), is held by Ryzur Medical and Wuxi Chinaleaf Medical Investment and Management Fund, a private fund that invests in growth opportunities in new technologies. We own a minimum 19.9% stake in the JV. Ryzur Medical and its partners have committed to invest a minimum of $8 million and up to $20 million in the JV over five years.

The JV Company was established on August 12, 2021. On December 29, 2021, we entered into an amendment to the JV Agreement, as well as a Technology License Agreement and a Trademark License Agreement (collectively, the "Agreements"). Under the Agreements, we and the JV Company have entered into a ten-year agreement to license our intellectual property, including recently issued patents in China and Hong Kong, and purchase MyoPro Control System units from us. Under the Agreements, we are entitled to receive an upfront license fee of $2.7 million, of which $1.0 million has been paid concurrent with the beginning of limited operations as of December 31, 2022. The JV Company has advised us that effects of COVID-19 in China are delaying the banking and government approvals necessary to pay the remainder of the license fee. We cannot be certain as to if or when the remaining license fee will be paid. If uncured, failure to pay us the required fees contemplated by the Agreements may entitle us to terminate such Agreements and withdraw from the joint venture. Pursuant to the Agreements, the JV Company has agreed to an escalating purchase commitment for a minimum of $10.75 million in MyoPro Control System Units during the next ten years, subject to receipt of regulatory approvals necessary to permit sales of the product in the greater China territory.

Equity Line of Credit

On August 2, 2022, the Company entered into a Common Stock Purchase Agreement ("Purchase Agreement") with Keystone Capital Partners ("Keystone"), establishing an equity line facility. On October 28, 2022, we filed a Definitive Proxy Statement for notice of a special Shareholders Meeting to be held on December 7, 2022 to vote on a proposal to permit us to sell additional shares of common stock under the Purchase Agreement, in excess of an exchange cap contained therein. We were unable to achieve a quorum for the meeting, and as a result, withdrew the proposal. See "Liquidity" for further discussion.

Equity Offering

In January 2023, we completed a public offering of our common stock, whereby we sold 13,169,074 shares of common stock and 6,830,926 pre-funded warrants at $0.325 per share. Each pre-funded warrant entitles the holder to one share of common stock upon exercise at a nominal exercise price of $0.0001 per share. Net proceeds from the transaction were approximately $5.7 million, and will be used to fund operations while we continue to work with CMS to obtain coverage and reimbursement for our products. See "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 in 2023 as we focus our efforts on patients with insurance payers who have reimbursed for the MyoPro in the past, grow our operations in Germany and invest in the enhancement of our MyoPro products.

Comparison of the year ended December 31, 2022 to the year ended December 31, 2021

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	
	2022	2021	$	%
Product revenue	$ 14,555,229	$ 13,856,374	$ 698,855	5%
License revenue	1,000,000	-	1,000,000	NM
Total revenue	15,555,229	13,856,374	1,698,855	12
Cost of revenue	5,302,133	3,544,097	1,758,036	50
Gross profit	$ 10,253,096	$ 10,312,277	$ (59,181)	-
Gross margin	65.9%	74.4%		(8.5%)

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 U.S. 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 our increased patient pipeline entering 2023 and through higher revenue from O&P practices outside of the United States.

Product revenue in 2022 increased by approximately $0.7 million, or 5% compared to 2021. The revenue increase was driven primarily by a higher average selling price, offset by a lower number of revenue units . Including the license revenue received from our joint venture partner in China, total revenue increased 12% compared to 2021. Revenues generated through the direct billing channel were approximately $10.7 million, or 74% of product revenue in 2022, compared to approximately $10.7 million, or 77% of product revenue in 2021.

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, royalties associated with licensed technologies and instruction.

Gross margin decreased to 65.9% for the year ended December 31, 2022, as compared to 74.4% in the comparable period of 2021. The decrease in gross margin was driven primarily by higher component costs and other costs in the current inflationary environment, unabsorbed fixed costs and an increase in the warranty reserve.

We expect our gross margins 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	
	2022	2021	$	%
Research and development	$ 2,482,489	$ 2,557,367	$ (74,878)	(3%)
Selling, general and administrative	18,442,811	18,022,975	419,836	2
Total operating expenses	$ 20,925,300	$ 20,580,342	$ 344,958	2%

Research and development

Research and development ("R&D") expenses consist of costs for our R&D personnel, including salaries, benefits, bonuses 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 enhance our existing products in 2023 and expect R&D costs to increase on an annual basis.

R&D expenses decreased by approximately $0.1 million or 3% in 2022 compared to 2021. The decrease during 2022 was driven primarily by lower prototype and other product development expenses related to the introduction of the MyoPro2+ in January 2022.

Selling, general and administrative

Selling expenses consist of costs for our field clinical staff, clinical training organization, and marketing personnel, including salaries, benefits, bonuses, 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 be roughly flat or decrease slightly in 2023 as a result of a reduction in force in January 2023 and efforts to reduce advertising spend while maintaining our existing lead generating capability.

General and administrative expenses consist primarily of costs for administrative, reimbursement, and finance personnel, including salaries, benefits, bonuses 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 slightly in 2023 as a result of increased incentive compensation expense, offset by the effect of the reduction in force in January 2023.

Selling, general and administrative expenses increased by approximately $0.4 million or 2% in 2022 compared to 2021. The increase was primarily due to higher advertising and insurance costs, offset by lower payroll costs related to lower bonus compensation in 2022.

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	
	2022	2021	$	%
Interest income	$ (88,731)	$ (1,612)	$ (87,119)	NM
Other expense, net	1,101	16,948	(15,847)	(94)%
Loss on equity investment	66,511	-	66,511	NM
Total other expense (income)	$ (21,119)	$ 15,336	$ (36,455)	(238)%

Interest income increased due to higher interest rates in 2022. Loss on equity investment represents our share of the losses incurred by the JV Company, which began limited operations in 2022.

Income tax expense

Income tax expense recorded during the years ended December 31, 2022 and 2021 represents the provision for income taxes for our wholly-owned subsidiary, Myomo Europe GmbH. The decrease in income tax expense relates to decreased income from Myomo Europe GmbH in 2022 compared to 2021.

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;
- 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 leased assets;
- 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:

	2022	2021
GAAP net loss	$ (10,721,022)	$ (10,372,329)
Adjustments to reconcile to Adjusted EBITDA:		
Interest income	(88,731)	(1,612)
Loss on equity investment	66,511	-
Income Taxes	69,937	88,928
Depreciation and amortization expense	192,799	145,995
Stock-based compensation	1,190,494	1,096,408
Adjusted EBITDA	$ (9,290,012)	$ (9,042,610)

Liquidity and Capital Resources

Liquidity

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

	December 31,	
	2022	2021
Cash	$ 5,345,967	$ 15,524,378
Working capital	5,613,521	14,903,804

We had working capital and stockholders' equity of approximately $5.6 million and $6.4 million respectively, as of December 31, 2022. We used $10.2 million in cash for operating activities during the year ended December 31, 2022.

We have historically funded our operations through financing activities, including raising equity and debt capital. 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. During the fourth quarter of 2022, we sold 692,914 shares of common stock under the Purchase Agreement with Keystone at a weighted average sales price of $0.683 per share, generating proceeds after fees and expenses of approximately $0.4 million. During 2021, $12.1 million was received from the exercise of warrants, including $4.8 million in net proceeds in October 2021 from a transaction to induce the exercise of warrants issued in conjunction with our equity offering in February 2020 at a reduced exercise price of $5.00 per share. These financing activities, in addition to funding of $1.1 million received from sales of common stock under our ATM Facility, with Alliance Global Partners during the year ended December 31, 2021 are helping us to sustain our operations. Considering our cash balance as of December 31, 2022 and net proceeds from the equity offering in January 2023 as well as our cash used from operations during the year ended December 31, 2022, management believes there is substantial doubt regarding our ability to continue as a going concern for the next 12 months from the date of this report.

Our operating plans are primarily focused on growing our revenues and limiting operating expenses through focusing our clinical and reimbursement efforts on patients with insurers that have previously reimbursed for the MyoPro. We believe the growth in our patient pipeline during 2022 provides us an opportunity to achieve increased revenue in 2023 compared to 2022. We intend to stop activities directed at increasing the number of payers that will reimburse for our products until CMS either begins to reimburse for the MyoPro or states its intention to do so. As a result, we have undertaken cost reduction activities, including the reduction of approximately 12% of our workforce in January 2023. This and other cost reduction efforts are expected to reduce our operating expenses by approximately $2.0 million in 2023. With respect to CMS, we expect to meet with the medical directors of the DME MAC's during the first quarter of 2023 to discuss coverage and reimbursement, and begin submitting claims on behalf of Medicare Part B beneficiaries as soon as practical thereafter.

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 achieve cash flow breakeven. If public health restrictions on travel and patient interaction are broadly reinstated in 2023 due to new variants of COVID-19 and increasing infections in the U.S., that will have an adverse effect on our business. We believe that we have access to capital resources through payment of the technology license fee associated with our JV in China, potential public or private equity offerings, exercises of outstanding warrants, additional debt financings, or other

means; however, we may be unable to raise sufficient additional capital when we need it or raise capital on favorable terms. As part of our equity offering in January 2023, we agreed to not sell any shares of our common stock to Keystone under the Purchase Agreement or under our ATM facility for a period of one year from the closing of the offering. We have remaining capacity under our Purchase Agreement with Keystone of approximately 1.0 million shares and approximately $0.3 million under our ATM facility. However, we are subject to the limitations imposed by General Instruction I.B.6 of Form S-3, which limits the amount of securities that we may issue under our registration statement on Form S-3 to one-third of our public float in any 12-month period. Further, the amount of stock that we may sell to Keystone under the Purchase Agreement is limited to a total of 1,349,334 shares of common stock, pursuant to an exchange cap imposed by the rules of the NYSE American, unless we obtain approval from our stockholders to lift such cap. As of December 31, 2022 1,008,458 million shares remain available under the exchange cap. Should we consider debt financing, such a transaction may require us to pledge certain assets and enter into covenants that could restrict certain business activities or our ability to incur further indebtedness and may contain other terms that are not favorable to our stockholders or us.

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,	
	2022	2021
Net cash used in operating activities	$ (10,233,542)	$ (9,547,695)
Net cash used in investing activities	(310,793)	(326,462)
Net cash provided by financing activities	376,858	13,167,666
Effect of foreign exchange rate changes on cash	(10,934)	(10,392)
Net increase (decrease) in cash and cash equivalents	$ (10,178,411)	$ 3,283,117

Operating Activities. The net cash used in operating activities for the year ended December 31, 2022 was primarily used to fund a net loss net approximately $10.7 million, adjusted for non-cash expenses in the aggregate amount of approximately $1.9 million of which approximately $1.1 million of non-cash adjustments related to stock-based compensation, and approximately $1.4 million of cash used from changes in operating assets and liabilities, primarily related to an increase in inventory and decreases in accounts payable and accrued expenses and operating lease liabilities.

The net cash used in operating activities for the year ended December 31, 2021 was primarily used to fund a net loss net approximately $10.4 million, adjusted for non-cash expenses in the aggregate amount of approximately $1.4 million of which approximately $1.1 million of non-cash adjustments related to stock-based compensation, and approximately $0.6 million of cash used 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, 2022 our cash used in investing activities of $0.3 million was primarily due to our investment in a joint venture with Ryzur Medical and purchases of equipment. Cash used in investing activities in 2021 was primarily for leasehold improvements to our new headquarters facility in Boston.

Financing Activities. During the year ended December 31, 2022 cash provided by financing activities of approximately $0.4 million was due to net proceeds received from stock issued under our equity line of credit.

During the year ended December 31, 2021 cash provided by financing activities of approximately $13.2 million was primarily due to approximately $12.1 million of net proceeds received from the exercise of warrants and net proceeds of approximately $1.1 million from the issuance of shares through our ATM facility.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements in the years ended December 31, 2022 and December 31, 2021.

Critical Accounting Policies and Estimates

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. Our significant estimates include the valuation of our deferred tax valuation allowances, valuation of stock-based compensation, warranty obligations, the discount rate on leases and inventory reserves.

Accounts Receivable

We carry accounts receivable at invoiced amounts less an allowance for doubtful accounts. We evaluate our accounts receivable on a continuous basis, and if necessary, establish an allowance for doubtful accounts based on a number of factors, including current credit conditions and customer payment history. We do not require collateral or accrue interest on accounts receivable and credit terms are generally 30 days.

Joint Venture

On March 28, 2022, we invested cash consideration of $199,000 for a 19.9% ownership stake in the JV Company. The JV Company, once fully operational will manufacture and sell our current and future products in greater China, including Hong Kong, Macau and Taiwan. We account for our investment in the JV Company under the equity method because we exert significant influence over its management. The investment is included in total assets on the consolidated balance sheet. There was no impairment charge for the year ended December 31, 2022 associated with this equity investment. We record our share of the JV Company's earnings in our consolidated statement of operations in other expense (income).

Inventories

Inventories are recorded at the lower of average cost or net realizable value. Cost is determined using average cost, which approximates the first-in, first out (FIFO) method. We reduce 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.

Research and Development Costs

We expense research and development costs as incurred. Research and development costs primarily consist of salaries and benefits, facility and overhead costs, and outsourced research activities.

Revenue Recognition

Accounting for revenues under ASC 606 and all the related amendments (Topic 606) requires revenue 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, we recognize revenue at a point in time.

We recognize 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
5) Recognition of revenue when, or as, performance obligations are satisfied

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

Product Revenue

Increasingly, we derive our revenue from direct billing. We also derive revenue from the sale of our products to O&P providers in the United States and internationally and the VA. Under direct billing, we recognize revenue when all of the following criteria are met:

(i) Our 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.

(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 certain insurance companies where we have demonstrated sufficient payment history, we recognize revenue when we receive 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 we expect to receive in exchange for the device. These insurers represented approximately 44% and 39% of the direct billing channel revenue in 2022 and 2021, respectively. Depending on the timing of product deliveries to customers, which is when cost of revenue must be recorded, and when we meet the criteria to record revenue, there may be fluctuations in gross margin.

For revenues derived from O&P providers, the VA and rehabilitation hospitals, we recognize revenue when control passes to the customer in an amount that reflects the consideration we expect to receive in exchange for those services. Revenues 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. In certain cases, we ship its products to O&P providers pending reimbursement from non-government, third-party payers. As a result of this arrangement, elements of the revenue recognition criteria have not been met upon shipment. In this instance, we recognize revenue when the amount is estimable and we determine it is probable that payment will be received. In many cases, we are not able to recognize revenue in these situations until payment is received, as then all of the revenue recognition criteria have been met.

We have elected to record taxes collected from customers on a net basis and do not include tax amounts in revenue or cost of revenue.

License Revenue

If a license to our intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, we recognize 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.

Under the JV Agreements, we are entitled to receive an upfront license fee of $2.7 million, of which $1.0 million has been paid and recognized during the year ended December 31, 2022. We will recognize revenue on the remaining amount due upon payment as the fee has not been paid according the to the contractual terms.

Leases

We account for leases under Accounting Standards Codification ("ASC") Topic 842, leases. We assess whether a contract is or contains a lease at inception of the contract and recognize 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, we recognize the lease payments as an operating expense on a straight-line basis over the term of the lease.

Income Taxes

We account for income taxes under ASC 740 Income Taxes. 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 our 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. We believe there are no uncertain tax positions that could have a material impact on our financial condition, results of operations or cash flows.

Stock-Based Compensation

We account for stock awards to employees and non-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.

Net Loss per Share

Basic loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding during the period. Diluted net loss per common share is computed by dividing net loss by the weighted average number of common shares outstanding, plus potentially dilutive common shares. Convertible debt, preferred stock, restricted stock units, stock options and warrants are excluded from the diluted net loss per share calculation when their impact is antidilutive. We reported a net loss for the years ended December 31, 2022 and 2021, and as a result, all potentially dilutive common shares are considered antidilutive for these years.

Recent Accounting Standards

In September 2022, the FASB issued ASU 2022-04, Liabilities - Supplier Finance Programs (Subtopic 405-50): Disclosure of Supplier Finance Program Obligations that requires entities that use supplier finance programs in connection with the purchase of goods and services to disclose the key terms of the programs and information about obligations outstanding at the end of the reporting period, including a rollforward of those obligations. The guidance does not affect the recognition, measurement or financial statement presentation of supplier finance program obligations. The new standard's requirements to disclose the key terms of the programs and information about obligations outstanding are effective for fiscal years, including interim periods, beginning after December 15, 2022, except for the requirement to disclose a rollforward of obligations outstanding will be effective for fiscal years beginning after December 15, 2023. Early adoption is permitted. We are currently evaluating the effect of this new standard, which is not expected to have a material impact on our financial position and results of operations.

In May 2021, the FASB issued ASU 2021-04 Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options (a consensus of the FASB Emerging Issues Task Force). The amendments in this update are effective for all entities for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Early application is permitted, including in an interim period as of the beginning of the fiscal year that includes that interim period. We adopted the provisions of ASU 2021-04 in the fourth quarter of 2021. The implementation resulted in a deemed dividend of approximately $640,000 on the discounting and repricing of certain warrants.

Quantitative and Qualitative Disclosure about Market Risk

Our unrestricted cash and cash equivalents, totaling approximately $5.3 million as of December 31, 2022, 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. 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, 2022, the end of the period covered by this Annual Report on Form 10-K. Based upon such evaluation, our Chief Executive Officer and our Chief Financial Officer have concluded that our disclosure controls and procedures were effective as of such date, such that the information required to be disclosed by us in our SEC reports is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosures.

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 internal control system was designed to provide reasonable assurance to our management and board of directors regarding the preparation and fair presentation of published financial statements.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2022. 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 we believe that as of December 31, 2022, our internal control over financial reporting is effective based on those criteria.

Changes in Internal Control over Financial Reporting

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, 2022 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

None.

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 2022 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, 2022.

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 2022 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, 2022.

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 2022 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, 2022.

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 2022 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, 2022.

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 2022 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, 2022.

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	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	License Agreement between the Company and the Massachusetts Institute of Technology, dated October 30, 2006 (Incorporated by reference to Exhibit 6.18 contained in the Registrant's Form 1-A filed on January 6, 2017)
10.5	First Amendment to the License Agreement between the Company and the Massachusetts Institute of Technology, dated May 5, 2010 (Incorporated by reference to Exhibit 6.19 contained in the Registrant's Form 1-A filed on January 6, 2017)

10.6+	Form of Indemnification Agreement (Incorporated by reference to Exhibit 6.21 contained in the Registrant's Form 1-A filed on January 6, 2017)
10.7	Waiver to License Agreement between the Company and the Massachusetts Institute of Technology, dated November 15, 2016 (Incorporated by reference to Exhibit 6.22 contained in the Registrant's Form 1-A filed on January 6, 2017)
10.8+	Employment Agreement between the Company and Paul R. Gudonis, dated December 23, 2016 (Incorporated by reference to Exhibit 6.24 contained in the Registrant's Form 1-A filed on January 6, 2017)
10.9+	Employment Agreement, dated February 6, 2019, by and between the Company and David Henry (Incorporated by reference to Exhibit 10.2 contained in the Registrant's Form 8-K file on February 6, 2019)
10.10+	Employment Agreement Amendment 1, dated December 13, 2019, by and between the Company and Paul R. Gudonis (Incorporated by reference to Exhibit 10.1 contained in the Registrant's Form 8-K filed on December 18, 2019)
10.11+	Executive Employment Agreement, dated April 22, 2021, by and between the Company and Paul Gudonis (Incorporated by reference to Exhibit 10.1 contained in the Registrant's Form 8-K filed on April 28, 2021)
10.12+	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)
10.13+	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)
10.14**	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).
10.15**	Sublease between Myomo, Inc. and Upstatement, LLC dated December 17, 2020. (Incorporated by reference to Exhibit 10.26 contained in the Registrant's Annual Report on Form 10-K filed March 10, 2021)
10.16**	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).
10.17**	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).
10.18	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 From 10-K dated March 11, 2022).
10.19	Common Stock Purchase Agreement dated August 2, 2022 by and between Myomo, Inc., and Keystone Capital Partners,LLC. (Incorporated by reference to Exhibit 1.1 contained in the Registrant's Form 8-K dated August 2, 2022)
10.20	Form of Securities Purchase Agreement between Myomo 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).
10.21	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).
21.1*	List of Subsidiaries

23.1*	Consent of Marcum LLP
31.1*	Certification of Chief Executive 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 Financial 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 Executive 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 Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101*	The following financial information from the Registrant's Annual Report on Form 10-K for the year ended December 31, 2022 formatted in 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 Company's Annual Report on Form 10-K for the year ended December 31, 2022, 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, on March 13, 2023.

Myomo, Inc.,

By: /s/ Paul R. Gudonis

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 13, 2023
/s/ David A. Henry **David A. Henry**	Chief Financial Officer (*Principal Financial and Accounting Officer)*	March 13, 2023
/s/ Amy Knapp **Amy Knapp**	Director	March 13, 2023
/s/ Thomas A. Crowley, Jr. **Thomas A. Crowley, Jr.**	Director	March 13, 2023
/s/ Thomas F. Kirk **Thomas F. Kirk**	Director	March 13, 2023
/s/ Milton M. Morris **Milton M. Morris**	Director	March 13, 2023
/s/ Yitzchak Jacobovitz **Yitzchak Jacobovitz**	Director	March 13, 2023

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Myomo, Inc.

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Myomo, Inc. (the "Company") as of December 31, 2022 and 2021, the related consolidated statements of operations, comprehensive loss, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2022, 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, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 1, the Company has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits 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 13, 2023

MYOMO, INC.
CONSOLIDATED BALANCE SHEETS

December 31,	2022	2021
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 5,345,967	$ 15,524,378
Accounts receivable, net	1,896,163	1,960,037
Inventories, net	1,399,865	808,308
Prepaid expenses and other current assets	573,462	799,164
Total Current Assets	9,215,457	19,091,887
Equipment, net	194,283	275,289
Operating lease assets with right-of-use	508,743	632,906
Investment in Jiangxi Myomo Medical Assistive Appliance Co. Ltd.	132,489	-
Other Assets	111,034	95,330
Total Assets	$ 10,162,006	$ 20,095,412
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable and accrued expenses	3,179,362	3,910,639
Current operating lease liability	353,701	333,380
Income taxes payable	48,220	39,145
Deferred revenue	20,653	249
Total Current Liabilities	3,601,936	4,283,413
Non-current operating lease liability	200,207	401,622
Deferred revenue	498	1,246
Total Liabilities	3,802,641	4,686,281
Commitments and Contingencies	—	—
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; 7,750,635 and 6,869,753 shares issued as of December 31, 2022 and 2021, respectively, and 7,750,608 and 6,869,726 shares outstanding as of December 31, 2022 and 2021, respectively.	775	687
Additional paid-in capital	95,105,071	93,537,807
Accumulated other comprehensive income (loss)	43,227	(60,677)
Accumulated deficit	(88,783,244)	(78,062,222)
Treasury stock, at cost; 27 shares of common stock	(6,464)	(6,464)
Total Stockholders' Equity	6,359,365	15,409,131
Total Liabilities and Stockholders' Equity	$ 10,162,006	$ 20,095,412

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

MYOMO, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

For the years ended December 31,	2022	2021
Revenue		
Product Revenue	$ 14,555,229	$ 13,856,374
License Revenue	1,000,000	-
	15,555,229	13,856,374
Cost of revenue	5,302,133	3,544,097
Gross profit	10,253,096	10,312,277
Operating expenses:		
Research and development	2,482,489	2,557,367
Selling, general and administrative	18,442,811	18,022,975
	20,925,300	20,580,342
Loss from operations	(10,672,204)	(10,268,065)
Other expense (income)		
Interest income	(88,731)	(1,612)
Other expense, net	1,101	16,948
Loss on equity investment	66,511	-
	(21,119)	15,336
Loss before income taxes	(10,651,085)	(10,283,401)
Income tax expense	69,937	88,928
Net loss	$ (10,721,022)	$ (10,372,329)
Deemed dividend on discounting and repricing of warrants	-	(639,953)
Net loss attributable to common stockholders	$ (10,721,022)	$ (11,012,282)
Weighted average number of common shares outstanding:		
Basic and diluted	7,051,447	5,830,353
Net loss per share available to common stockholders:		
Basic and diluted	$ (1.52)	$ (1.89)

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,	2022	2021
Net loss	$ (10,721,022)	$ (10,372,329)
Other comprehensive gain (loss), net of tax:		
Foreign currency translation gain (loss)	103,904	(47,987)
Other comprehensive gain (loss)	103,904	(47,987)
Comprehensive loss	$ (10,617,118)	$ (10,420,316)

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, 2022 and 2021

	Common stock		Additional paid-in capital	Comprehensive (loss) income	Accumulated deficit	Treasury stock		Total Stockholders' Equity
	Shares	Amount				Shares	Amount	
Balance, January 1, 2021	4,593,184	$ 457	$ 79,273,964	$ (12,690)	$ (67,689,893)	27	$ (6,464)	$ 11,565,374
Exercise of warrants, net of offering costs of $349,400	2,015,243	204	12,067,661	—	—	—	—	12,067,865
Common stock issued upon vesting of restricted stock units	153,357	15	(15)	—	—	—	—	—
Proceeds from issuances under at-market sales facility, net of offering costs of $152,853	107,500	11	1,099,789	—	—	—	—	1,099,800
Restricted stock vested	30			—	—	—	—	—
Exercise of stock options	439	—	—	—	—	—	—	—
Stock-based compensation	—	—	1,096,408	—	—	—	—	1,096,408
Unrealized loss on foreign currency	—	—	—	(47,987)	—	—	—	(47,987)
Net loss	—	—	—	—	(10,372,329)	—	—	(10,372,329)
Balance, December 31, 2021	6,869,753	687	93,537,807	(60,677)	(78,062,222)	27	(6,464)	15,409,131
Exercise of warrants	666	—	—	—	—	—	—	—
Common stock issued upon vesting of restricted stock units	137,302	14	(14)	—	—	—	—	—
Common stock issued for commitment fee under equity line of credit	50,000	5	(5)	—	—	—	—	—
Proceeds from issuances under equity line of credit net of costs	692,914	69	376,789	—	—	—	—	376,858
Stock-based compensation	—	—	1,190,494	—	—	—	—	1,190,494
Unrealized gain on foreign currency	—	—	—	103,904	—	—	—	103,904
Net Loss	—	—	—	—	(10,721,022)	—	—	(10,721,022)
Balance, December 31, 2022	7,750,635	$ 775	$ 95,105,071	$ 43,227	$ (88,783,244)	27	$ (6,464)	$ 6,359,365

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,	2022	2021
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (10,721,022)	$ (10,372,329)
Adjustments to reconcile net loss to net cash used in operations:		
Depreciation	192,799	145,995
Stock-based compensation	1,190,494	1,096,408
Loss on disposal of asset	-	202
Bad debt expense	26,075	—
Loss on equity investment	66,511	—
Amortization of right-of-use assets	349,828	189,968
Other non-cash charges	111,755	(19,929)
Changes in operating assets and liabilities:		
Accounts receivable	47,445	(1,046,282)
Inventories	(607,400)	(118,222)
Prepaid expenses and other current assets	224,677	(323,644)
Other assets	(15,704)	—
Accounts payable and accrued expenses	(711,898)	1,113,235
Operating lease liabilities	(406,759)	(92,525)
Deferred revenue	19,657	(2,512)
Other liabilities	—	(118,060)
Net cash used in operating activities	(10,233,542)	(9,547,695)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of equipment	(111,793)	(326,462)
Investment in China Joint Venture	(199,000)	-
Net cash used in investing activities	(310,793)	(326,462)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from issuances under equity line of credit net of costs	376,858	—
Proceeds from exercise of warrants	—	12,067,865
Proceeds from at the market offering, net of offering costs	—	1,099,801
Net cash provided by financing activities	376,858	13,167,666
Effect of foreign exchange rate changes on cash	(10,934)	(10,392)
Net (decrease) increase in cash and cash equivalents	(10,178,411)	3,283,117
Cash and cash equivalents beginning of year	15,524,378	12,241,261
Cash and cash equivalents end of year	$ 5,345,967	$ 15,524,378
SUPPLEMENTAL DISCLOSURE OF CASH FLOW INFORMATION		
Cash paid during the period for income taxes	$ 4,889	$ —
Non-cash financing and investing activities		
Issuance of 50,000 shares of common stock as commitment fee for future financing	$ 5	$ —
Right of use assets obtained in exchange for lease obligations	$ 225,665	$ 654,091

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 Boston, 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.

Going Concern and Management Plans

The Company incurred net losses of approximately $10,721,000 and $10,372,000 during the years ended December 31, 2022 and 2021, respectively, and has an accumulated deficit of approximately $88,783,000 and $78,062,000 at December 31, 2022 and 2021, respectively. Cash used in operating activities was approximately $10,234,000 and $9,548,000 for the years ended December 31, 2022 and 2021, respectively.

The Company has historically funded its operations through financing activities, including raising equity and debt capital. In January 2023, the Company completed an equity offering under which it 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. (See Note 13 - Subsequent Events for further discussion.) During the fourth quarter of 2022, the Company sold 692,914 shares of common stock under a Common Stock Purchase Agreement (the "Purchase Agreement") with Keystone Capital Partners ("Keystone"), generating proceeds after fees and expenses of approximately $0.4 million. (See Note 7 - Common Stock for further discussion.) During 2021, $12.1 million was received from the exercise of warrants, including $4.8 million in net proceeds in October 2021 from a transaction to induce the exercise of warrants issued in conjunction with its equity offering in February 2020 at a reduced exercise price of $5.00 per share. These financing activities, in addition to funding of $1.1 million received from sales of common stock under an At Market Sales Facility, or ATM facility, with Alliance Global Partners ("AGP") during the year ended December 31, 2021 is enabling the Company to sustain its operations. Considering the Company's cash balance as of December 31, 2022 and net proceeds from the equity offering in January 2023 and its cash used from operations during the year ended December 31, 2022, management believes there is substantial doubt regarding its ability to continue as a going concern.

Management's operating plans are primarily focused on growing its revenues and limiting operating expenses through focusing its clinical and reimbursement efforts on patients with insurers that have previously reimbursed for the MyoPro. The Company believes the growth in its patient pipeline during 2022 provides an opportunity to accelerate its revenue growth in 2023. The Company has stopped activities geared toward increasing the number of payers that will reimburse for its products until the Company receives reimbursement for its products provided to Medicare Part B beneficiaries from the Centers for Medicare and Medicaid Services ("CMS"), or CMS states in intention to reimburse for its products. As a result, the Company has undertaken cost reduction activities, including the reduction of approximately 12% of its workforce in January 2023. This and other cost reduction efforts are expected to reduce its operating expense run-rate by approximately $2.0 million in 2023. With respect to CMS, the Company expects to meet with the medical directors of CMS's administrative billing contractors, referred to as the DME MAC's, before the end of the first quarter of 2023 to discuss coverage and reimbursement, and begin submitting claims on behalf of Medicare Part B beneficiaries as soon as practical thereafter. The Company's success is dependent upon reimbursement of its products by insurance companies and government-controlled health care plans such as Medicare and Medicaid in the United States and Statutory Health Insurance plans in Germany, which could prevent our revenues from growing to the level necessary to achieve cash flow breakeven. If public health restrictions on travel and patient interaction are broadly reinstated in 2023 due to new variants of COVID-19 and

increasing infections in the U.S., that will have an adverse effect on the Company's business, and it is possible that the Company will need to raise additional capital to sustain its operations through 2023.

The Company believes that it has access to capital resources through payment of the technology license fee associated with its joint venture in China, possible public or private equity offerings, exercises of outstanding warrants, additional debt financings, or other means; however, the Company may be unable to raise sufficient additional capital when it needs it or raise capital on favorable terms. As part of the Company's equity offering in January 2023, the Company agreed to not sell any shares of its common stock to Keystone under the Purchase Agreement or under its ATM Facility for a period of one year from the closing of the offering. The Company has remaining capacity under its Purchase Agreement with Keystone of approximately 1.0 million shares and approximately $0.3 million under its ATM Facility. However, due to its public float, the amount of securities the Company may sell from time to time under the registration statement which registered the ATM Facility may be subject to the limitations imposed by General Instruction I.B.6 of Form S-3. Further, selling the full $5 million to Keystone under the Purchase Agreement requires approval from shareholders to sell shares in excess of the exchange cap under the rules of the NYSE American. Should the Company consider debt financing, such a transaction may require the Company to pledge certain assets and enter into covenants that could restrict certain business activities or its ability to incur further indebtedness and may contain other terms that are not favorable to its stockholders or the Company.

If the Company is unable to obtain adequate funds on reasonable terms, the Company may be required to significantly curtail or discontinue operations or obtain funds by entering into financing agreements on unattractive terms. There can be no assurance that the Company will be successful in implementing its plans.

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.

Reclassifications

Certain prior year amounts have been reclassified to conform to current year's presentation, which management does not consider to be material.

Comprehensive Loss

Comprehensive loss includes all changes in equity during a period, except those resulting from investments by stockholders and distributions to stockholders. The Company's comprehensive loss includes changes in foreign currency translation adjustments. There were no reclassifications out of accumulated other comprehensive loss in the years ended December 31, 2022 and 2021.

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 deferred tax valuation allowances, valuation of stock-based compensation, warranty obligations and reserves for slow-moving inventory.

Cash and Cash Equivalents

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, 2022 and 2021.

Accounts Receivable and Allowance for Doubtful Accounts

The Company reports accounts receivable at invoiced amounts less an allowance for doubtful accounts. The Company evaluates its accounts receivable on a continuous basis, and if necessary, establishes an allowance for doubtful 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, 2022 and 2021, the Company recorded an allowance for doubtful accounts which was immaterial to the financial statements.

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 consigned inventories is reduced by the value of MyoPro devices that will not be sold based on historical experience.

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 depreciated 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 sometimes provided by the Company to its indirect sales channel for marketing and patient evaluation purposes. These units are manufactured by the Company and are expensed in the statements of operations to selling, general, and administrative expense. During the years ended December 31, 2022 and 2021, the Company charged to operations approximately $19,700 and $22,200, respectively, for these units. Demonstrations units provided to its own sales force are capitalized as equipment on the Company's balance sheet.

Test units are provided to research and development staff to use in their development process and to end users who are given free 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, 2022 and 2021 the Company charged to operations approximately $11,200 and $17,400, respectively, 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, 2022 and 2021.

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 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"). Under the Agreements, we and the JV Company have entered into a ten-year agreement to license our 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 is included in total assets on the consolidated balance sheet. There was no impairment charge for the year ended December 31, 2022, associated with this equity investment. The Company records its share of the JV Company's earnings in its consolidated statement of operations in other expense (income). The Company recorded a loss on equity investment of approximately $66,500 for the year ended of December 31, 2022.

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
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 O&P providers in the U.S. 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.

(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 certain insurance companies where the Company has demonstrated sufficient payment history, the Company recognizes 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 expect to receive in exchange for the device. During 2022 and 2021, the Company made such a determination for certain insurers. These insurers represented approximately 44% and 39% of direct billing channel revenue in 2022 and 2021, respectively.

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, 2022 and 2021, the Company recognized revenue of approximately $2,044,000 and $2,050,300, respectively, from O&P providers or 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, the VA, and distributors, 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. In certain cases, the Company ships its products to O&P providers pending reimbursement from non-government, third-party payers. As a result of this arrangement, elements of the revenue recognition criteria have not been met upon shipment. In this instance, the Company recognizes revenue when payment has been received, as then all of the revenue recognition criteria has been met.

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, of which $1.0 million has been paid and recognized as licensee revenue during the year ended December 31, 2022. The Company will recognize revenue on the remaining amount due upon payment as the fee has not been paid according the to the contractual terms and as a result collectability is not 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 $21,200 and $1,500 of deferred revenue as of December 31, 2022 and 2021, respectively. The Company expects the current portion of deferred revenue as of December 31, 2022 to be recognized in 2023.

Disaggregated Revenue from Contracts with Customers

The following table presents revenue by major source:

	2022	2021
Clinical/medical providers	$ 4,841,424	$ 3,186,248
Direct-to-patient	10,713,805	10,670,126
License revenue	1,000,000	-
Total revenue from contracts with customers	$ 15,555,229	$ 13,856,374

Geographic Data

The Company generated 81% of its revenue from the United States, 12% from Germany, 6% from China and 1% from other international locations for the year ended December 31, 2022. The Company generated 89% of its revenue from the United States, 10% from Germany and 1% from other international locations for the year ended December 31, 2021.

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, 2022 and December 31, 2021, the Company recorded cost of goods sold of approximately $441,600 and $21,400, 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 statement 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 2019. Currently, there are no income tax audits in process.

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 gain (loss). The Company recorded a gain of approximately $103,900 and a loss of approximately $48,000 during the years ended December 31, 2022 and 2021, respectively, which are included in accumulated other comprehensive income (loss) in the consolidated balance sheets. Transaction and translation foreign exchange gains and losses from a foreign currency to the functional currency are included in selling, general and administrative expenses in the consolidated statement of operations. Such amounts were immaterial for the years ended December 31, 2022 and 2021. 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, 2022 and 2021, respectively, and as a result, all potentially dilutive common shares are considered antidilutive for these periods.

Potentially common shares issuable at December 31, 2022 and 2021 consist of:

	2022	2021
Options	29,605	31,447
Warrants	680,363	693,643
Restricted stock units	454,447	292,473
Total	1,164,415	1,017,841

Advertising

The Company charges the costs of advertising to operating expenses as incurred. Advertising expense amounted to approximately $4,069,300 and $3,587,300 in 2022 and 2021, respectively.

Research and Development Costs

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

Recent Accounting Standards

In September 2022, the FASB issued ASU 2022-04, Liabilities - Supplier Finance Programs (Subtopic 405-50): Disclosure of Supplier Finance Program Obligations that requires entities that use supplier finance programs in connection with the purchase of goods and services to disclose the key terms of the programs and information about obligations outstanding at the end of the reporting period, including a rollforward of those obligations. The guidance does not affect the recognition, measurement or financial statement presentation of supplier finance program obligations. The new standard's requirements to disclose the key terms of the programs and information about obligations outstanding are effective for fiscal years, including interim periods, beginning after December 15, 2022, except for the requirement to disclose a rollforward of obligations outstanding will be effective for fiscal years beginning after December 15, 2023. Early adoption is permitted. The Company is currently evaluating the effect of this new standard, which is not expected to have a material impact on its financial position and results of operations.

In May 2021, the FASB issued ASU 2021-04 Earnings Per Share (Topic 260), Debt—Modifications and Extinguishments (Subtopic 470-50), Compensation—Stock Compensation (Topic 718), and Derivatives and Hedging—Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options (a consensus of the FASB Emerging Issues Task Force). The amendments in this update are effective for all entities for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. Early application is permitted, including in an interim period as of the beginning of the fiscal year that includes that interim period. The Company adopted the provisions of ASU 2021-04 in the fourth quarter of 2021. The implementation resulted in a deemed dividend of approximately $640,000 on the discounting of certain warrants.

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:

	2022	2021
Finished goods	$ 512,028	$ 176,082
Work in Process	18,971	23,161
Rental units	51,694	62,531
Parts and subassemblies	903,581	584,996
	1,486,274	846,770
Less: Reserve for rental and trial units	(86,409)	(38,462)
Inventories, net	$ 1,399,865	$ 808,308

Note 4 — Equipment, net

Equipment consists of the following at December 31:

	2022	2021
Computer equipment	$ 249,621	$ 180,979
Sales demonstration units	210,624	186,951
R&D tools and molds	52,644	52,644
Leasehold improvements	254,043	246,268
Furniture and fixtures	60,836	40,341
	827,768	707,183
Less: accumulated depreciation	(633,485)	(431,894)
Equipment, net	$ 194,283	$ 275,289

Depreciation expense was approximately $192,800 and $146,000 for the years ended December 31, 2022 and 2021, 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 and Disclosures" ("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 are a money market fund that limits its investments to only short-term U.S. Treasury securities and repurchase agreements related to these securities.

Cash equivalents, which are measured at fair value, were as follows At December 31, 2022:

	In Active Markets for Identical Assets or Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	December 31, 2022 Total
Cash equivalents	$ 4,350,657	—	—	$ 4,350,657

Cash equivalents, which are measured at fair value, were as follows at December 31, 2021:

	In Active Markets for Identical Assets or Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)	December 31, 2021 Total
Cash equivalents	$ 14,803,456	—	—	$ 14,803,456

Note 6 – Accounts Payable and other Accrued Expenses

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

	2022	2021
Trade payables	$ 569,681	$ 723,352
Accrued compensation and benefits	959,228	2,188,869
Accrued professional services	124,548	108,417
Deferred payroll taxes under CARES Act	-	113,423
Warranty reserve	234,647	176,281
Customer Deposits	753,232	192,501
Other	538,026	407,796
	$ 3,179,362	$ 3,910,639

Note 7 — Common Stock

On August 2, 2022, ("the "Agreement Date"") the Company entered into a Purchase Agreement with Keystone, establishing an equity line facility under which the Company, at its sole discretion, can direct Keystone to purchase the Company's common stock from time to time through delivery of a purchase notice ("Notice"). The purchase price is at the lesser of prevailing market prices of the Company's common stock as defined in the Purchase Agreement, at a 10% discount. The Company can sell shares of common stock to Keystone up to the Maximum Amount, provided that the Company has agreed to issue no more than 1,399,334 shares of common stock at a discount (the "Minimum Shares"), representing 19.99% of the Company's outstanding shares on the Agreement Date (the "Exchange Cap"), of which 50,000 shares were issued to Keystone as a commitment fee after closing of the transaction. During the fourth quarter of 2022, the Company sold 692,914 shares to Keystone at a weighted average sales price of $0.683 per share, generating proceeds after fees and expenses of approximately $376,900. In order to sell more than the Minimum Shares the Company's shareholders must vote in favor of permitting the Company to sell shares in excess of the Exchange Cap. Of the shares sold to Keystone, sales of 352,038 shares were made above market according to the rules of the NYSE American, thus were not subject to the Exchange Cap. As a result, 1,008,458 shares remain to be sold under the Exchange Cap as of December 31, 2022. Keystone's obligation to purchase shares of the Company's common stock is subject to the Company's ability to maintain an effective registration statement, continued listing on the NYSE American or other trading market and a minimum price per share of $0.50, among other conditions. Keystone's beneficial ownership of the common stock is limited to 4.99% of the Company's outstanding common stock during the Term.

In addition to the commitment fee, on the Agreement Date the Company paid Keystone $20,000 for its expenses incurred in conjunction with the transaction. The commitment fee was recorded to common stock and Keystone's expenses reimbursed by the Company were recorded to additional paid-in capital as of December 31, 2022.

In June 2021, the Company entered into an ATM Facility with AGP. Under the ATM Facility, the Company may sell up to an aggregate of $15 million of the Company's common stock from time to time and shall pay to AGP cash commissions of 3.0% of the gross proceeds of sales of common stock under the ATM Facility. There were no sales under the ATM Facility during the year ended December 31, 2022. The Company sold 107,500 shares under the ATM Facility during the year ended December 31, 2021, at an average selling price $12.02 per share, generating net proceeds after sales commissions and offering expenses of approximately $1,099,800. In conjunction with entering into the Purchase Agreement with Keystone, the Company reduced the amount available to sell under the ATM Facility to $0.3 million. This amount remains available for sale at December 31, 2022.

In conjunction with the Company's equity offering in January 2023 (See Note 13 - Subsequent Events), the Company agreed to not sell any shares of its common stock under the Purchase Agreement or its ATM facility for a period of one year from the closing date.

No shares of common stock were issued through the exercise of stock options during the year ended December 31, 2022. The Company issued 439 shares of common stock through the exercise of stock options in the year ended December 31, 2021.

During the years ended December 31, 2022 and 2021, the Company issued 137,302 and 153,357 shares of common stock respectively, upon the vesting of restricted stock units.

During the year ended December 31, 2021, the Company issued 30 shares of common stock upon the vesting of restricted stock awards.

Note 8 — Stock Award Plans and Stock-Based Compensation

Equity Incentive Plan

On June 19, 2018, the Company's Shareholders and 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.

On January 1, 2022 and 2021, the number of shares reserved and available for issuance under the 2018 Plan increased by 274,789 and 183,726 shares, respectively. At December 31, 2022, there were 74,120 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 Company's 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, 2022 and 2021 is as follows:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Life (years)	Intrinsic Value
Balance at January 1, 2021	24,088	$ 51.2900	7.51	$ 23,194
Granted	9,250	17.0700		
Forfeited or cancelled	(1,452)	50.9600		
Exercised	(439)	0.0500		
Balance at December 31, 2021	31,447	40.5800	7.51	$ 23,194
Granted	1,700	8.0000		
Forfeited or cancelled	(3,293)	28.0400		
Expired	(249)	9.1900		
Balance at December 31, 2022	29,605	$ 40.5000	6.52	$ 587
Options exercisable at December 31, 2021	17,390	$ 63.2600	5.97	$ 12,392
Options exercisable at December 31, 2022	20,229	$ 54.9600	5.67	$ 587

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, 2022 and 2021. The weighted-average grant date fair value per share was $6.92 and $8.32 for the years ended December 31, 2022 and 2021, respectively. The following weighted average assumptions underlying the calculation of grant date fair value are as follows:

	2022	2021
Volatility	117.18%	111.90%
Risk-free interest rate	1.68%	1.15%
Weighted-average expected option term (in years)	6.25	6.25
Dividend yield	0%	0%

The stock price volatility for the Company's options was determined using the Company's historical volatility since its initial public offering in June 2017. The risk-free interest rate was derived from U.S. Treasury rates existing on the date of grant for the applicable expected option term. The expected term represents the period of time that options are expected to be outstanding. Because the Company has only very limited historical exercise behavior, it determines the expected life assumption using the simplified method, which is an average of the contractual term of the option and its ordinary vesting period. The expected dividend yield assumption is based on the fact that the Company has never paid, nor has any intention to pay, cash dividends.

Restricted Stock Awards

There were no restricted stock awards outstanding as of December 31, 2022 and 2021. Restricted stock activity for the year ended December 31, 2021 is summarized below:

	Number of Shares	Weighted average grant date fair value	Weighted average remaining contractual life (in years)
Outstanding as January 1, 2021	30	$ 202.50	0.62
Awarded	-	-	
Vested	(30)	202.50	
Canceled	-	-	
Outstanding as December 31, 2021	-	$ —	-

Restricted Stock Units

Restricted stock unit "RSU" activity for the years ended December 31, 2022 and 2021 is summarized below:

	Number of Shares	Weighted average grant date fair value	Weighted average remaining contractual life (in years)
Outstanding as of January 1, 2021	276,568	$ 4.22	2.36
Awarded	194,295	13.29	
Vested	(153,357)	5.18	
Canceled	(24,948)	5.33	
Outstanding as of December 31, 2021	292,558	9.64	2.27
Awarded	340,923	2.13	
Vested	(137,302)	2.47	
Canceled	(41,702)	5.10	
Outstanding as of December 31, 2022	454,477	$ 5.06	1.44

In 2022 and 2021, the Company granted an aggregate of 340,923 and 194,295 RSUs to employees, respectively, of which 172,500 and 79,600 RSU's were granted to executive officers, respectively, which vest over a period of two years and three years, respectively. In 2021, the Company granted 11,780 RSU's to independent members of the board of directors, which vest in four equal quarterly installments. No RSU's were granted to independent members of the board of directors in 2022.

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.

During the year ended December 31, 2021, the Company's compensation committee granted certain executives a performance-based stock grant with a target of 52,900 RSU's, a maximum of 105,800, and a minimum of 0. The number of RSU's earned is dependent on the total shareholder return of the Company's common stock compared to a set of peer companies from the grant date through March 9, 2024. Any RSU's earned will vest in their entirety on June 9, 2024. As these grants are subject to market-based vesting criteria, the Company is recognizing compensation expense for these awards subject to market-based vesting conditions regardless of whether it becomes probable that these conditions will be achieved or not, and compensation expense for share-settled awards is not reversed if vesting does not actually occur. The Company recognizes compensation expense based on the fair value on the date of grant as determined by a Monte Carlo valuation model over the expected vesting period.

Awards of RSU's 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 statements of operations as follows:

	2022	2021
Cost of goods sold	$ 75,778	$ 53,130
Research and development	127,198	132,610
Selling, general and administrative	987,518	910,668
Total	$ 1,190,494	$ 1,096,408

As of December 31, 2022, there was approximately $59,500 of unrecognized compensation cost related to unvested stock options which is expected to be recognized over a weighted-average period of 2.3 years.

As of December 31, 2022, there was approximately $1,389,900 of unrecognized compensation cost related to unvested restricted stock unit awards which is expected to be recognized over a weighted-average period of 1.4 years.

Note 9 — Warrants

The following table presents the Company's common stock warrant activity for the years ended December 31, 2022 and 2021:

	Warrants		Weighted Average Exercise Price	
	Outstanding	Exercisable	Outstanding	Exercisable
Balance, Jan 1, 2021	2,709,159	2,709,159	$ 7.77	$ 7.77
Expired	(273)	(273)	194.10	194.10
Exercised	(2,015,243)	(2,015,243)	7.40	7.40
Balance, Dec 31, 2021	693,643	693,643	8.76	8.76
Expired	(12,614)	(12,614)	29.30	29.30
Exercised	(666)	(666)	—	—
Balance, Dec 31, 2022	680,363	680,363	$ 8.30	$ 8.30

The weighted average remaining contractual life of warrants outstanding and exercisable at December 31, 2022 was 2.1 years.

Note 10 — Related Party Transactions

The Company sells its products to an orthotics and prosthetics practice whose ownership includes an individual who was both a shareholder and executive officer of the Company. The executive resigned his position with the Company effective March 31, 2021. As a result, the orthotics and prosthetics practice is no longer a related party effective April 1, 2021. Sales to this related party were sold at standard list prices. During the year ended December 31, 2021 (the portion of the year the party was related to the Company) revenue recognized on sales to this orthotics and prosthetics practice amounted to approximately $25,900.

The Company also obtains consulting and fabrication services, reported in cost of goods sold, from the same previously related party. Charges for these services amounted to approximately $112,900 during the year ended December 31, 2021 (the portion of the year the party was related to the Company).

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. While the Company disputes this claim, it believes that it is probable that a loss will be incurred for this matter and has recorded a loss contingency of $135,000 to accounts payable and accrued expenses as of December 31, 2022. The Company expects its insurance to cover the majority of the loss that may be incurred. There is no other material litigation against the Company at this time.

Operating Leases

The Company has a non-cancelable sublease agreement for its corporate headquarters in Boston, MA expiring in August 2023, consisting of 9,094 square feet of office and laboratory space. In conjunction with entering into a lease in the same building for 3,859 square feet of space to be used for manufacturing, the Company agreed to lease its corporate headquarters space from the landlord after expiration of the sublease. Both leases expire in January 2025. In addition, it has a non-cancelable lease agreement for its office space in Fort Worth, TX expiring in 2025 with early termination available at the company's discretion in 2023. Certain of the 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, 2022, operating lease assets were approximately $508,700 and operating lease liabilities were approximately $553,900. The maturity of the Company's operating lease liabilities as of December 31, 2022, are as follows:

	As of December 31, 2022
2023	411,142
2024	159,872
2025	67,981
Thereafter	—
Total future minimum lease payments	638,995
Less imputed interest	85,087
Total operating lease liabilities	$ 553,908
Included in the consolidated balance sheet:	
Current operating lease liabilities	$ 353,701
Non-current operating lease liabilities	200,207
Total operating lease liabilities	$ 553,908

For the twelve months ended December 31, 2022, the total lease cost is comprised of the following amounts:

	Years ended December 31,	
	2022	2021
Operating lease expense	493,203	372,114
Short-term lease expense	3,250	29,759
Total lease expense	$ 496,453	$ 401,873

The Company paid cash of approximately $557,500 and $275,300 for its operating leases for the years ended December 31, 2022 and 2021, respectively.

The following summarizes additional information related to operating leases:

	As of December 31	
	2022	2021
Weighted-average remaining lease term	1.8	2.5
Weighted-average discount rate	20%	20%

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 U.S., or in an international location. As part of the agreement, the Company must pay to MIT a nonrefundable annual license maintenance fee which may be credited to any royalty amounts due in that same year. The license agreement can be terminated if certain sales targets are not achieved. The royalty charge for each of the years ended December 31, 2022 and 2021 was approximately $264,200 and $262,200, respectively, and is included as a component of cost of revenue.

The future minimum amount due under this agreement for 2023, the final year of the agreement, is $25,000:

Under the MIT License, the Company has issued 205 shares of Common Stock to MIT. The MIT License includes a share adjustment provision in the event that the Company has a dilutive financing, as defined. The MIT License also includes an anti-dilution provision such that MIT's ownership of the outstanding common stock shall not fall below 1% on a fully diluted basis. Under this anti-dilution provision, MIT has the right to purchase additional shares of common stock at the then current market price in order to maintain its pro rata ownership. As a result of the follow-on equity offering in January 2023 (See Note 13), MIT is entitled to receive an additional 928 shares of common stock.

On November 15, 2016, the Company and MIT entered into a waiver agreement with regard to certain revenue and commercialization milestones of the Company required under the License Agreement. Under the waiver agreement, MIT waived the compliance with any and all of such milestone obligations prior to the date of the waiver agreement. For the year ended December 31, 2022 the Company met its minimum sales covenant of $750,000.

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:

	2022	2021
Accrued warranty liability, beginning of year	$ 176,281	$ 119,713
Accrual provided for warranties issued during the period	117,986	79,142
Adjustments to prior accruals	—	26,735
Actual warranty expenditures	(59,620)	(49,309)
Accrued warranty liability, end of year	$ 234,647	$ 176,281

Credit Risk

Financial instruments that potentially expose the Company to a concentration of credit risk consist primarily of cash, cash equivalents and restricted cash and accounts receivable. The Company maintains its cash, cash equivalents and restricted cash, with balances in excess of federally insured limits, 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 restricted cash are limited based upon the creditworthiness of the financial institutions holding these funds.

Major Customers

For the year ended December 31, 2022 and 2021, there were no customers which accounted for more than 10% of revenues. For the year ended December 31, 2022 a U.S. insurance payer represented 32% of product revenues. For the year ended December 31, 2021, a U.S insurance payer represented 30% of product revenues and another represented 11% of revenues, respectively.

For the year ended December 31, 2022 and 2021, one insurer and its affiliates accounted for approximately 62% and 43% of accounts receivable, respectively.

For the year ended December 31, 2022 and 2021, approximately 60% and 59% of the Company's product revenues were derived from patients with Medicare Advantage insurance plans, respectively.

Note 12 — Income Taxes

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

	2022	2021
United States	$ (10,831,796)	$ (10,494,693)
Foreign	$ 180,711	$ 211,292
Loss before income taxes	$ (10,651,085)	$ (10,283,401)

The income tax provision (benefit) for the years ended December 31, 2022 and 2021 consist of the following:

	2022	2021
U.S. federal		
Current	$ —	$ —
Deferred	(2,791,239)	(2,038,000)
State and local		
Current	—	—
Deferred	(615,573)	(510,000)
Foreign		
Current	69,937	88,928
Deferred	—	—
	(3,336,876)	(2,459,072)
Change in valuation allowance	3,406,813	2,548,000
Income tax provision	$ 69,937	$ 88,928

The reconciliation between the U.S statutory federal income tax rate and the Company's effective rate for the years ended December 31, 2022 and 2021 is as follows:

	2022	2021
U.S. federal statutory rate	21.00%	21.00%
State income taxes, net of federal benefit	5.60%	5.21%
State rate change and other	(0.06)%	1.36%
Foreign tax rate differential	(0.15)%	(0.86)%
Other permanent items	(0.28)%	(2.79)%
Prior year taxes	5.91%	0.00%
Change in valuation allowance	(32.67)%	(24.78)%
Effective rate	(0.66)%	(0.86)%

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

	2022	2021
Net operating loss carryover	$ 18,052,725	$ 16,067,000
Tax credits	423,036	311,000
Research & Experimental cost capitalization	657,076	-
Stock-based compensation	900,144	27,000
Other	411,258	648,000
Total deferred tax asset	20,444,240	17,053,000
Less: valuation allowance	(20,444,240)	(17,053,000)
Deferred tax asset, net of valuation allowance	$ —	$ —

There were no deferred tax liabilities at December 31, 2022 or 2021.

As of December 31, 2022 and 2021, the Company had approximately $72,726,000 and $64,709,000 of Federal NOL's and $67,302,000 and $55,721,000 of state NOL's, respectively available to offset future taxable income. The Federal NOL's incurred prior to 2018 of approximately $26,425,0000, if not utilized, begin expiring in the year 2028. The Federal NOL's incurred after 2017 of approximately $46,001,000 have an indefinite carryforward period. The state NOL's if not utilized begin to expire in 2023 through 2043.

Additionally, the Company has U.S. federal and state research and development tax credits of $337,000 and $109,400, respectively which will begin to expire in the year 2027 and 2036, respectively.

NOL carryforwards may face limitations caused by changes in ownership under Section 382 of the Internal Revenue Code. During 2020, the Company experienced an ownership change within the meaning of Section 382 of the Internal Revenue Code of 1986. In 2022, the Company did not perform a section 382 study, which may identify a potential ownership change. 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 approximate $281,000 annual limitation on its ability to utilize pre-change NOLs during the carryforward period and has determined that approximately $437,000 of the Company's pre-change NOLs will expire unutilized. Accordingly, the deferred tax asset and valuation allowance have been adjusted by approximately $92,000 to reflect the Federal NOL's that will expire unutilized.

On August 16, 2022, the Inflation Reduction Act of 2022, which includes changes to the U.S. federal taxation of corporations, was enacted into law. The Inflation Reduction Act among other things implements a corporate book minimum tax ("BMT") 15% rate that could apply to companies with average revenues in excess of $1.0 billion over a three-year period. The BMT has various limitations, including a more restrictive limit on availability of net operating loss carryforwards. The Company does not believe the new law will have any impact on its financial statements.

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, 2021 and 2020. As of December 31, 2022 and December 31, 2021, the change in valuation allowance was an increase of $3,365,000 and an $2,548,000, 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 statement of operations as of December 31, 2022 and December 31, 2021. 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, 2019. 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 are no accrued interest and penalties at December 31, 2022 and December 31, 2021.

Note 13 — Subsequent Events

On January 17, 2023, the Company completed an equity offering, selling 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. The offering was conducted pursuant to a registration statement on Form S-1 (Registration No. 333-268705), as amended, which was declared effective on January 11, 2023. 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. Members of management and a board advisor purchased an aggregate of 1,422,074 shares in the offering.

It is likely that as a result of the offering, the Company experienced an ownership change within the meaning of Section 382 of the Internal Revenue Code. As of the issuance date of these financial statements, the Company has not completed this analysis.

The Company evaluated subsequent events through the issuance date of the financial statements and determined that except for the events discussed above, there have been no additional subsequent events that would require recognition in the financial statements or disclosure in the notes to the financial statements.

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 7, 2023
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, 137 Portland St., 4th Floor Boston, MA. 02114; 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
Chief Executive Officer, American Surgical Professionals

Amy Knapp
Former President, Markets Bright Health

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

Yitzchak Jacobovitz
Partner and Lead Healthcare Analyst
AIGH Capital Management

Board Advisor

Steve Sanghi
Executive Chair, Microchip Technology

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Website
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Ticker Symbol
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Outside Legal Counsel
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