Risk Factors Comparison 2024-02-20 to 2023-02-21 Form: 10-K

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Our business, financial condition, and operating results may be affected by a number of factors, whether currently known or unknown. Any one or more of such factors could directly or indirectly cause our actual results of operations and financial condition to vary materially from past or anticipated future results of operations and financial condition. Any of these factors, in whole or in part, could materially and adversely affect our business, financial condition, results of operations, and stock price. We have provided a summary of some of these risks below, with a more detailed explanation of the risks applicable to us in Part I, Item 1A. " Risk Factors " and elsewhere in this report: Risks Related to Our Business, Operations and Strategy- Current or worsening economic conditions, including inflation, rising interest rates or a recession, could adversely affect our business and financial condition.- If we are unable to achieve and maintain adequate levels of coverage or reimbursement for our products, our business and results of operations will be adversely affected.- Changes to the level of Medicare coverage or coverage criteria for our products could have an adverse effect on our business and results of operations.- We utilize third- party, single- source suppliers for some components and materials used in our products, and the loss of any of these suppliers could have an adverse impact on our business.- Our revenue is primarily generated from our lymphedema products and we are therefore highly dependent on these products.- We are increasingly dependent on sophisticated information technology and if we fail to effectively maintain or protect our information systems or data, including from cyber- attacks or data breaches, our business could be adversely affected.- Consolidation in the healthcare industry could lead to demands for price concessions, which may impact our ability to sell our products at prices necessary to support our current business strategies.- Our long- term growth depends on awareness and adoption of our products.- If we are unable to expand, manage and maintain our direct sales and marketing organizations, as well as our relationships with distributors, we may not be able to generate anticipated revenue.- Physicians and payers may require additional clinical studies prior to prescribing our products or prior to providing or maintaining coverage and reimbursement for our products. Any subsequent clinical studies that are conducted and published may not be positive or consistent with our existing data, which would adversely affect the rate of adoption of our products.- ~~The~~ **Our business, financial condition and results of operations may be negatively impacted by health epidemics or other disease outbreaks, such as the** COVID- 19 pandemic ~~has had, and may continue to have, an adverse effect on our business, financial condition and results of operations~~ . Government Regulation, Compliance and Legal Risks- We are subject to extensive federal and state regulation, and if we fail to comply with applicable regulations, we could be required to repay amounts previously received, and could suffer severe criminal or civil sanctions or be required to make significant changes to our operations that could adversely affect our business, financial condition and operating results.- We are subject to significant regulation by numerous government agencies, including the FDA. We cannot market or commercially distribute our products without obtaining and maintaining necessary regulatory clearances or approvals.- If clinical studies of our future products do not produce results necessary to support regulatory clearance or approval in the United States or, with respect to our current or future products, elsewhere, we will be unable to expand the indications for or commercialize these products.- If the third parties on which we rely to conduct our clinical trials and to assist us with pre- clinical development do not perform as contractually required or expected, we may not be able to obtain regulatory clearance or approval for or commercialize our products.- If we fail to comply with state and federal fraud and abuse laws, including anti- kickback, false claims and anti- inducement laws, we could face substantial penalties and our business, operations and financial condition could be adversely affected.- Failure to maintain the licenses and accreditations necessary to operate under our direct- to- patient and- provider model would adversely affect our business.- Our products are currently made available to authorized users of the Department of Veterans Affairs Federal Supply Schedule and if we were no longer eligible to sell our products through such channel, our business may be adversely affected. Financial Condition, Credit and Tax Risks- If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, investors' views of us and, as a result, the value of our common stock.- The level of our indebtedness under our credit facility may adversely impact us ~~, and the phase- out, replacement or unavailability of LIBOR and / or other interest rate benchmarks could adversely affect our indebtedness.~~ - Our credit facility contains covenants that restrict our business and financing activities, and the property that secures our obligations under the credit facility may be subject to foreclosure. Risks Related to Ownership of Our Common Stock- The trading price of the shares of our common stock has been and could continue to be highly volatile, and purchasers of our common stock may not be able to resell their shares of our common stock at or above the price at which they purchased their shares and could incur substantial losses. 4PART IItem 1. Business. OverviewTactile Systems Technology, Inc. (" we, " " us, " and " our ") is a medical technology company that develops and provides innovative medical devices for the treatment of underserved chronic diseases. We were originally incorporated in Minnesota under the name Tactile Systems Technology, Inc. on January 30, 1995. During 2006, we established a merger corporation and subsequently, on July 21, 2006, merged with and into this merger corporation resulting in us being reincorporated as a Delaware corporation. The resulting corporation assumed the name Tactile Systems Technology, Inc. and in September 2013, we began doing business as " Tactile Medical ". Our mission is to help people suffering from chronic diseases live better and care for themselves at home. We focus our efforts on advancing the standard of care in treating underserved chronic diseases in the home to improve patient outcomes and quality of life and help control rising healthcare expenditures. Our areas of therapeutic focus are (1) vascular disease, with a goal of advancing the standard of care in treating lymphedema and chronic venous insufficiency, (2) oncology, where lymphedema is a common consequence among cancer survivors and (3) providing airway

clearance therapy for those suffering from chronic respiratory conditions. We possess a unique, scalable platform to deliver at-home healthcare solutions throughout the United States. This evolving home care delivery model is recognized by policymakers and insurance payers as a key for controlling rising healthcare costs. Our solutions deliver cost- effective, clinically proven, long- term treatment for people with these chronic diseases. We **generally** employ a direct- to- patient and- provider model within our lymphedema portfolio, through which we obtain patient referrals from clinicians, manage insurance claims on behalf of our patients and their clinicians, deliver our solutions directly to patients and train them on the proper use of our solutions. This model allows us to engage directly with patients and clinicians, which are both critical audiences to which we can provide clinical evidence and education. For our respiratory therapy products, we have a durable medical equipment (" DME ") distribution model, utilizing mature comprehensive respiratory DME providers to service patients. We sell the AffloVest product to accredited DME providers. They gather and submit documentation for payer reimbursement, train patients on use of the device, and provide ongoing patient support. For the year ended December 31, ~~2022~~ **2023**, we generated revenue of $ ~~246~~ **274**. ~~8~~ **4** million and had ~~a~~ net ~~loss~~ **income** of $ ~~17~~ **28**. ~~9~~ **5** million. Our revenue increased ~~19~~ **11** % during the year ended December 31, ~~2022~~ **2023**, compared to the year ended December 31, ~~2021~~ **2022**. Lymphedema is a type of chronic swelling, or edema, which occurs in the arms, legs, neck, trunk or other body parts when the lymphatic vessels are unable to adequately drain protein- rich lymph fluid from these regions. Lymphedema is progressive in nature, worsens over time, and has no known cure. Chronic venous insufficiency is a condition that occurs when the venous wall and / or valves in the veins are not working effectively, making it difficult for blood to return to the heart from the affected region (s). Phlebolymphedema is the convergence of lymphedema and chronic venous insufficiency. When the venous system does not effectively transfer blood from the lower limbs, it can result in venous hypertension and the development of painful, slow- healing wounds on the lower leg called venous leg ulcers. Venous hypertension can also lead to a marked increase in fluid build- up in the limbs, overwhelming the lymphatic system and causing lymphedema. Our proprietary Flexitouch and Entre systems are clinically proven at- home solutions for patients with vascular disorders such as lymphedema. Patients with lymphedema or chronic venous insufficiency are typically treated by vascular surgeons, vascular medicine physicians, oncology care teams, wound physicians, nurses and therapists. Our current lymphedema products are the Flexitouch **Plus** and Entre **Plus** systems. A predecessor to our Flexitouch system received 510 (k) clearance from the U. S. Food and Drug Administration (the " FDA ") in July 2002, and we introduced the system to address the many limitations of self- administered home- based manual lymphatic drainage therapy. We began selling our more advanced Flexitouch system after receiving 510 (k) clearance from the FDA in October 2006. In September 2016, we received 510 (k) clearance from the FDA for the Flexitouch system in treating lymphedema of the head and neck. In June 2017, we announced that ~~we~~ **5we** received 510 (k) clearance from the FDA for the Flexitouch Plus, the third- generation version of our Flexitouch system. In December 2020, we received 510 (k) clearance for two new indications for our Flexitouch Plus system: phlebolymphedema and lipedema. We introduced our Entre system in the United States in February ~~52013~~ **2013 and the second generation, Entre Plus, in March 2023**. The Entre **Plus** system is sold or rented to patients who need a simple pump or who do not yet qualify for insurance reimbursement for an advanced compression device such as our Flexitouch **Plus** system. Sales and rentals of our lymphedema products generated $ **241. 7 million, or 88 %, of our revenue in 2023, and $** 212. 3 million, or 86 %, of our revenue in 2022 ~~, and $ 202. 9 million, or 98 %, of our revenue in 2021~~. On September 8, 2021, we acquired the assets of the AffloVest airway clearance product line from International Biophysics Corporation (" IBC "), a privately- held company which developed and manufactured AffloVest. AffloVest is a portable, **battery- powered,** wearable vest that provides airway clearance to treat patients with chronic respiratory conditions such as bronchiectasis or conditions resulting from neuromuscular disorders. The AffloVest product line generated $ **32. 7 million, or 12 %, of our revenue in 2023 and $** 34. 5 million, or 14 %, of our revenue in 2022 ~~and $ 5. 1 million, or 2 %, of our revenue in 2021~~. To support the growth of our business, we **continue to** invest in our commercial infrastructure, consisting of our direct sales force, DME sales team, patient ~~training resources~~ **education team**, reimbursement capabilities and clinical expertise. We are a national, accredited provider of home medical equipment services approved for coverage by private payers, Medicare, the Veterans Administration and certain Medicaid programs in the United States. Our field commercial team is focused on increasing clinician awareness of our lymphedema solutions. As of December 31, ~~2022~~ **2023**, we employed **254** ~~a field staff of 287, which consisted of 250~~ field sales representatives ~~and 24 field managers~~ for our lymphedema products **and** ~~, as well as~~ a team of ~~13~~ **16** supporting our airway clearance products. This compares to **241** ~~a field staff of 262 as of December 31, 2021, which consisted of approximately 233~~ field sales representatives ~~and 19 field~~ **(excluding 9 key account** managers **)** for our lymphedema products **and** ~~, as well as~~ a team of 10 **specialists** supporting our airway clearance products **as** ~~. In concert with COVID- 19 social distancing requirements and recommendations, beginning in 2020, our patient training model includes both in- person training and virtual patient training options. This provides additional options for us to connect with patients to ensure they receive the appropriate training, while protecting the health and limiting the exposure~~ of **December 31,** ~~both our trainers and patients. In~~ 2022 ~~, we provided patient training primarily through a team of employee trainers to educate patients on the proper use of our solutions~~. Our reimbursement function includes payer relations and reimbursement operations. Our payer relations function focuses on payer policy development, education, contract negotiations, and data analysis. Our reimbursement operations function is responsible for verifying patient insurance benefits, individual patient case development, prior authorization submissions, case follow- up, and appeals when necessary. Our clinical function, consisting of a scientific advisory board, in- house therapists and nurses, and our Chief Medical Officer, serves as a resource to clinicians and patients and guides our development of clinical evidence in support of our products. We believe these investments are critical to driving payer, clinician and patient adoption of our technologies, and together with our commercial infrastructure, represent a significant competitive advantage. Health insurance coverage for our Flexitouch **Plus** and Entre **Plus** systems is in place with private payers, Medicare, the Veterans Administration and certain Medicaid programs. Based on our estimates, we are contracted or enrolled as an in- network provider with payers covering ~~nearly~~ **over** 275 million lives in the United States. In ~~2022~~ **2023** we served over ~~65~~ **77**, 000 patients with our

compression therapy devices and cumulatively have served over ~~395~~ **472** , 000 patients since they launched ~~. This compares to over 330, 000 patients cumulatively as of December 31, 2021~~ . AffloVest also benefits from a relatively mature reimbursement landscape. Health insurance coverage is in place for High Frequency Chest Wall Oscillation (“ HFCWO ”) vest therapy with Medicare and most private insurers. Respiratory DME partners serve the role of receiving prescriptions, verifying coverage criteria, shipping, billing and training the patient. ~~Coronavirus (COVID- 19) The United States economy in general and our business specifically have been negatively affected by the COVID- 19 pandemic. We have seen adverse impacts as it relates to the decline in the number of patients that healthcare facilities and clinics are able to treat due to enhanced safety protocols, including during most of 2021 and the first quarter of 2022. We have also seen staffing challenges, both in our organization and at the 6clinics we serve, as another lingering consequence of the COVID- 19 pandemic. While we saw some level of recovery in 2022 after the first quarter, ongoing consequences of the pandemic remain uncertain. There are no reliable estimates of how long the pandemic will last, whether any recovery will be sustained or will reverse course, the severity of any resurgence of COVID- 19 or variant strains of the virus, the effectiveness of vaccines and attitudes towards receiving them, or what ultimate effects the pandemic will have. For that reason, we are unable to reasonably estimate the long- term impact of the pandemic on our business at this time.~~ Overview of Lymphedema and Chronic Venous Insufficiency LymphedemaThe lymphatic system, a fundamental part of the cardiovascular system, consists of lymph vessels and lymph organs that protect the body against harmful bacteria and transport lymph fluid from the body’ s tissues back to the cardiovascular system. Lymph vessels are thin- walled capillaries that absorb fluids, bacteria and proteins, and propel them to lymph nodes, small lymph organs that filter and process the lymph fluid by eliminating waste and bacteria. Lymph nodes are located in several areas of the body, including superficial and deep lymph nodes under each arm, at the hip, in the groin, above the collar bones in the neck, in the abdomen, ~~tonsils~~ **6tonsils** and spleen, and in bone marrow. Lymph vessels and lymph nodes work together with larger lymph structures to help maintain a normal healthy fluid balance. Lymphedema occurs when there is impairment to the lymphatic system, disrupting normal transport of lymph fluid within the body and causes severe and debilitating symptoms, including swelling, decreased mobility, skin breakdown, pain, increased risk of serious infection and marked psychosocial impairment, resulting in significant negative implications for a patient' s health. When the lymphatic system becomes overwhelmed, damaged, or blocked for an extended period of time, lasting swelling (referred to as chronic edema) occurs. Symptoms related to lymphedema can present anywhere in the body, including the head, neck, arms, legs, trunk and genitals. For most patients with lymphedema, it has a negative impact on their quality of life. Performing daily activities of cooking, shopping, cleaning and yard work can often become difficult, if not impossible, for patients who suffer from lymphedema. For patients with head and neck lymphedema, critical functions such as swallowing, breathing and range of motion can be negatively impacted. Over time, the accumulation of lymph fluid can result in significant changes in the structure of the tissues, causing thickening and hardening of the skin, referred to as fibrosis. Recurrent skin infections such as erysipelas and cellulitis, a more serious skin infection, are common complications of lymphedema. Lymphedema worsens over time if not properly treated, and currently has no known cure. When untreated, lymphedema can become painful and debilitating. The symptoms of lymphedema can be managed however, and patients who are educated about effective treatment options can improve their quality of life. Misdiagnosis of lymphedema is common, and often patients do not get the medical care they need until significant symptoms have occurred. Proper diagnosis of lymphedema may require evaluation by a physician or other healthcare provider with knowledge of lymphedema and its visible symptoms. While not required to develop a lymphedema diagnosis, some clinicians may choose to perform diagnostic testing. Diagnostic tests for lymphedema include history and physical examination, soft tissue and vascular imaging, lymph node imaging, volume measurements, changes in electrical conductance, changes in biomechanical properties, genetic testing and blood tests for other conditions that have similar symptoms to lymphedema. The International Society of Lymphology categorizes the progression of lymphedema from Stage 0, the least severe stage, to Stage 3, the most severe stage. Chronic Venous Insufficiency and Phlebolymphedema The most common form of lymphedema in the Western world is ~~phelobolymphedema~~ **phlebolymphedema** , a mixed etiology swelling due to chronic venous insufficiency (“ CVI ”) and lymphatic insufficiency. The inability of the lymphatic system to adequately drain the interstitial fluid that accumulates in severe chronic venous hypertension causes this ‘ combined’ condition, phlebolymphedema. CVI is prevalent among patients who are obese or pregnant and may also be caused by high blood pressure, trauma, lack of exercise, smoking, deep vein thrombosis and inflammation of the vein walls. As the valves deteriorate, blood is no longer able to effectively travel in the ~~7normal~~ **normal** direction, leading to increased pressure in the vascular system, stretching and dilating vessels, which exacerbates the problem. Prolonged or untreated chronic venous insufficiency may cause an increase in the buildup of interstitial fluid (the fluid surrounding cells), which in turn, can cause skin and tissue changes that can permanently damage the lymphatic system. As hypertension increases, more fluid is pushed out of the vascular system leading to swelling, progressive tissue breakdown, skin infections and venous leg ulcers. Ulcers develop in areas with edema as swelling interferes with the movement of oxygen and nutrients through tissues, and if left untreated, these ulcers can quickly become infected or even gangrenous. Physicians diagnose chronic venous insufficiency based on appearance, symptoms and imaging techniques and classify it based upon a scale endorsed by the Society for Vascular Surgery. Market Opportunity Lymphedema and CVI are costly and lifelong conditions with debilitating physical and psychological impacts on patients. Based on a study performed by Dr. Steven Dean et al., it is estimated that more than 16 million people in the United States are living with lymphedema due to CVI. This, in addition to the estimated five million individuals living in the U. S. with cancer- related and primary lymphedema, increases the prevalence estimates to over 20 million individuals. For people with cancer, the build- up of lymph fluid can be caused by ~~surgery~~ **7surgery** , especially when lymph nodes are removed, radiation therapy that can damage lymph nodes and vessels, infections that damage surrounding tissue or cause scarring, and other conditions. In the fourth quarter of 2016 we expanded the indications for use of the Flexitouch system. We received U. S. FDA clearance to market a first- of- its- kind system to treat patients suffering from lymphedema of the head and neck, a frequent consequence of head and neck cancer and its treatment.

Patient symptoms often include significant skin changes, pain and discomfort, as well as difficulty breathing and swallowing. The American Cancer Society estimates that there are 430, 000 survivors of head and neck cancers in the United States, and more than 65, 000 new patients are diagnosed each year. In a 2016 clinical publication, researchers at Vanderbilt University School of Medicine estimated that more than 75 % of patients with head and neck cancer develop lymphedema requiring treatment. Our Flexitouch head and neck system is the only pneumatic compression device with an indication to treat patients suffering from debilitating head and neck lymphedema **and our therapy is protected with several patents issued in 2022** . We estimate the market opportunity for our Flexitouch head and neck system is approximately $ 1 billion in the United States, which is based on 75 % of the total number of patients suffering from cancers of the head and neck and our average selling price per device. In June 2020, a study published in Supportive Care in Cancer recognized the effectiveness of Flexitouch in treating patients with head and neck related lymphedema. The study, led by Vanderbilt University was a pilot randomized clinical trial reflecting statistically significant reductions in swelling, pain and improvements in the ability to swallow. In addition, in September 2021, we initiated a randomized, controlled clinical trial evaluating the effectiveness of our Flexitouch Plus system for the treatment of head and neck lymphedema. We believe this study will represent the largest randomized, controlled clinical trial ever conducted for the treatment of head and neck cancer- related lymphedema. The trial will consist of approximately 250 subjects enrolled at ten clinical sites and will span three years. ~~Current~~ **Traditional** Treatment and Limitations A traditional treatment for lymphedema is complete decongestive therapy consisting of manual lymphatic drainage, which is a specialized application of gentle pressure to the skin applied by a trained therapist that encourages drainage of lymph fluid, as well as decongestive exercises, skin care and compression with multilayered bandages, compression garments or pumps. Typically, this therapy begins with clinic visits three to five times per week for four to eight weeks, which is costly, inconvenient for the patient, and time consuming. Access to therapy clinics can also be limited, leading to many patients not completing their prescribed in- clinic treatments. Following the in- clinic visits, typically clinical improvement plateaus or reimbursement for the therapy ends, and patients transition to self- administered home- based care. Manual lymphatic drainage is difficult for patients to self- administer due to limited range of motion and treatment techniques that are difficult to replicate, and pump- based compression using simple pumps can be uncomfortable and has not demonstrated the clinical and economic benefits of our Flexitouch advanced pneumatic pump. To address these limitations, our at- home Flexitouch **Plus** system was developed to provide automated lymphatic drainage therapy through an advanced, easy- to- use, self- applied at- home system. Peer-reviewed, published studies have shown that our Flexitouch **Plus** system provides improved quality of life and clinical outcomes and delivers significant cost savings to payers and patients. ~~8The~~ **The** standard of care treatment for CVI is compression therapy. Compression stockings and wraps are typically used to provide added pressure, increasing the effectiveness of the calf-muscle pump in returning blood to the heart, but these products can be challenging for patients to apply. As the disease progresses, patients may develop a venous leg ulcer, which is commonly treated using multilayered bandages to minimize swelling and enhance blood flow. A clinician applies these typically non- removable bandages to patients at a precise pressure and patients wear the bandages between weekly visits to the wound clinic during which they are then removed and reapplied. Treatment typically occurs for several months and impairs patient quality of life by limiting bathing, range of motion, comfort and other activities of daily living. Treatment efficacy is inconsistent because bandages can lose their precise pressure between treatments. Enhancing standard of care treatments for CVI with our pneumatic compression systems has been proven to reduce the recurrence of ulcer formations as well as recurrent skin infections (cellulitis) leading to better patient quality of life and lower overall cost of clinical care. In 2022, three independent societies' consensus endorsements were published in Phlebology: The Journal of Venous Disease. Experts from the American Venous Forum, American Venous and Lymphatic ~~Society~~ **8Society** and Society for Vascular Medicine provided the consensus guidance on diagnosis and patient treatment pathways for lymphedema. Over a majority of the panel (92 %) agreed with the statement that sequential pneumatic compression should be recommended for lymphedema patients, with 34 % strongly agreeing. In addition, 72 % of the panel agreed with the statement that all patients with CVI (stages C3- C6) should be considered as lymphedema patients, with 38 % strongly agreeing. Overview of Bronchiectasis ~~and Cystic Fibrosis~~ Bronchiectasis is a COPD- associated condition where the lung' s bronchi become inflamed, widened, permanently damaged and scarred. As more of the bronchial wall thickens, mucus gets trapped, creating a breeding ground for infection. The inability to fully clear mucus and pathogens from the lungs can result in a chronic cycle of infections and inflammation. Airway clearance therapies help break this vicious cycle and need to be used regularly to maintain a healthy respiratory system ~~. Cystic fibrosis is an inherited disease that causes thickened mucus to form in the lungs, pancreas and other organs. In the lungs, this mucus blocks the airways, creating lung damage and making it hard to breathe. There is no cure for COPD or cystic fibrosis~~ . Market OpportunityBronchiectasis is one of the most common respiratory diseases with over 500, 000 U. S. adults diagnosed and is estimated to be growing in the high single- digits annually. More than 16 million people in the U. S. are living with COPD and it is estimated that over 4 million of them may be affected by bronchiectasis. High frequency chest wall oscillation is used to treat bronchiectasis and over 40 other International Classification of Disease (" ICD ")- 10 diagnosis codes. **Traditional** ~~Over 30, 000 people in the U. S. struggle with the effects of cystic fibrosis every day. Cystic fibrosis treatment includes airway clearance therapy, of which HFCWO is the standard of care. The Cystic Fibrosis Foundation Patient Registry reports 77 % of cystic fibrosis patients use HFCWO. Current~~ Treatment and Limitations Airway clearance therapy (" ACT ") utilizes physical or mechanical means of percussion or vibration to mobilize mucus and phlegm to facilitate airway clearance by coughing. ACT options include huff coughing, chest physiotherapy performed by a therapist or caregiver, active cycle breathing, positive expiratory pressure devices and HFCWO vests. These treatments need to be performed daily to support bronchial hygiene for at- risk respiratory patients. Adherence to treatments and effectiveness of treatments are a significant challenge for patients with these chronic conditions. AffloVest is a HFCWO therapy vest that has eight anatomically positioned oscillating motors that create individual pressure waveforms to target all lobes of the lungs to loosen, thin and mobilize lung secretions. ~~9~~ Our StrategyOur goal is to become ~~a~~ **the** leader in the at- home treatment of **select**

underserved chronic diseases. We intend to leverage our established product, service and fulfillment platforms to be a global provider of clinically proven easy- to- use and cost- effective solutions. The key elements of our strategy include: ● Increase awareness of our solutions and establish them as the standards of care. We believe that many patients with lymphedema, chronic venous insufficiency and chronic respiratory conditions remain undiagnosed or undertreated. We intend to further educate physicians, nurses, therapists, patients, payers and DME providers to raise awareness of these diseases, the associated health burdens of such diseases on patients and society, and the clinical and economic benefits of using our products. Further, we intend to continue promoting this awareness through training and educating clinicians, advertising campaigns, exhibiting at tradeshows and physician meetings and publishing additional clinical and economic outcome data demonstrating the benefits of our solutions. Our ongoing marketing initiatives focus on increasing referrals from physicians trained in the diagnosis and treatment of venous and lymphatic diseases, oncology and chronic respiratory conditions. In addition, we plan to launch more extensive direct- to- provider and patient marketing programs that we believe will further increase awareness of our solutions. ● Utilize direct sales and customer support teams. We rely on a large direct sales force and marketing organization to drive greater product adoption by patients suffering from lymphedema and CVI and their clinicians. We also intend to expand and support our respiratory DME channels, in an effort to help demonstrate HFCWO as a staple among the host of treatments they bring to chronic ~~respiratory~~ **9respiratory** patients. We intend to strengthen our distribution network by continuing to recruit, train and retain talented sales representatives. With an expanded sales force, our goal is to expand the existing prescriber base. ● Demonstrate ongoing innovation to grow our technology platform and expand adoption of our therapies. We are actively developing new products and features for our portfolio in order to expand the number of patients using our products and allow us to enter new clinical adjacencies. We pursue both internal research, design and development, and also work with external collaborators to expand our product offerings. In addition, we evaluate opportunities to license or acquire additional technologies and products to expand our total addressable market opportunity. ● Continue the development of clinical and economic outcome data. A key part of our success is our ability to demonstrate the effectiveness of our products through clinical and economic outcome data. We intend to invest in additional studies to support peer- reviewed, published articles that evidence the clinical and economic benefits of our solutions as compared to traditional treatments. We intend to use these data to continue to educate clinicians, payers and patients on the proven advantages of our products compared to other therapies and expand our network of key opinion leader advocates. ● Expand third- party reimbursement. Most of our products are covered under existing reimbursement codes, and we have secured coverage for our solutions with commercial payers, Medicare, the Veterans Administration and certain Medicaid programs. Our team has experienced significant success in obtaining positive coverage policies from payers by developing direct relationships with payer decision- makers, leveraging our relationships with physician societies and key opinion leaders, providing clinical data, demonstrating the efficacy of our products and educating payers on the limitations of traditional treatments. We intend to continue this strategic approach to further expand coverage for our solutions, as well as to meet payer- specific requirements on behalf of patients. 10Our Products We market Flexitouch **Plus** and Entre **Plus** systems as at- home therapies for the treatment of lymphedema and chronic venous insufficiency. We market AffloVest as an at- home therapy intended to promote airway clearance. These products have received 510 (k) clearance from the FDA to be marketed in the United States. We believe our products have unique features and benefits that address the shortcomings of traditional treatments, are more cost- effective and enable more consistent and effective therapy, leading to enhanced patient quality of life, improved clinical outcomes and reduced cost of care. Flexitouch **Plus** System Our Flexitouch Plus system is a fully automated, programmable, advanced pneumatic compression device, or APCD, designed for treatment of lymphedema in the home setting. Our Flexitouch **Plus** system has received 510 (k) clearance for the treatment of lymphedema, phlebolymphedema, lipedema, certain types of other edema, venous insufficiencies and certain types of leg ulcers. We introduced our first- generation Flexitouch system in the United States in 2003, our second- generation Flexitouch system in 2006, and our third- generation Flexitouch system, the Flexitouch Plus, in 2018. The mechanism of action of our patented Flexitouch Plus system is designed to stimulate the lymphatic system similar to manual lymphatic drainage therapy, the current standard of care in patient treatment. By automating this technique, we believe our system offers an effective, cost- efficient, convenient and accessible at- home treatment for patients. Our Flexitouch Plus system consists of an electronic controller unit that offers 17 treatment settings and multiple contoured garment configurations for the trunk, chest, head, neck and the arm or leg. Our Flexitouch Plus is the only pneumatic compression system offering the flexibility for treating upper and lower extremities, the trunk and chest, and the head and neck. The electronic controller is a pneumatic compressor with four connector outlets. Each connector has eight outflow ports into which the garment hoses are connected. Our unique garments contain up to 32 air chambers, are made of a soft, pliable fabric and are designed with zippers and hook- and- loop fasteners to fit snugly around affected areas for maximum comfort and optimum pressure delivery. The garments come in a variety of sizes that can be easily adjusted to patients of all sizes. When our system is activated, air passes through the hoses, delivering sequential inflation and deflation to the garments and applying gentle pressure to the skin. The inflation sequence is designed to stimulate the lymphatic system, moving lymph fluid from the impaired areas toward healthy regions of the body. The electronic controller unit adjusts the amount of pressure and the timing of the pressure and release cycles. This unit is lightweight and easily portable, providing maximum convenience for at- home treatment. A typical therapy session using our Flexitouch Plus system lasts up to one hour, with additional treatment options available if prescribed by a clinician. Beginning in November 2022, Flexitouch Plus controllers include Bluetooth capability that enables therapy data from the controller to be reported through Kylee, a companion application. Entre **Plus** System We introduced our Entre system in the United States in February 2013 to offer a lightweight, portable pneumatic compression solution for patients with cognitive or dexterity issues who need a basic (simple) pump or for patients who do not yet qualify for insurance coverage of an advanced compression device such as our Flexitouch Plus system. Our Entre system is a basic pneumatic compression device used for the at- home treatment of venous disorders including lymphedema and chronic venous insufficiency, including venous leg ulcers. Our Entre system is a pump with garments covering

the arm or leg with eight chambers that inflate in sequence and remain inflated for a preset time period. ~~All chambers deflate at once. Our~~ **In 2023, our second- generation system,** Entre **Plus, was introduced** ~~system moves fluid from fingers or toes toward areas closer to the trunk. The system can be programmed to a variety of pressures delivering a prescribed treatment customized to meet the patient's needs~~. KyleeIn 2022, we introduced Kylee ™, a free mobile application to help patients learn about lymphedema, track their symptoms and treatment, and share their progress with their doctor. The purpose behind Kylee is to help support and encourage patients to embrace self- care and become more educated about their condition. Our customers can use Kylee to track their orders for our devices and view onboarding tutorials for using the ~~11device~~ -- **device** . Once a patient starts using the device, they can use Kylee to record their treatments and symptoms, ~~and~~ **11and** capture photos of their condition for sharing with their healthcare team. Flexitouch Plus controllers include Bluetooth technology, which is ~~now~~ viewable using Kylee. AffloVestWe acquired the AffloVest business in September 2021. The AffloVest is the first truly portable high- frequency chest wall oscillation (HFCWO) vest. The device is battery- powered and affords patients the ability to ambulate while receiving treatment, as well as increases the likelihood that their treatment will travel with them. The AffloVest treats patients with retained pulmonary secretions resulting from bronchiectasis, cystic fibrosis and a host of neuromuscular disorders. The AffloVest offers various treatment modes and intensities. The user can set and store their personalized default treatment settings. Our AffloVest system has received 510 (k) clearance as a HFCWO device and is intended for promoting airway clearance and improvement of bronchial drainage by enhancing mobilization of bronchial secretions where manipulation of the thorax is the physician' s choice of treatment. Clinical Results and Studies Overview A key part of our success is our ability to demonstrate the effectiveness of our products by funding studies that generate clinical and economic outcome data supporting our products. We have developed a significant body of clinical data supporting the efficacy and safety of our products. We intend to continue to invest in additional studies to support peer- reviewed, published articles that evidence the clinical and economic benefits of our solutions as compared to traditional treatments. To date, more than 25 studies regarding the safety and efficacy of our products have been completed, in which over 2, 100 subjects have been included. Economic Impact of our Flexitouch System in Patients with Phlebolymphedema A retrospective longitudinal matched case- control analysis of de- identified private insurance claims published by the Journal of Vascular Surgery in 2018 indicated significant benefits attributable to our Flexitouch system as compared to alternative compression therapies currently employed to help reduce the notable economic burden of phlebolymphedema (chronic venous insufficiency- related lymphedema). The study used administrative claims data from Blue Health Intelligence for the years 2012 through 2016. Patients were required to be continuously enrolled in the health plan for at least 18 months, diagnosed with phlebolymphedema, and had received at least one claim for conservative therapy either alone or in addition to a pneumatic compression device, or PCD. The main outcomes included direct phlebolymphedema- and sequelae- related medical resource utilization and costs. Prior to case matching, 1, 065 patients met these criteria. After case matching, the study included: 86 patients using conservative therapy matched with 87 patients on Flexitouch; 34 patients on simple PCDs, or SPCDs, matched with 23 patients on Flexitouch; and 69 patients on other advanced PCDs, or APCDs, matched with 67 patients on Flexitouch. Compared with conservative therapy alone, Flexitouch patients were associated with 69 % lower per patient per year total phlebolymphedema- and sequelae- related costs net of any PCD- related costs ($ 3, 839 vs $ 12, 253; P = 0. 001). This was driven by 59 % fewer mean annual hospitalizations (0. 13 vs 0. 32; P < 0. 001) corresponding to 82 % lower inpatient costs and 55 % lower outpatient hospital costs. Flexitouch patients were also associated with 52 % lower outpatient physical therapy and occupational therapy costs and 56 % lower other outpatient- related costs. Compared with SPCDs, Flexitouch was associated with 85 % lower total costs ($ 1, 153 vs $ 7, 449; P = 0. 008) driven by 93 % lower inpatient costs ($ 297 vs $ 4, 215; P = 0. 002), 84 % lower outpatient hospital costs ($ 368 vs $ 2, 347; P = 0. 020), and 85 % lower other outpatient- related costs ($ 353 vs $ 2, 313; P = 0. 023). Compared with other APCDs, Flexitouch was associated with 53 % lower total costs ($ 3, 973 vs $ 8, 436; P = 0. 032) because of lower outpatient costs and lower rates of cellulitis infections (22. 4 % vs 44. 9 % of patients; P = 0. 02). 12Impact on Clinical Outcomes and Healthcare Costs with Use of our Flexitouch System A retrospective study published by the American Medical Association in JAMA Dermatology demonstrated significant improvement in key clinical endpoints and immediate cost reductions for individuals with lymphedema following receipt of our Flexitouch system. The study was conducted in the United States and included 718 patients with a lymphedema diagnosis who had continuous insurance coverage during the 12 months prior to and the 12 months after receiving our Flexitouch system from 2007 through 2013. The study evaluated a broad, clinically relevant set of healthcare use outcomes for each patient for the 12 months before and the 12 months after receipt of our Flexitouch system, including cellulitis infections, inpatient hospitalizations, physical therapy and outpatient hospital visits. Receipt of our Flexitouch system was associated with a significant decline in the rate of cellulitis diagnosis in the cancer- related lymphedema patients of 79 % (from 21. 1 % to 4. 5 %; p < 0. 001) and in the non- cancer- related lymphedema patients of 75 % (from 28. 8 % to 7. 3 %; p < 0. 001). The inpatient hospitalization rate declined 22 % in the cancer- related group (from 2. 7 % to 2. 1 %; p = 0. 63) and declined 54 % in the non- cancer- related group (from 7. 0 % to 3. 2 %; p = 0. 02). The manual therapy rate decreased 30 % in the cancer- related lymphedema patients (from 35. 6 % to 24. 9 %; p = 0. 001) and decreased 34 % in the non- cancer- related lymphedema patients (from 32. 3 % to 21. 2 %; p = 0. 001). In addition, outpatient hospital visits declined 29 % in the cancer- related patients (from 58. 6 % to 41. 4 %; p < 0. 001) and 40 % in the non- cancer- related patients (from 52. 6 % to 31. 4 %; p < 0. 001). The study also reviewed lymphedema- related healthcare costs for each patient in the study for the 12 months before and the 12 months after receipt of our Flexitouch system. Among the cancer- related lymphedema patients, total costs per patient, excluding durable medical equipment costs, were reduced by 37 %, from $ 2, 597 to $ 1, 642 (p = 0. 002) following receipt of our Flexitouch system. The greatest contributor to this change was a 54 % reduction in outpatient hospital costs from $ 1, 517 to $ 694 (p < 0. 001). Total costs per non- cancer- related lymphedema patient, excluding durable medical equipment costs, were reduced by 36 % from $ 2, 937 to $ 1, 883 (p = 0. 007). Outpatient hospital costs for the non- cancer patients declined by 65 % from $ 1, 726 to $ 606 (p < 0. 001). Flexitouch System Impact on Limb Volume and Patient- Reported Outcomes A prospective

study published in the European Journal of Vascular and Endovascular Surgery demonstrated that use of our Flexitouch system is associated with statistically significant reduction in limb volume, improvement in quality of life and no significant adverse effects. The study was conducted in the United States and collected data from a patient registry required by a third- party payer for 196 patients with lower extremity lymphedema who were prescribed our Flexitouch system from January 2009 to May 2012. The primary objective of the study was to examine the effectiveness of our Flexitouch system in reducing lower extremity limb volume, with a secondary objective of evaluating clinician- assessed and patient- reported outcomes. Use of our Flexitouch system was associated with a statistically significant reduction in limb volume with 88 % of patients experiencing a reduction in limb volume and with 35 % enjoying a substantial reduction in limb volume of greater than 10 %. Twelve percent of patients experienced an increase in limb volume. Clinician assessment indicated that the majority of patients experienced improvement in the condition of their skin. Eighty- six percent of the patients exhibited a reduction in skin hardening (fibrosis) based on manual assessment of the skin. Based on clinical observation of function, 85 % of patients demonstrated an increased ability to perform activities of daily living. Additionally, 77 % of patients demonstrated improved range of motion. Patients reported a significant increase in their ability to control lymphedema through treatment with our Flexitouch system, with an increase in function and a reduction in pain. Of the 98 patients who responded, 66 % reported being" very satisfied" with the treatment by our Flexitouch system and 29, or 30 %, of patients reported being" satisfied" with the treatment by our Flexitouch system. Comparison of our Flexitouch System with Simple Pneumatic Compression Devices A prospective, randomized controlled trial published in Supportive Care in Cancer demonstrated that our Flexitouch system provides better clinical outcomes as compared to those achieved with a simple 13pneumatic compression device for home- based treatment of breast cancer- related lymphedema. The study was conducted in the United States and involved 36 patients. The number of participants in this study is considered to be a small sample size and a limitation of the study. However, it is one of the only published randomized controlled trials comparing PCDs, and we believe is currently the only published study of PCDs that reported comprehensively on adverse events. The patients were randomized to our Flexitouch system or a simple pneumatic compression device used for home treatment of one- hour per day for 12 weeks. The simple pneumatic compression device used in the study was a Bio Compression 2004 Sequential Circulator pneumatic compression device. The primary objective of the study was to determine whether our Flexitouch system provides better outcomes, as measured by arm edema and tissue water reductions, compared to a simple pneumatic compression device in patients with arm lymphedema. The study does not reflect a comparison of our Flexitouch system to a product that is billed under the same Healthcare Common Procedure Coding System, or HCPCS, Code as our Flexitouch system. Thirty- six patients with unilateral upper extremity lymphedema with at least 5 % arm edema volume at the time of enrollment completed treatments over the 12- week period, with 26 patients being evaluated for edema volume change and 28 patients being evaluated for changes in arm tissue water content. Arm edema volumes were determined from arm girth measurements and suitable model calculations, and tissue water was determined based on measurements of the arm tissue. The patients were randomized into two groups of 18 patients each, with one group receiving treatment with our Flexitouch system and the other group receiving treatment using a simple pneumatic compression device. The group using our Flexitouch system experienced an average reduction in edema of 29 % compared to a 16 % increase in the group using a simple pneumatic compression device. Study of Patient- Reported Satisfaction with Use of our Flexitouch System A retrospective study published in the Oncology Nursing Forum demonstrated that patients using our Flexitouch system were satisfied with the device and perceived it to be beneficial in managing their lymphedema. The study was conducted in the United States and involved 155 patients with lymphedema whose treatment was initiated from March 2004 to May 2006. The primary objective of the study was to compare treatment protocol adherence, satisfaction and perceived changes in emotional and functional status between patients with cancer- related lymphedema and non- cancer- related lymphedema using our Flexitouch system. Ninety percent of the 155 study patients reported being" satisfied" with our Flexitouch system. Of these patients, more than 65 % reported being" extremely satisfied." Further, 95 % of patients reported a positive limb volume outcome, which was defined as a patient perceiving that limb volume had been maintained or reduced with device use. Of these patients, 42 % reported limb volume decreases as much as 20 %, and an additional 20 % reported decreases of less than 20 %. In addition, clinically and statistically significant improvements occurred in all areas of physical and emotional health ($p < 0.006$). Flexitouch System Impact on Patient- Reported Improved Quality- of- Life A prospective observational study published in Annals of Vascular Surgery demonstrated that use of our Flexitouch system is associated with patient- reported overall improvement in quality- of- life and lower extremity- related symptoms. The study was conducted in the United States and collected data from patients presenting for treatment of lower- extremity lymphedema from March 2011 to September 2014. A total of 100 consecutive patients with lower- extremity lymphedema met inclusion criteria and were included in the study. The primary objective of the study was to demonstrate improved quality- of- life in patients with lower- extremity lymphedema with Flexitouch system treatment. The secondary objective was to demonstrate reduced infectious complications of lymphedema with Flexitouch system treatment, and to determine the incidence of concomitant venous insufficiency in patients with lymphedema. Use of our Flexitouch system was associated with overall improvement in lower extremity- related symptoms, with 54 % of patients reporting greatly improved symptom control after use of our Flexitouch system, 35 % moderately improved and 11 % mildly improved. In the year before use of our Flexitouch system, 15 % of the patients reported 26 episodes of cellulitis, which decreased to five episodes after initiation of the Flexitouch system ($P = 0.002$) in subsequent median follow- up of 12. 7 months. Eight percent of patients reported skin ulceration of the affected extremity in the year before presentation for treatment. The number of lower- extremity 14ulcers pre- and post- Flexitouch system use decreased from seven to two ($P = 0.007$). Overall, 46 % of the patients had complete limb girth measurements at the ankle and calf, and there was a statistically significant decreased overall limb girth after Flexitouch system treatment in pre- and post- ankle (28. 3 cm vs. 27. 5 cm, $P = 0.01$), and calf mean girths (44. 7 cm vs. 43. 8 cm, $P = 0.018$). In addition, venous reflux was present in 18 % of patients, 14 % and 4 % within the superficial and deep venous system respectively. In patients with venous reflux, moderate to great improvement in symptoms was reported in 7 % and

11 %, respectively compared with 28 % and 43 % in patients without venous reflux (P = 0. 257). Advanced Pneumatic Compression for Treatment of Lymphedema of the Head and NeckAn open label, randomized wait- list controlled trial published in the Supportive Care in Cancer journal supported the safety and feasibility of the Flexitouch system APCD for the treatment of secondary lymphedema in head and neck cancer, or HNC, patients. This study was conducted in the United States and included 49 head and neck cancer patients. Eligible patients had completed treatment for HNC, were disease free, and had lymphedema at enrollment. Participants were randomized to wait- list lymphedema self- management (standard of care) or lymphedema self- management plus the use of the APCD bib. Safety (CTCAE V4. 0) and feasibility were primary endpoints; secondary endpoints included efficacy measure by objective examination and patient reported outcomes (symptoms, quality of life, function) adherence barriers, and satisfaction. Assessments were conducted at baseline and weeks 4 and 8. No device- related serious adverse events were reported. Most patients used the APCD once per day, instead of the prescribed twice per day, citing time related factors as barriers to use. Patients in the intervention group reported improvement in perceived ability to control lymphedema (baseline: 5 / 19, 26 % good or excellent; 8 weeks: 16 / 19, 84 % good or excellent, p = 0. 003) and visible external swelling (front view p < 0. 001, right view p = 0. 004, left p = 0. 005), as well as less reported pain. Relative to patients in the control group, at 8- weeks patients using the Flexitouch system had statistically significant reductions in the reported severity of soft tissue (p = 0. 008, d = − 0. 86) and neurological symptoms (p = 0. 047, d = − 0. 60) clusters on the Lymphedema Symptom Intensity and Distress Survey- Head and Neck. Relative to patients in the control group, patients using the Flexitouch system had statistically significant improvement in swallowing solids (p = 0. 016) and mucous related symptoms (p = 0. 050, d = − 0. 80 and − 0. 57 respectively) on the Vanderbilt Head and Neck Symptom Survey plus General Symptom Survey. AffloVest Clinical EvidenceThe use of the AffloVest in patients with cystic fibrosis (“ CF ”) has been studied and reported on in non- peer reviewed journals. In 2016, a prospective study was conducted of 25 patients who were asked to augment their current airway treatment regimen with the AffloVest. These patients ranged from 11 to 18 years old and used AffloVest for periods of one month to almost a full year. Twelve patients demonstrated measurable improvement in multiple lung function tests: Forced Vital Capacity (“ FVC ”) increased 15. 22 %, Forced Expiratory Volume 1 (“ FEV1 ”) increased 17. 41 % and Forced Expiratory Flow (“ FEF ”) 25- 75 % increased 11. 21 % respectively. Eleven of the 12 patients who demonstrated positive improvement in their lung scores, and in whom those scores were maintained for nearly one year, had been using air bladder style vests previously. The remaining 13 patients saw no significant increase, and no decrease, in lung function. A prospective, single- site study was published in Respiratory Therapy in 2018 and compared the impact of traditional compressor / bladder- style HFCWO vests with that of the mobile, battery- powered AffloVest on lung function measures in 32 healthy patients. The results showed no significant difference between the technologies in increased airflow in the lungs during treatment. AffloVest performed favorably to traditional vests in that it produced no significant decline in forced vital capacity or forced expiratory volume, while the traditional vests did show statistically significant declines in these measures. In 2020, a chart review study of 30 patients compared the need for antibiotic therapy due to exacerbation, based on the number of prescriptions, emergency room visits and hospitalizations in the period approximately six months before each patient started AffloVest HFCWO therapy compared to the period six months after initiating AffloVest HFCWO therapy. The results showed a 96. 2 % reduction in hospitalizations, 82. 4 % reduction in emergency room visits, and 87. 3 % reduction in antibiotic usage for the post- AffloVest group. ~~15The~~ **15In 2023, a patient preference study was published demonstrating a strong preference for the** AffloVest **over** ~~has a history of clinical evidence, and Tactile Medical is committed to supporting additional~~ **traditional** ~~studies~~ **bladder- style vests. 93 % of symptomatic adults preferred the AffloVest** to ~~further support~~ **bladder- style vests and 90 % reported the AffloVest therapy would fit with** ~~the~~ **their** ~~benefits~~ **lifestyle. The independent, randomized study** of ~~this differentiated HFCWO technology~~ **30 vest- naïve adults was published in RT Magazine in June 2023** . Sales and Marketing Unlike many of our competitors, we **generally** utilize a direct- to- patient and- provider model to market our lymphedema products directly to patients and clinics, providing high- quality customer service and capturing both the manufacturer and distributor margins **for the majority of this business** . The direct channel allows us to focus on two of our primary call points, vascular and oncology. For AffloVest, we utilize the respiratory DME channel as our go- to- market method. Our utilization of DME representatives gives us access to a larger channel than competitors that market and sell directly. The respiratory DME channel also already serves the chronic respiratory community, enabling them to identify **complex respiratory** candidates who are regularly on other respiratory therapies (such as oxygen, nebulizers, ~~non~~ **16non** - invasive ventilators, etc.) and who might benefit from the use of our AffloVest. The below chart reflects these models: Our direct- to- patient and- provider lymphedema business is composed of a direct sales force, patient training and support, reimbursement capabilities and medical expertise to educate, expand awareness, coordinate referrals and obtain payment for our products. The chart below describes our U. S. direct- to- patient and- provider model for **the majority of** our lymphedema business. We sell the AffloVest to DME providers in the U. S. that service patients and bill third- party payers for the product. The DME providers obtain the prescription and coordinate with patients and payers to determine insurance eligibility and payment. These DME providers are staffed by trained respiratory therapists who are required in some states to set up patients on at- home prescription respiratory therapies like AffloVest. We ~~16market~~ **market** to, and educate, DME providers and clinicians about the AffloVest advantages. As of December 31, ~~2022~~ **2023** , we also employed a small group of respiratory specialists, who educate DME provider representatives, provide product demonstrations for targeted clinicians and support technical questions related to the AffloVest. ~~The~~ **17The** chart below describes our DME model. As of December 31, ~~2022~~ **2023** , we employed ~~a~~ **270** field ~~staff of 287 Tactile employees, made up of~~ sales representatives ~~, as well as managers,~~ who provide support throughout the United States for our lymphedema and respiratory therapies **compared to 251 field sales representatives as of December 31, 2022** . Our marketing team leads our efforts in brand development, product messaging, tradeshow attendance, medical educational forums, website development, social media and advertising. Reimbursement, Payer Relations and Customer Support ProcessPrivate insurers and other payers represented approximately **54 % and** 57 % ~~and 68 %~~ of our revenue in **2023 and** 2022 ~~and 2021~~ , respectively, while Medicare represented

approximately **24 % and** 19 % ~~and 17 %~~ of our revenue in **2023 and** 2022 ~~and 2021~~, respectively, Veterans Administration hospitals represented approximately 10 % ~~and 13 %~~ of our revenue in **each of 2023 and** 2022 ~~and 2021, respectively~~, and DME distributors represented approximately **12 % and** 14 % ~~and 2 %~~ of our revenue in **2023 and** 2022 ~~and 2021~~, respectively. When we sell our solutions directly to patients, we generally bill third- party payers, such as commercial insurance or Medicare, on behalf of our patients and bill the patient for their copayment obligations and deductibles. As a nationwide provider, we have developed a broad expertise in obtaining billing codes, in- network contracts, developing coverage policies, overcoming payer barriers and obtaining authorization and payment from payers across all regions of the United States. Our model utilizes our strategic and operational reimbursement proficiency to meet the varying requirements of hundreds of payers across the country. Our reimbursement function includes payer relations and reimbursement operations. Our payer relations function focuses on payer policy development and education for our entire portfolio, as well as contract negotiations for our direct business, and data analysis. Our reimbursement operations function is responsible for verifying patient insurance benefits, individual patient case development, prior authorization submissions, case follow- up, **gathering documentation from clinics,** and appeals when necessary. The reimbursement operations function is organized into ~~" regional~~ **regions** ~~payer lanes "~~ so that each case is handled throughout the process by experts in specific payer requirements. ~~17We~~ **We** have strong and established payer relationships, including most of the largest private payers in the United States. Based on our estimates, we are contracted or enrolled as an in- network provider with payers covering nearly 275 million lives. These contracts allow us to be an in- network provider for patients, enabling them to access our systems at a competitive rate and copay comparable to other suppliers and easing our administrative burden in processing authorizations and claims. We have enjoyed a consistent commercial payer ~~approval~~ **18approval** rate of greater than 80 % for the last ~~six~~ **seven** years, and a greater than 90 % Medicare claims submitted approval rate for the last ~~six~~ **seven** years (post- arbitration and based on the number of claims, not dollar amount of claims, submitted across all our products). We began doing business with Medicare in 2007. We have an in- depth understanding of specific payer coverage criteria, and our submission materials are tailored to address an individual payer' s distinct requirements. Our dedicated customer service team is available to answer patient questions regarding reimbursement, account status, device operation and troubleshooting during normal business hours. We receive no additional reimbursement for patient support, but provide high- quality customer service and continuity to enhance patient comfort, satisfaction, compliance and safety with our products. Our Flexitouch Plus system controller is reimbursed under HCPCS code E0652, and our Entre **Plus** system controller is reimbursed under HCPCS code E0651. Garments that cover various parts of the body are used with these systems and billed using HCPCS codes **E0656, E0657,** E0667, E0668 and E0669. Our head and neck garments do not currently have billing codes assigned. To date, over 1, 100 payers have paid for our products. Our respiratory DME partners contract directly with commercial payers and regularly serve as a consolidated source for various respiratory- related therapies. The DME distributor obtains the prescription and, in coordination with the patient and payer, determines insurance eligibility and payment. The AffloVest is reimbursed under HCPCS code E0483, high frequency chest wall oscillation for bronchiectasis, and over ~~40~~ **65** other ICD- 10 diagnosis codes. Research and Clinical OperationsWe are committed to ongoing research and development as part of our efforts to be at the forefront of physician and patient preference in the area of chronic disease, especially lymphedema, cancer- related lymphedema, chronic venous insufficiency, bronchiectasis and other chronic respiratory conditions. Our research and development and clinical operations functions include scientists, clinical monitors and project managers with expertise in pneumatics, electronics, garment design, embedded software, mechanical design, sensors, manufacturing technologies and clinical trial management. Our current research and development efforts are focused primarily on ~~increasing efficacy,~~ improving design for ease- of- use, enhancing clinical functionality and reducing production costs of our solutions. Our clinical development efforts are focused on further differentiating our products from our competitors. We coordinate our development efforts with our intellectual property strategies in order to enhance our ability to obtain patent and other intellectual property protection. Our research and development expenses, including spending on our clinical evidence development efforts, totaled $ 7. **8 million and $ 7.** 1 ~~million and $ 5. 7~~ million for the years ended December 31, **2023 and** 2022 ~~and 2021~~, respectively. Manufacturing and Quality AssuranceOur manufacturing and quality assurance model combines our internal manufacturing resources and expertise, including assembly, quality assurance, material procurement and inventory control, with approved third- party manufacturers and suppliers of system components. Our internal manufacturing activities, located in Minneapolis, Minnesota, include quality inspection, assembly, packaging, warehousing and shipping of our products. We outsource the manufacture of components, which are produced to our specifications and shipped to our facilities for inspection and final assembly. We use third- party manufacturers and suppliers worldwide to source our components, maintaining dual- source vendors of critical components whenever possible, and leveraging competitive bids among third- party manufacturers and suppliers to control costs. Quality control, risk management, efficiency and the ability to respond quickly to changing requirements are the primary goals of our manufacturing operations. We believe our manufacturing model permits us to operate with low capital expenditure requirements. We carefully manage our supply chain in an effort to take costs out of the manufacturing process. ~~18We~~ **We** manage our arrangements with our third- party manufacturers and suppliers to adjust delivery schedules and quantities of components to match our changing manufacturing requirements. We forecast our component needs based on historical trends, current utilization patterns and sales forecasts of future demand. We establish our relationships with our third- party manufacturers and suppliers through supplier contracts and ~~purchase~~ **19purchase** orders. In most cases, these supplier relationships may be terminated by either party upon reasonable notice. In order to mitigate against the risks related to a single source of supply, we qualify alternative suppliers, when possible, and develop contingency plans for responding to disruptions, including maintaining adequate inventory of any single source components, along with requiring each supplier to maintain specified quantities of inventory. To date, we have not experienced material delays in obtaining any of our components, nor has the ready supply of finished products to our patients or clinicians been adversely impacted by component supply issues. We have implemented a quality management system designed to comply with FDA regulations and International Standards

Organization, or ISO, standards governing medical device products. In the United States, we and some of our manufacturers are required to manufacture our products in compliance with the FDA' s Quality System Regulation, which covers the methods and documentation of the design, testing, control, manufacturing, labeling, quality assurance, packaging, storage and shipping for our products. We maintain a quality management system to control compliance with such requirements and have procedures in place designed to ensure that all products and materials purchased by us conform to our requirements and FDA regulations. Our quality management system has been certified to ISO 13485: 2003 in 2012, 2014 and 2017, and to ISO 13485: 2016 in 2019, 2020, 2021 ~~and ,~~ 2022 **and 2023** . In 2021, we also received our Medical Device Single Audit Program (" MDSAP ") certification **, which was renewed in 2023** . An MDSAP allows an MDSAP- recognized Auditing Organization to conduct a single regulatory audit of a medical device manufacturer that satisfies the relevant requirements of the regulatory authorities participating in the program. Many of our manufacturers' quality management systems also have been certified to ISO. Order Fulfillment and Patient Education With respect to our Flexitouch **Plus** and Entre **Plus** systems, once we have a complete patient order and appropriate documentation from the payer, we package and ship the system, configured to their physician' s prescription, directly to the patient. We utilize third- party carriers for delivery and pick up of our devices. After delivery and when requested by our patient, we coordinate a virtual or at- home visit from one of our trainers to provide education and instruction on use and care of their therapy system. These trainers are professionally trained and instructed on proper use of our products. Patient visits are coordinated from our offices in Minneapolis and training sessions are assigned by our staff. Additional materials including training videos and support content is available on our website to support patients and their training needs. Kylee ™ allows patients to manage their conditions by tracking treatments and symptoms, as well as having direct access to educational resources. Our AffloVest product is packaged and shipped to the DME provider or drop- shipped directly to a patient, as directed. We utilize third- party carriers for delivery and pick up of our AffloVest products. In situations in which the product is shipped to the DME provider, they are responsible for completing the delivery to the patient. Upon receipt of the product, patients are able to utilize materials included with the product to complete self- training or engage with the DME provider for additional support. Competition The pneumatic compression pump market is composed of a number of manufacturers and distributors of pneumatic compression pumps. Our most significant manufacturing competitors are Bio Compression Systems, Inc. and Lympha Press USA. ~~Other competitors are Koya Medical, Inc. and Aria Health.~~ Given the growth of the pneumatic compression pump market, we expect that the industry will become increasingly competitive in the future. Manufacturing companies compete for sales to patients primarily based on product features and service. ~~19We~~ **We** believe we are the only pneumatic compression home- therapy device company with a meaningful U. S. market position supported by a direct sales force. We believe our manufacturing competitors' complete reliance on DME distribution intermediaries compresses their margins and limits their ability to invest in clinical evidence and product features that address consumer preferences. To pursue a direct- to- patient and- provider ~~sales~~ **20sales** model, our manufacturing competitors would need to meet national accreditation and state- by- state licensing requirements, secure Medicare billing privileges, as well as compete directly with the home medical equipment providers that many rely on across their entire home care businesses. We anticipate that, given the size of the available market, we will face increased competition in the future as existing companies and competitors develop new or improved products and distribution strategies and as new companies enter the market with new technologies and distribution strategies. Our ability to compete successfully and to increase our market share is dependent upon our reputation for providing responsive, professional and high- quality products and services and achieving strong customer satisfaction. Competitors within the airway clearance market consist largely of three other HFCWO vest manufacturers: Baxter (formerly Hill- Rom), Philips Medical and Electromed. While we believe AffloVest' s portability and our use of DME distributors are differentiators, we anticipate that given the size of the airway clearance market, we will continue to see vigorous competition. We intend to further expand and support our respiratory DME relationships, as well as invest in product development **,** to better support this still- underserved area. Government Regulation Our systems are medical devices subject to extensive and ongoing regulation by numerous governmental authorities, principally the FDA, and corresponding state and foreign regulatory agencies. FDA Regulation In the United States, the FDA regulates medical devices, including the following activities that we perform, or that are performed on our behalf with respect to our devices: product design and development, pre- clinical and clinical testing, manufacturing, labeling, storage, **servicing,** premarket clearance or approval, record keeping, product marketing, advertising and promotion, sales and distribution, and post- marketing surveillance. Failure to comply with applicable U. S. requirements may subject us to a variety of administrative or judicial sanctions, such as warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution. The FDA can also refuse to clear or approve pending applications. Unless an exemption applies, each medical device we seek to distribute commercially in the United States requires marketing authorization from the FDA prior to distribution. The two primary types of FDA marketing ~~authorization~~ **authorizations** applicable to a device are premarket notification, also called **a** 510 (k) clearance, and premarket approval. The type of marketing authorization is generally linked to the classification of the device, which is based on the degree of risk the FDA determines to be associated with a device and the level of regulatory control deemed necessary to ensure the device' s safety and effectiveness. ~~Our~~ **All of our past and current models of our** Flexitouch, Entre and AffloVest systems ~~(all models)~~ are Class II devices under the FDA classification system requiring 510 (k) clearance. We obtained 510 (k) clearance for our Flexitouch system in October 2006 and for a discontinued predecessor system in July 2002. In September 2016, we received 510 (k) clearance from the FDA for the Flexitouch system for treating lymphedema of the head and neck. In June 2017, we announced that we received 510 (k) clearance from the FDA for the Flexitouch Plus, the third- generation version of our Flexitouch system. In December 2020, we received 510 (k) clearance for two new indications for our Flexitouch Plus system: phlebolymphedema and lipedema. We obtained 510 (k) clearance for our Entre system in May 2015. 510 (k) clearance for the AffloVest system was obtained in 2013. All of our Class II devices have obtained 510 (k) clearance and that status remains current as of the date of this filing. After a device receives **a** 510 (k)

clearance or a premarket approval, ~~in general~~ any modification that could significantly affect its safety or effectiveness ~~,~~ or that would constitute a major change in its intended use ~~,~~ will **generally** ~~20require~~ -- **require** a new clearance or approval. Thus, modifications ~~to~~ **or changes in use of** our existing devices will be evaluated to ensure ongoing compliance to the FDA requirements. ~~Further~~ **21Further** , even after a device receives clearance or approval by the FDA and is placed on the market, numerous regulatory requirements apply. These include: ● establishment registration and device listing; ● quality system regulation, which requires manufacturers, including third- party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the manufacturing process; ● labeling regulations and the FDA prohibitions against the promotion of products for un- cleared, unapproved or" off- label" uses, and other requirements related to promotional activities; ● medical device reporting regulations, which require that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction were to recur; ● corrections and removals reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation that may present a risk to health; and ● post- market surveillance regulations, which apply when necessary to protect the public health or to provide additional safety and effectiveness data for the device. Any new Class II devices developed by us will be submitted to the FDA as required by the 510 (k) process. Under this process, when a 510 (k) clearance is required, we must submit a premarket notification to the FDA demonstrating that our proposed device is" substantially equivalent" to a previously cleared and legally marketed 510 (k) device or a device that was in commercial distribution before May 28, 1976 for which the FDA has not yet called for the submission of a premarket approval application, which is commonly known as the" predicate device." In 2019, the FDA released an optional Safety and Performance Based Pathway for 510 (k) clearance, which allows a submitter to demonstrate that an eligible new device of a well- understood type meets FDA- identified performance criteria to demonstrate that the device is as safe and effective as a legally marketed device. If the FDA determines that the device, or its intended use, is not substantially equivalent to a previously- cleared device or use, the FDA will issue a not substantially equivalent decision. This means the device cannot be cleared through the 510 (k) process and will require marketing authorization through the premarket approval pathway. **In September 2023 the FDA released additional draft guidance around best practices for selecting a predicate device to support a premarket notification submission which further provides best practices for selecting a predicate device.** A premarket approval application must be submitted to the FDA if the device cannot be cleared through the 510 (k) process. The premarket approval application process is much more demanding **and in- depth** than the 510 (k) premarket notification process and requires the payment of significant user fees. A premarket approval application must be supported by valid scientific evidence, which typically requires extensive data, including but not limited to technical, pre- clinical, clinical trials, manufacturing and labeling to demonstrate to the FDA' s satisfaction reasonable evidence of safety and effectiveness of the device. Failure to comply with applicable regulatory requirements can result in enforcement action by the FDA, which may include **, but are not limited to,** any of the following **compliance and enforcement** ~~sanctions~~ -- **actions** : ~~Warning~~ **warning** ~~Letters~~ **letters** , fines, injunctions, civil or criminal penalties, recall or seizure of our products, operating restrictions, partial suspension or total shutdown of production, denying our request for 510 (k) clearance or premarket approval of new products, rescinding previously granted 510 (k) clearances or withdrawing previously granted premarket approvals. We are also subject to announced and unannounced inspections by the FDA, and these inspections may include the manufacturing facilities **or other sites** of our subcontractors **to audit any part of our quality system** . We were audited three times since January 2010 by the FDA and found to be in compliance with the Quality System Regulation. We cannot assure you that we can maintain a comparable level of regulatory compliance in the future at our facilities. ~~21FTC~~ **22FTC** Regulation Device advertising and promotional activity in certain circumstances is also subject to scrutiny by the Federal Trade Commission, as well as similar state consumer protection agencies, which enforce laws related to false and deceptive trade practices. A company that is found to have advertised its product in violation of these laws may be subject to liability, including monetary penalties. Centers for Medicare and Medicaid Services Centers for Medicare and Medicaid Services, or CMS, requires providers **and suppliers** of products or services to attain and maintain accreditation in order to participate in federally funded healthcare programs. To attain and maintain accreditation, **among other requirements** companies are required to institute policies and procedures that ~~, among other things,~~ formalize the interaction of the company with patients. Accrediting bodies that are approved (“ deemed ”) by CMS will perform audits of these policies and procedures every three years. Should a company fall out of compliance with the requirements of the accrediting body, expulsion from the Medicare program could follow. In May 2008, we became a Durable, Medical Equipment, Prosthetics, Orthotics, and Supplies accredited supplier by the Accreditation Commission for Health Care. This accreditation must be renewed every three years through a recredentialing process that includes an on- site review. We last renewed our accreditation with our accrediting body in May ~~2020~~ **2023** . Maintaining our accreditation and Medicare enrollment requires that we comply with numerous business and customer support standards. If we are deemed out of compliance with accreditation standards ~~,~~ our enrollment status in the Medicare program could be jeopardized, up to and including termination. Licensure Several states require that durable medical equipment providers be licensed in order to sell products to patients in that state. Certain of these states require that durable medical equipment providers maintain an in- state location. Most of our state licenses are renewed on an annual or bi- annual basis. In addition, we are subject to certain state laws regarding professional licensure. Fraud and Abuse Regulations Federal Anti- Kickback and Self- Referral Laws. The Federal Anti- Kickback Statute, among other things, prohibits the knowing and willful offer, payment, solicitation or receipt of any form of remuneration, whether directly or indirectly and overtly or covertly, in return for, or to induce the referral of an individual for the: ● furnishing or arranging for the furnishing of items or services reimbursable in whole or in part under Medicare, Medicaid or other federal healthcare programs; or ● purchase, lease, or order of, or the arrangement or recommendation of the purchasing, leasing, or ordering of any item or service reimbursable in whole or in part under Medicare, Medicaid or other federal healthcare programs.

The Federal Anti- Kickback Statute applies to certain arrangements with healthcare providers, product end users and other parties, including marketing arrangements and discounts and other financial ~~incentives~~ **arrangements** offered to our clinicians in connection with the ~~sales~~ **sale** of our products. The statute is very broad, but includes statutory safe harbors (such as a discount safe harbor) to ensure that if a company tailors its conduct in accordance with a safe harbor, it will not violate the statute. Noncompliance with the Federal Anti- Kickback Statute can result in civil, administrative and criminal penalties, restrictions on our ability to operate in certain jurisdictions, and exclusion from participation in Medicare, Medicaid or other federal healthcare programs. In addition, to the extent we are found to not be in compliance, we may be required to curtail or restructure our operations. The Ethics in Patient Referrals Act, commonly known as the" Stark Law," prohibits a physician from making referrals for certain" designated health services" payable by Medicare to an entity, including a company ~~22that~~ **23that** furnishes durable medical equipment, in which the physician or an immediate family member of such physician has an ownership or investment interest or with which the physician has entered into a compensation arrangement unless an exception applies. Violation of the Stark Law could result in denial of payment, disgorgement of reimbursements received under a noncompliant arrangement, civil penalties and exclusion from Medicare or other ~~governmental~~ **Federal health care** programs. Additionally, because some of these laws continue to evolve, we lack definitive guidance as to the application of certain key aspects of these laws as they relate to our arrangements with providers ~~with respect to patient training~~. We cannot predict the final form that these regulations will take or the effect that the final regulations will have on us. As a result, our provider arrangements may ultimately be found to be non- compliant with applicable federal law. False statements. The federal false statements statute **, relating to health care matters,** prohibits knowingly and willfully falsifying, concealing, or omitting a material fact or making any materially false statement in connection with the delivery of healthcare benefits, items, or services. In addition to criminal penalties, violation of this statute may result in collateral administrative sanctions, including exclusion from participation in Medicare, Medicaid and other federal health care programs. Federal False Claims Act and Civil Monetary Penalties Law. The Federal False Claims Act provides, in part, that the federal government may bring a lawsuit against any person whom it believes has knowingly presented, or caused to be presented, any false or fraudulent request for payment from the federal government, or who has made a false statement or used a false record to get a claim paid or to avoid, decrease or conceal an obligation to pay money to the federal government or knowingly retained an overpayment. **The** ~~In addition, amendments to the~~ Federal False Claims Act **' s qui tam provisions** have made it easier for private parties to bring whistleblower lawsuits against companies. The Civil Monetary Penalties Law provides, in part, that the federal government may seek civil monetary penalties against any person that, like under the Federal False Claims Act, presents or causes to be presented claims to a Federal health care program that the person knows or should know is for an item or services that was not provided as claimed or is false or fraudulent or that has made a false statement or used a false record to get a claim paid. The federal government may also seek civil monetary penalties for a wide variety of other conduct, including offering remuneration to influence a Medicare or Medicaid beneficiary' s selection of providers and violations of the Federal Anti- Kickback Statute. If we are found to be in violation of the Federal False Claims Act or the Civil Monetary Penalties laws, penalties include fines for each false claim violation of the Federal False Claims Act and varying amounts based on the type of violation of the Civil Monetary Penalties Law, plus up to three times the amount of damages that the federal government sustained because of the act of that person. In addition, the federal government may also seek exclusion from participation in all federal health care programs. In addition, we bill Medicare Part B **, Medicaid, the Veterans Administration** and other insurers directly for ~~each sale~~ **lymphedema products provided** to patients. As a result, we must comply with all laws, rules and regulations associated with filing claims with the Medicare program, including the Social Security Act, Medicare regulations, the Federal False Claims Act and the Civil Monetary Penalties Law, as well as a variety of additional federal and state laws. During an audit, insurers typically expect to find explicit documentation in the medical record to support a claim. Physicians and other clinicians, who are responsible for prescribing our products for patients, are expected to create and maintain the medical records that form the basis for the claims we submit to Medicare and other insurers. Any failure to properly document the medical records for patients using our products could invalidate claims, impair our ability to collect submitted claims and subject us to overpayment liabilities, Federal False Claims Act liabilities and other penalties including exclusion from the Medicare, Medicaid **, other government health care programs** or private insurance programs. State fraud and abuse provisions. Many states have also adopted some form of anti- kickback and anti- referral laws and false claims acts that apply regardless of payer, in addition to items and services reimbursed under Medicaid and other state programs. In some states, these laws apply, and we believe that we are in compliance with such laws. Nevertheless, a determination of liability under such laws could result in fines and penalties and restrictions on our ability to operate in these jurisdictions. ~~23The~~ **24The** U. S. Foreign Corrupt Practices Act and Other Anti- Corruption Laws. We may be subject to a variety of domestic and foreign anti- corruption laws with respect to our regulatory compliance efforts and operations. The U. S. Foreign Corrupt Practices Act **(,** ~~, commonly known as~~ the **“** FCPA ~~,~~ **”)** is a criminal statute that prohibits an individual or business from paying, offering, promising or authorizing the provision of money (such as a bribe or kickback) or anything else of value (such as an improper gift, hospitality, or favor), directly or indirectly, to any foreign official, political party or candidate for the purpose of influencing any act or decision in order to assist the individual or business in obtaining, retaining, or directing business or other advantages (such as favorable regulatory rulings). In addition to the FCPA, there are other federal and state anti- corruption laws to which we may be subject, including, the U. S. domestic bribery statute contained in 18 USC § 201 (which prohibits bribing U. S. government officials) and the U. S. Travel Act (which in some instances addresses private- sector or commercial bribery both within and outside the United States). Also, a number of other countries have their own domestic and international anti- corruption laws, such as the UK Bribery Act 2010. We could be held liable under the FCPA and other anti- corruption laws for the illegal activities of our employees, representatives, contractors, collaborators, agents, subsidiaries, or affiliates, even if we did not explicitly authorize such activity. Although we will seek to comply with anti- corruption laws, there can be no assurance that all of our employees, representatives,

contractors, collaborators, agents, subsidiaries or affiliates will comply with these laws at all times. Violation of these laws could subject us to whistleblower complaints, investigations, sanctions, settlements, prosecution, other enforcement actions, disgorgement of profits, significant fines, damages, other civil and criminal penalties or injunctions, suspension and / or debarment from contracting with certain governments or other persons, the loss of export privileges, reputational harm, adverse media coverage and other collateral consequences. In addition, our directors, officers, employees, and other representatives who engage in violations of the FCPA and certain other anti- corruption statutes may face imprisonment, fines and penalties. State and federal transparency / reporting requirements. As part of the Patient Protection and Affordable Care Act, or ACA, the Federal government has created a transparency program known as Open Payments (the Physician Payments Sunshine Act) which requires **applicable** manufacturers of drugs, devices, biologicals and medical supplies to report annually to the CMS, an agency within the U. S. Department of Health and Human Services, or HHS, information related to payments and other transfers of value provided to physicians and teaching hospitals (" covered recipients ") and certain ownership and investment interests held by physicians and their immediate family members. Beginning in 2021, tracking and reporting was expanded to include additional covered recipients, namely physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists and certified nurse- midwives. Failure to submit timely, accurate and complete information may result in **significant** civil monetary penalties ~~of up to an aggregate of $ 150, 000 per year and up to an aggregate of $ 1. 0 million per year~~ for" knowing failures to report." Certain states **have their own versions of the Physician Payments Sunshine Act, and may also** require implementation of commercial compliance programs and compliance with the device industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, impose restrictions on marketing practices, and / or prohibition and tracking and reporting of gifts, compensation and other remuneration or items of value provided to physicians and other healthcare professionals and entities. The laws described above impact the kinds of financial arrangements we may have with hospitals, healthcare professionals or other potential purchasers of our products. If our operations are found to be in violation of any of the laws or regulations described above or others that apply to us, we may be subject to penalties, including potentially significant criminal, civil and / or administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations. HIPAA. The Health Insurance Portability and Accountability Act of 1996, or HIPAA, established uniform standards governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of individually identifiable health information maintained or transmitted by healthcare providers, health plans and healthcare clearinghouses, which are referred to as covered entities. The standards promulgated under HIPAA' s regulations include those that: ● restrict the use and disclosure of individually identifiable health information, or" protected health information"; ~~24~~ **25** ● establish standards for common electronic healthcare transactions, such as claims information, plan eligibility, payment information and the use of electronic signatures; ● require covered entities to implement and maintain certain security measures to safeguard certain electronic health information, including the adoption of administrative, physical and technical safeguards to protect such information; and ● require covered entitles to provide notification to affected individuals, the Department of Health and Human Services and the media in the event of a breach of unsecured protected health information. The American Recovery and Reinvestment Act of 2009, or ARRA, expanded HIPAA' s privacy and security standards. ARRA includes the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, which, among other things, made HIPAA' s privacy and security standards directly applicable to business associates of covered entities. A business associate is a person or entity that performs certain functions or activities on behalf of a covered entity that involve the use or disclosure of protected health information. As a result, business associates are now subject to significant civil and criminal penalties for failure to comply with applicable standards. Moreover, HITECH creates a new requirement to report certain breaches of unsecured, individually identifiable health information and imposes penalties on entities that fail to do so. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons 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 attorney fees and costs associated with pursuing federal civil actions. The 2013 final HITECH omnibus rule, or the HITECH Final Rule, modifies the breach reporting standard in a manner that makes more data security incidents qualify as reportable breaches. The costs of complying with privacy and security related legal and regulatory requirements are burdensome. The HITECH Final Rule will continue to be subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us, as well as referring providers. In addition to federal regulations issued under HIPAA, several states have enacted privacy and security statutes or regulations that, in certain cases, are more stringent than those issued under HIPAA. In those cases, it may be necessary to modify our planned operations and procedures to comply with the more stringent state laws. Most states have also adopted breach notification laws that require notification to affected individuals and certain state agencies if there is a security breach of certain individually- identifiable information. If we suffer a privacy or security breach, we could be required to expend significant resources to provide notification to the affected individuals and address the breach, as well as reputational harm associated with the breach. If we fail to comply with applicable state laws and regulations, we could be subject to additional sanctions. Any liability from failure to comply with the requirements of HIPAA, HITECH or state privacy and security statutes or regulations could adversely affect our financial condition. The costs of complying with privacy and security related legal and regulatory requirements are burdensome and could have a material adverse effect on our business, financial condition and results of operations. Environmental Regulation Our research and development and manufacturing processes and operations may involve the controlled use of hazardous materials, including flammables, toxics and corrosives and produce hazardous chemical waste products. We are subject to numerous foreign, federal, state, and local environmental, health and safety laws and regulations relating to, among other matters, safe working conditions, product stewardship and end- of- life handling or disposition of products, and environmental protection,

including those governing the generation, storage, handling, use, transportation and disposal of hazardous or potentially hazardous materials. Some of these laws and regulations require us to obtain licenses or permits to conduct our operations. Environmental laws and regulations are complex, change frequently and have tended to become more stringent over time. ~~25Foreign~~ **26Foreign** Government Regulation International sales of medical devices are subject to foreign governmental regulations, which vary substantially from country to country. The time required to obtain clearance or approval by a foreign country may be longer or shorter than that required for FDA clearance or approval, and the requirements may be different. Many countries also impose product standards, packaging requirements, environmental requirements, labeling requirements, and import restrictions on medical devices. Each country has its own tariff regulations, duties and tax requirements. Failure to comply with applicable foreign regulatory requirements may subject a company to fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions, criminal prosecution or other consequences. The European Union is the primary regulator in Europe, which has adopted numerous directives / regulations and has promulgated standards regulating the design, manufacture, clinical trials, labeling and adverse event reporting for medical devices. Medical devices that comply with the requirements of applicable directives / regulations will be entitled to bear the CE conformity marking, indicating that the device conforms with the essential requirements of the applicable directives / regulations and, accordingly, can be commercially distributed throughout the member states of the European Union, and other countries that comply with or mirror these directives. At this time, we have no products that are CE marked ~~. In March 2012, we received our Medical Device License in Canada for our Flexitouch (classic) system and in June 2021 for our Flexitouch (Plus) system. In October 2021, we discontinued our Flexitouch (classic) system Medical Device License in Canada, but our Flexitouch (Plus) system License remains current as of the date of this filing~~ . Third- Party Reimbursement In the United States and elsewhere, sales of medical devices depend in significant part on the availability of coverage and reimbursement to providers and patients from third- party payers. Third- party payers include private insurance plans and governmental programs. As with other medical devices, reimbursement for our products can differ significantly from payer to payer, and our products are not universally covered by third- party commercial payers. Further, third- party payers continually review existing technologies for continued coverage and can, with limited notice, deny or reverse coverage for existing products. Two principal governmental third- party payers in the United States are Medicare and Medicaid. Medicare is a federal program that provides certain medical insurance benefits to persons age 65 and over, certain disabled persons and others. In contrast, Medicaid is a medical assistance program jointly funded by federal and state governments to serve certain individuals and families with low incomes and who meet other eligibility requirements. Each state administers its own Medicaid program which determines the benefits made available to the Medicaid recipients in that state. The Medicare and Medicaid statutory framework is subject to administrative rulings, interpretations and discretion that affect the amount and timing of reimbursement made under Medicare and Medicaid. CMS, which is the agency within the Department of Health and Human Services that administers both Medicare and Medicaid, has the authority to decline to cover particular products or services if it determines that they are not" reasonable and necessary" for the treatment of Medicare beneficiaries. A coverage determination for a product, which establishes the indications that will be covered, and any restrictions or limitations, can be developed at the national level by CMS through a National Coverage Determination, or NCD, or at the local level through a Local Coverage Determination, or LCD, by a regional Medicare Administrative Contractor, which is a private contractor that processes and pays claims on behalf of CMS for the geographic area where the services were rendered. Obtaining a coverage determination, whether an NCD or LCD, is a time- consuming, expensive and highly uncertain endeavor, especially for a new device. Under ~~a~~ **the current** NCD that has been effective since January 14, 2002, pneumatic compression devices, or PCDs, including our products, are covered for the treatment of lymphedema or for the treatment of chronic venous insufficiency with venous stasis ulcers. A LCD, administered by the ~~four~~ **two** Medicare Administrative Contractors responsible for processing durable medical equipment claims, sets forth additional coverage criteria that impacts Medicare coverage for our products. **The validity of the coverage criteria in the LCD is currently under dispute in the District Court of the District of Columbia.** Our Medicare business was **24 % of revenue in 2023 compared to** 19 % ~~of revenue~~ in 2022 ~~compared to 17 % in 2021~~ . ~~26Because~~ -- **Because** Medicare criteria is extensive, we have a team dedicated to educating ~~prescribers~~ **clinicians** to help them understand how Medicare policy affects their patients and the medical record documentation needed to meet Medicare requirements. We maintain open communication with physician key opinion leaders and with Medicare contractors to provide data as it becomes available that could potentially influence coverage ~~decisions~~ **27decisions** . We also continue to closely monitor our Medicare business to identify trends that could have a negative impact on certain Medicare patients' access to our products, which in turn could have an adverse effect on our business and results of operations. Commercial payers that reimburse for our products do so in a variety of ways, depending on the insurance plan' s policies, employer and benefit manager input, and contracts with their provider network. Moreover, Medicaid programs and some commercial insurance plans, especially Medicare Advantage plans (commercial insurers that are administering Medicare benefits to certain beneficiaries), are frequently influenced by Medicare coverage determinations. In working with payers who follow Medicare criteria, we have focused on clear communications with insurers to ensure mutual understanding of criteria interpretation, which differs significantly among the plans from very restrictive to quite lenient, and we then work closely with ~~prescribers~~ **clinicians** to educate them accordingly. While this approach has had positive impact, we do not know if or when additional payers may adopt **more restrictive criteria like** the LCD ~~criteria~~ nor do we know how they will choose to interpret it. We believe a reduction or elimination of coverage or reimbursement of our products by Medicare would likely cause some commercial third- party payers to implement similar reductions in their coverage or reimbursement of our products. If we are unable to expand coverage of our products by additional commercial payers, or if third- party payers that currently cover or reimburse for our products reverse or limit their coverage or reimbursement levels in the future, our business and results of operations could be adversely affected. Intellectual Property Our intellectual property consists of patented designs and methods and proprietary know- how. In addition to the patented designs and methods discussed below, we have made

significant investments in proprietary know- how, including the manufacture of fabrics and garments used in our systems and the algorithms used to manage the inflation and deflation of our systems and other functions of the controllers. To maintain and protect our proprietary technologies and products, we rely on a combination of patent, copyright, trademark, trade secret and other intellectual property laws, and confidentiality provisions in our contracts. We have a policy to enter into confidentiality agreements with employees, consultants, third parties and our advisors to protect our intellectual property and maintain our competitive position. We also require our employees and consultants to sign agreements requiring that they assign to us their interest in intellectual property such as patents and copyrights arising from their work for us. We also require all employees to sign an agreement not to compete unfairly with us during their employment and upon termination of their employment through the misuse of confidential information, soliciting employees, and soliciting customers. Despite any measures taken to protect our intellectual property, unauthorized parties may attempt to copy aspects of our systems or to obtain and use information that we regard as proprietary. Patents Our patent portfolio consists of ~~three~~ **four** sets of patents, including patents relating to our Flexitouch system **, our AffloVest system** and other ~~wearable compression-~~ related technologies. As of December 31, ~~2022~~ **2023** , we owned about ~~188~~ **171** issued patents globally, of which ~~62~~ **63** were issued U. S. patents. As of December 31, ~~2022~~ **2023** , we owned about ~~30~~ **24** pending patent applications pending globally, of which 9 were pending patent applications in the United States. Our U. S. issued patents have varying patent terms, expiring between ~~2023~~ **2024** and through at least 2040, subject to payment of required maintenance fees, annuities and other charges. U. S. patents covering various aspects of our Flexitouch system expired in 2017. Trademarks We have registered the trademarks Tactile Medical, Flexitouch, **Flexitouch Plus,** the Flexitouch logo design, **ComfortEase,** Entre, AffloVest, ~~and~~ AffloVest Pro **, and Kylee** with the United States Patent and Trademark Office on the Principal Register. We rely in the United States on common law rights to the Tactile Medical design trademark. The Tactile Medical ~~27trademark --~~ **trademark** is registered in Australia and Japan, and the AffloVest trademark is registered in Australia, the European Union, New Zealand and the United Kingdom. ~~SeasonalityOur~~ **28SeasonalityOur** business is affected by seasonality. See " Management' s Discussion and Analysis of Financial Condition and Results of Operations – Seasonality. " Human Capital Resources As a company, our focus is on developing and selling solutions that help increase clinical efficacy, reduce overall healthcare costs and improve the quality of life for patients with chronic conditions by treating them at home. We believe the strength of our employees is the cornerstone to achieving these goals. As of December 31, ~~2022~~ **2023** , we had ~~982~~ **992** employees. We have ~~566~~ **592** employees who are based throughout the United States, as well as ~~416~~ **400** employees who are primarily based in our corporate / manufacturing locations in the Minneapolis metropolitan area. Our employees are our most important resource and they set the foundation for our ability to achieve our strategic objectives. The success and growth of our business depends, in large part, on our ability to attract, retain and develop a diverse population of talented and high- performing employees at all levels of our organization, including the individuals who comprise our workforce as well as executive officers and other key personnel. To succeed in a competitive labor market, we have developed key recruitment and retention strategies, objectives and measures that we focus on as part of the overall management of our business. These strategies, objectives and measures form the pillars of our human capital management framework and are advanced through the following programs, policies and initiatives: Total Rewards: Rewarding and supporting our employees is essential to Company morale. To maintain a competitive salary and benefits package, we utilize an independent third party to evaluate employee compensation. We continue to explore and utilize benefits options in line with our growing and diverse workforce to attract and retain top talent. These benefits include but are not limited to retirement savings, an employee stock purchase plan, a variety of health insurance options, including dental and vision, discounts on healthy foods and fitness memberships, disability insurance, paid maternity / paternity leave, and a company volunteer program ~~implemented in 2022~~ providing employees paid time to give back to the community ~~. Our Remote Work Policy also allows for a flexible work schedule and location, depending on business needs and the specific role~~ . Diversity, Equity, and Inclusion: We consider diversity, equity, inclusion, and employee engagement as cornerstones to the future growth of the business. Our diverse and inclusive workplace encourages different perspectives and ideas, which we believe enables better business decisions and rapid innovation. We are committed to constructive and critical self- evaluation that leads to concrete steps that continually enhance and strengthen our corporate culture. Based on employee feedback, we have assessed our company practices and developed goals to guide our diversity, equity, and inclusion initiatives including: ● Increased diversity awareness programs for all areas of our organization; and ● Increased focus on enhancing inclusiveness in our culture and understanding unintentional bias. Fair Labor Practices: We seek fair labor practices throughout our business, including from our partners and key suppliers who share our values for human rights, dignity, and respect. We have adopted a Human Rights Policy formalizing this commitment and implemented a Supplier Code of Conduct, requiring from our suppliers the same commitment to human rights, fair labor practices, and anticorruption that we value here at Tactile Medical. Health and Safety: The health and safety of our employees is a vital aspect to the success of the Company. We provide all employees training on workplace safety and require employees to follow standards and practices supporting a safe and healthy work environment. ~~28Talent --~~ **Talent** and Retention: In ~~2022~~ **2023** , we continued to focus on recruitment, hiring, and retention to ensure high quality talent and a strong fit for specific roles ~~and~~ **within** the Company. Our recruitment efforts are expanding through strong recruiting and hiring processes, as well as **the expansion** ~~utilization and enhancements~~ of our **new internship program** ~~recruiting platform we implemented~~ in ~~2021~~ **2023** . The company intranet facilitates employee inclusion, provides resources, and advances transparent ~~communication~~ **29communication** efforts. We ~~have~~ also ~~implemented~~ **introduced a number of new learning** ~~an~~ **and** ~~internal platform~~ **development options** for **our team members in 2023** ~~employees to acknowledge achievements of colleagues and highlight company values, encouraging a culture of collaboration and positive reinforcement~~ . We continue to be diligent and remain focused on our employee engagement strategies, including through exit interview analyses, talent management and retention risk analyses and ~~an~~ **periodic** employee engagement ~~survey~~ **surveys** ~~that we rolled out in December 2022~~ . Available InformationWe file annual, quarterly and current reports, proxy statements and other information with the SEC. The SEC

maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC at http: / / www. sec. gov. We also make financial information, news releases and other information available on our corporate website at www. tactilemedical. com. Our annual reports on Form 10- K, quarterly reports on Form 10- Q, current reports on Form 8- K, and any amendments to those reports filed or furnished pursuant to Section 13 (a) or 15 (d) of the Securities Exchange Act of 1934 are available free of charge on this website as soon as reasonably practicable after we electronically file these reports and amendments with, or furnish them to, the SEC. The information contained on or connected to our website is not incorporated by reference into this Annual Report on Form 10- K and should not be considered part of this or any other report filed with the SEC. Item 1A. Risk Factors. Risk factors which could cause actual results to differ from our expectations and which could negatively impact our financial condition and results of operations are discussed below and elsewhere in this report. Additional risks and uncertainties not presently known to us or that are currently not believed to be significant to our business may also affect our actual results and could harm our business, financial condition and results of operations. If any of the risks or uncertainties described below or any additional risks and uncertainties actually occur, our business, results of operations and financial condition could be materially and adversely affected. Risks Related to Our Business, Operations and Strategy Current or worsening economic conditions, including inflation, rising interest rates or a recession, could adversely affect our business and financial condition. General global economic downturns and macroeconomic trends, including heightened inflation, capital market volatility, interest rate fluctuations, and economic slowdown or recession, may result in unfavorable conditions that could negatively affect demand for our products and exacerbate some of the other risks that affect our business, financial condition and results of operations. Further, current or worsening economic conditions may adversely impact payment terms or rates, and the amount spent on healthcare generally, which could result in decreased demand for our products. If we are unable to achieve and maintain adequate levels of coverage or reimbursement for our products, our business and results of operations will be adversely affected. Any decline in the amount payers are willing to pay for our products could create pricing pressure for us. If we are forced to lower the price we charge for our products, our gross margins will decrease, which will adversely affect our business, financial condition and results of operations. Also, insurance benefit levels vary substantially by health plan, meaning that some patients have high annual out- of- pocket medical costs, which may make it difficult for those patients to afford our products. ~~29Third~~ -- **Third** - party payers, whether foreign or domestic, or governmental or commercial, are developing increasingly sophisticated methods of controlling healthcare costs. In the United States, no uniform policy of coverage and reimbursement for our products exists among third- party payers. Therefore, reimbursement for our products can differ significantly from payer to payer and our products are not universally covered by third- party commercial payers. In addition, payers, including Medicare, continually review existing technologies for ~~continued~~ **30continued** coverage and can, without notice, deny or reverse coverage for existing products. We believe a reduction or elimination of coverage or reimbursement of our products by Medicare would likely cause many commercial third- party payers to implement similar reductions or elimination of their coverage or reimbursement of our products. If we are unable to expand coverage of our products by additional commercial payers, or if third- party payers that currently cover or reimburse for our products reverse or limit their coverage or reimbursement levels in the future, our business and results of operations could be adversely affected. Further, we believe that future coverage and reimbursement may be subject to increased restrictions, such as additional preauthorization requirements. If we are unable to satisfy any new preauthorization requirements or adjust to any future new restrictions on our products, third- party coverage and reimbursement may be limited in the future, which could have an adverse impact on our business. In addition, payers often conduct routine audits and request customer records and other documents to support ~~our~~ claims submitted for payment. Recent increases in the frequency and scope of such audits, as well as findings as a result of such audits, could lead to our inability to collect receivables, or require us to repay amounts previously received, which could adversely affect our business and results of operations. Changes to the level of Medicare coverage or coverage criteria for our products could have an adverse effect on our business and results of operations. Determinations of which products or services will be reimbursed under Medicare can be developed at the national level through a National Coverage Determination, or NCD, by CMS, or at the local level through a Local Coverage Determination, or LCD, by the four regional Medicare Administrative Contractors, which are private contractors that process and pay claims on behalf of CMS for different regions. These NCDs and LCDs may be subject to review and revision from time to time, which revisions may not be favorable for coverage of our products. Additional NCDs or LCDs, or changes in NCDs or LCDs for our products, could have adverse effects on our business. Further, we believe that a reduction or elimination of coverage or reimbursement of our products by Medicare would likely cause some commercial third- party payers to implement similar reductions in their coverage or reimbursement of our products. Given the evolving nature of the healthcare industry and ongoing healthcare cost reforms, we are and will continue to be subject to changes in the level of Medicare coverage for our products, and unfavorable coverage determinations at the national or local level could adversely affect our business and results of operations. We utilize third- party, single- source suppliers for some components and materials used in our products, and the loss of any of these suppliers could have an adverse impact on our business. We rely on third- party manufacturers and suppliers to supply all components and materials used in our Flexitouch **Plus** , Entre **Plus** and AffloVest systems. Our ability to supply our products commercially depends, in part, on our ability to obtain components and materials in accordance with our specifications and with regulatory requirements and in sufficient quantities to meet demand for our products. Our ability to obtain components and materials may be affected by matters outside our control, including that our suppliers may cancel our arrangements on short notice, we may be relatively less important as a customer to certain suppliers and our suppliers may have disruptions to their operations. If we are required to establish additional or replacement suppliers for any of our components or materials, it may not be accomplished quickly and our operations could be disrupted. Even if we are able to find replacement suppliers, the replacement suppliers would need to be qualified and may require additional regulatory authority approval, which could result in further delay. In the event of a supply disruption, our product inventories may be insufficient to supply our patients. If our

third- party suppliers fail to deliver the required commercial quantities of materials on a timely basis and at commercially reasonable prices, and we are unable to find one or more replacement suppliers ~~30capable~~ -- **capable** of production at a substantially equivalent cost in substantially equivalent volumes and quality on a timely basis, the continued commercialization of our products, the supply of our products to customers and the development of any future products would be delayed, limited or prevented, which could have an adverse impact on our business. ~~Our~~ **31Our** revenue is primarily generated from our lymphedema products and we are therefore highly dependent on these products. Our lymphedema products accounted for **88 % and** 86 ~~% and 98~~ % of our revenue for the years ended December 31, **2023 and** 2022 ~~and 2021~~, respectively. We expect that sales of our lymphedema products will continue to account for a majority of our revenue going forward. Therefore, our ability to execute our growth strategy will depend not only upon increasing awareness of lymphedema, but also on the adoption of our products to treat this condition. Many physicians and clinicians may have experience with, and / or invested substantial resources in, developing expertise in traditional or alternative treatments for lymphedema, which may make them less willing to adopt our products. If our lymphedema products fail to achieve wide market acceptance for any reason, our business, financial condition and results of operations could be adversely affected. We are increasingly dependent on sophisticated information technology and if we fail to effectively maintain or protect our information systems or data, including from cyber- attacks or data breaches, our business could be adversely affected. We are increasingly dependent on sophisticated information technology for our products and infrastructure. In some cases, we have outsourced elements of our operations to third parties, and, as a result, we manage a number of third- party vendors who may or could have access to our intellectual property, proprietary business information, personal information of patients and employees and other confidential information. Our information systems, and those of third- party vendors with whom we contract, require an ongoing commitment of significant resources to maintain, protect and enhance existing systems and develop new systems to keep pace with continuing changes in information technology, evolving systems and regulatory standards and the increasing need to protect patient, customer and employee information, including personally- identifiable information. In addition, given their size and complexity, these systems could be vulnerable to service interruptions or to security breaches from inadvertent or intentional actions by our employees, third- party vendors and / or business partners, or from cyber- attacks by malicious third parties attempting to gain unauthorized access to our products, systems or confidential information (including, but not limited to, intellectual property, proprietary business information and personal information of our patients, customers and employees). We are subject to cyber- attacks, including state- sponsored cyber- attacks, industrial espionage, insider threats, computer denial- of- service attacks, computer viruses, ransomware and other malware, phishing attacks, payment fraud or other cyber incidents. Cyber incidents are becoming more sophisticated, frequent and adaptive. If we fail to maintain or protect our information systems and data integrity effectively, we could: ● lose existing customers; ● have difficulty attracting new customers; ● have problems in determining product cost estimates and establishing appropriate pricing; ● suffer outages or disruptions in our operations or supply chain; ● have difficulty preventing, detecting, and controlling fraud; ● have disputes with customers, physicians, and other healthcare professionals; ● have regulatory sanctions or penalties imposed; ● incur increased operating expenses; ~~31~~ ● be subject to issues with product functionality that may result in a loss of data, risk to patient safety, field actions and / or product recalls; ● incur expenses or lose revenue as a result of a data privacy breach; or ● suffer other adverse consequences. ~~We~~ **32We** cannot assure you that cyber- attacks or data breaches will not occur or that systems issues will not arise in the future. Any significant breakdown, intrusion, breach, interruption, corruption or destruction of these systems could have a material adverse effect on our business and reputation. In addition, we accept payments for many of our sales through credit and debit card transactions, which are handled through a third- party payment processor. As a result, we are subject to a number of risks related to credit and debit card payments, including that we pay interchange and other fees, which may increase over time and could require us to either increase the prices we charge for our products or experience an increase in our costs and expenses. In addition, as part of the payment processing process, we transmit our patients' and clinicians' credit and debit card information to our third- party payment processor. We may in the future become subject to lawsuits or other proceedings for purportedly fraudulent transactions arising out of the actual or alleged theft of our patients' credit or debit card information if the security of our third- party credit card payment processor is breached. We and our third- party credit card payment processor are also subject to payment card association operating rules, certification requirements and rules governing electronic funds transfers, which could change or be reinterpreted to make it difficult or impossible for us to comply. Failure to comply with these rules or requirements may result in fines and higher transaction fees, or we may lose the ability to accept credit and debit card payments from our patients, and there may be an adverse impact on our business. Consolidation in the healthcare industry could lead to demands for price concessions, which may impact our ability to sell our products at prices necessary to support our current business strategies. Healthcare costs have risen significantly over the past decade, which has resulted in or led to numerous cost reform initiatives by legislators, regulators and third- party payers. Cost reform has triggered a consolidation trend in the healthcare industry to aggregate purchasing power, which may create more requests for pricing concessions in the future. We expect that market demand, government regulation, third- party coverage and reimbursement policies and societal pressures will continue to change the healthcare industry worldwide, resulting in further business consolidations and alliances among our payers, which may exert increasing downward pressure on the prices of our products in the future. Our long- term growth depends on awareness and adoption of our products. A primary growth strategy is to establish our products as the standard of care for the treatment of chronic diseases. In order to achieve this growth strategy, we must: ● increase clinician and consumer awareness of these diseases, which are often underserved; ● introduce the clinical and economic benefits of our solutions to physicians, therapists and other clinicians across several specialties and in various clinical settings; and ● demonstrate consistent coverage and reimbursement for our solutions by private payers, Medicare, the Veterans Administration and certain Medicaid programs. Clinicians may not adopt our solutions as the standard of care for lymphedema, chronic venous insufficiency and chronic respiratory conditions or may not prescribe our products for a number of reasons, including: ● our inability to educate a

sufficient number of clinicians on these diseases or our products; ● the unavailability or inadequacy of insurance coverage or reimbursement for our products; ~~32~~ ● failure of evidence supporting clinical benefits or cost- effectiveness of our products over existing alternatives to convince clinicians to change their treatment methods; and ● resistance from clinicians to replace traditional treatments with our solutions. ~~We~~ **33We** believe recommendations and support of our products by key opinion leaders can influence market acceptance and adoption. If these key opinion leaders choose to not support our products, our ability to achieve broad market acceptance for our products may be impaired. If we are unable to expand, manage and maintain our direct sales and marketing organizations, as well as our relationships with distributors, we may not be able to generate anticipated revenue. Our operating results are directly dependent upon the sales and marketing efforts of our employees and upon our relationships with our distributors and their sales and marketing efforts. If our direct sales force or our distributors fail to adequately promote, market and sell our products, our sales may suffer. **At** ~~During most of 2020, 2021 and~~ the **height** ~~first quarter~~ of ~~2022~~ **the pandemic** , our direct sales force ~~for our lymphedema product line~~ experienced increased turnover and difficulty in recruiting qualified replacements. ~~Although~~ **The recruiting and retention of our sales force remains an important element of our commercial execution. Our future success depends largely on our ability to hire, train, retain and motivate skilled sales personnel with significant technical knowledge of lymphedema, chronic venous insufficiency and bronchiectasis. Failure to hire or retain qualified sales personnel would prevent us from building awareness of our solutions, expanding our business and maintaining or generating additional sales. If** we ~~saw some level of recovery in 2022 after the first quarter~~ **are unable to maintain or expand our sales and marketing capabilities** , we **may not** ~~cannot assure you that this recovery will continue or that we will~~ be able to ~~recruit~~ **effectively commercialize our products, which could have** ~~and~~ **an adverse impact on** ~~retain quality candidates for~~ our **business** ~~direct sales force~~ . For our respiratory therapy products, we rely on DME providers for all aspects of sales, reimbursement, training and support **. Our future success with respect to our respiratory therapy products depends largely on our ability to maintain and expand relationships with our current, and to enter into relationships with new, distributors of our airway clearance products** . Our ability to continue to market, distribute, and sell our airway clearance products may be at risk if key or multiple of the DME providers choose to stop selling our products or if we are unable to enter into relationships with new distributors. ~~Our future success will depend largely~~ **Further, because we fully rely** on ~~our ability~~ **DME providers related** to ~~hire, train, retain and motivate skilled~~ sales ~~personnel with significant technical knowledge~~ of ~~lymphedema and chronic venous insufficiency, and~~ our **AffloVest product** ~~ability to maintain and expand relationships with our current~~ , ~~and enter into relationships with new~~ **any disruption affecting those DMEs could adversely impact our results** , ~~distributors~~ **such as the large DME provider that experienced slowed placements** of **AffloVest due to eligibility requirement changes that led to the decrease in** our airway clearance ~~products~~ **product line revenue in 2023** ~~. Failure to do so would prevent us from building awareness of our solutions, expanding our business and maintaining or generating additional sales. If we are unable to maintain or expand our sales and marketing capabilities and our distributor relationships, we may not be able to effectively commercialize our products, which could have an adverse impact on our business~~ . Physicians and payers may require additional clinical studies prior to prescribing our products or prior to providing or maintaining coverage and reimbursement for our products. Any subsequent clinical studies that are conducted and published may not be positive or consistent with our existing data, which would adversely affect the rate of adoption of our products. Our success depends in large part on the medical and third- party payer community' s acceptance of our products as being useful in treating patients with lymphedema, chronic venous insufficiency or chronic respiratory conditions. While the results of our studies collectively indicate a favorable safety and efficacy profile, the study designs and results may not be viewed as compelling to physicians and insurers. In particular, payers and physicians may see limitations in the design and results of the studies because certain studies were not specifically based on our products, involved a limited number of total subjects or subjects outside the control group and made" quality of life" conclusions based upon criteria contained in patient questionnaires that required subjective conclusions. Certain physicians and insurers may also prefer to see longer- term efficacy data than we have produced or are able to produce. If physicians or insurers do not find our data compelling or wish to wait for additional or independently- performed studies, they may choose not to prescribe or to provide coverage and reimbursement for our products. We cannot assure you that any data that we or others generate will be consistent with that observed in the existing studies or that results will be maintained beyond the time points studied. We also cannot assure you that any data that may be collected will be compelling to the medical community because the data may not be scientifically meaningful or may not demonstrate that our products are attractive alternatives to traditional treatments. If subsequent studies are not positive or consistent with our existing data, adoption of our products may suffer and, accordingly, our business could be adversely impacted. ~~33The~~ **34Our business, financial condition and results of operations may be negatively impacted by health epidemics or other outbreaks, such as the** COVID- 19 pandemic ~~has had, and may continue to have, an adverse effect on our business, financial condition and results of operations~~ . The United States economy in general and our business specifically **were** ~~have been~~ negatively affected by the COVID- 19 pandemic **, including a** ~~. We have seen adverse impacts as it relates to the~~ decline in the number of patients that healthcare facilities and clinics are able to treat due to enhanced safety protocols **,** particularly during most of 2020 and 2021, and during the first quarter of 2022 **, and** ~~. We have also seen~~ staffing challenges, both in our organization and at the clinics we serve, as another lingering consequence of the COVID- 19 pandemic. While we saw **further** ~~some level of~~ recovery in ~~2022~~ **2023** ~~after~~ the **full** ~~first quarter, ongoing~~ consequences of the pandemic remain uncertain ~~. There are no reliable estimates of how long the pandemic will last, whether any recovery will be sustained or will reverse course, the severity of any resurgence of COVID- 19 or variant strains of the virus, the effectiveness of vaccines and attitudes towards receiving them, or what ultimate effects the pandemic will have. For that reason, we are unable to reasonably estimate the long- term impact of the pandemic on our business at this time~~ . Further, the extent to which the COVID- 19 pandemic, including any resurgence or variant strains of the virus **, or other health epidemics and disease outbreaks** , will impact our business, financial condition and results of operations in the future will depend on future

developments, which are highly uncertain and cannot be predicted, including, but not limited to, the duration, spread, severity, and impact ~~of the COVID- 19 pandemic,~~ the effects ~~of the COVID- 19 pandemic~~ on our clinician customers and their patients, our suppliers and our payers, **and** the remedial actions, any vaccine mandates and stimulus measures adopted by governmental authorities ~~, and to what extent normal economic and operating conditions can resume~~ . **Any** ~~Even after the COVID- 19 pandemic has subsided, we may continue to experience adverse impacts to our business as a result of any related economic recession or depression that has occurred or may occur in the future. Given the evolving~~ health **epidemics or** ~~, economic, social and governmental impacts of the~~ **other disease outbreaks** ~~COVID- 19 pandemic, the potential impact that the COVID- 19 pandemic could have on us remains uncertain, but it~~ could have a material adverse effect on our business, financial condition and results of operations. U. S. patent protection covering various aspects of our Flexitouch system expired in 2017, and thus may subject us to increased competition and reduce or eliminate our opportunity to generate product revenue. U. S. patents covering various aspects of our Flexitouch system expired in 2017. Given the expiration of these patents, third parties may be permitted to incorporate aspects of our Flexitouch system into their products or create substantially similar or generic versions of our Flexitouch system. This could subject us to increased competition from products attempting to replicate our technology. Moreover, these competitors could sell their competing products for a substantially lower price, which could substantially limit our opportunity to increase or maintain revenue from our Flexitouch system and, in fact, our revenue could be substantially reduced, causing a material adverse effect on our business. Changes in government trade policies, including additional tariffs and the resulting consequences, may have a material adverse impact on our business and results of operations. The United States government from time to time has adopted new approaches to trade policy, including in some cases renegotiating or terminating certain existing bilateral or multi- lateral trade agreements, or imposing tariffs on certain foreign goods, including certain raw materials that are included in our products. Changes in U. S. trade policy have and could continue to result in one or more of its trading partners adopting responsive or retaliatory trade policies, making it more difficult or costly for us to export our products to those countries in the future or import our products or raw materials utilized in making our products. These measures have resulted in, and in the future could result in, increased costs for our goods imported into the United States. Since our prices are often fixed due to the reimbursement policies of, and arrangements with, third- party payers, this could result in lower margins on our products. There is also a concern that the imposition of additional tariffs by the United States could result in the adoption of tariffs by other countries. The resulting trade war could have a significant adverse effect on world ~~34trade~~ -- **trade** and the world economy. To the extent that trade tariffs and other restrictions imposed by the United States increase the price of, or limit the amount of, the raw materials and products we import into the United States, the costs of our raw materials may be adversely affected and the demand from our customers for products and services may be diminished, which could adversely affect our revenue and profitability. In addition, our margins could be significantly impacted. We cannot predict future trade policy or the terms of any renegotiated trade agreements and their impact on our business. The adoption and expansion of trade restrictions, the occurrence of a trade war, or other governmental action related to tariffs or trade agreements or policies have the potential to adversely impact demand for our products, our costs, our customers, our suppliers and the United States economy, which in turn could adversely impact our business, financial condition and results of operations. ~~Increases~~ **35Increases** in our operating costs could have an adverse effect on our financial condition and results of operations. Reimbursement rates are established by fee schedules mandated by private payers, Medicare, the Veterans Administration, and certain Medicaid programs. Although Medicare and certain private payers index their reimbursement rate off of a subset of cost of living, the Veterans Administration, certain Medicaid programs and other private payers are more likely to remain constant or slightly decrease their reimbursement rates. As a result, we may not be able to offset the effects of general inflation on our operating costs through increases in prices for our products. In particular, labor and related costs account for a significant portion of our operating costs and we compete with other healthcare providers to attract and retain qualified or skilled personnel and with various industries for administrative and service employees. This competitive environment could result in increased labor costs. Failure to control our operating costs, particularly labor and related costs, could adversely affect our financial conditions and results of operations. Our operating costs may fluctuate significantly in the future as a result of a variety of factors, many of which are outside of our control. These factors include: ● increased sales and marketing costs to increase awareness of our products; ● costs to develop new and enhanced features for current products and research and development costs for new products; ● the time, resources and expense required to develop and conduct clinical trials and seek additional regulatory clearances and approvals for additional treatment indications for our products and for any additional products we develop or acquire; ● the costs of preparing, filing, prosecuting, defending and enforcing patent claims and other patent related costs, including litigation costs and the results of such litigation; ● any product liability or other lawsuits related to our products and the costs associated with defending them or the costs related to the results of such lawsuits; ● the costs to attract and retain personnel with the skills required for effective operations; ● the costs associated with being a public company; and ● costs associated with entering and maintaining international markets. Our failure to anticipate and minimize the impact of these costs could adversely affect our business and results of operations. ~~35We~~ **We** compete and may compete in the future against other companies, some of which have longer operating histories, more established products or greater resources than we do, which may harm our business. The medical device industry is highly competitive. Our success depends, in part, upon our ability to maintain a competitive position in the development of technologies and solutions for the at- home treatment of lymphedema, chronic venous insufficiency and chronic respiratory conditions or for market adjacencies. Any product we develop will have to compete for market acceptance and market share. We face significant competition, and we expect the intensity of competition will increase over time. Our primary competitors are Bio Compression Systems, Inc., Lympha Press USA, **Baxter (formerly** Hill- Rom **)** , Philips Medical and Electromed. Other competitors include **Medi,** Airos Medical, Inc. ~~and ,~~ NormaTec Industries **and Koya Medical** . ~~Many~~ **Some** of the companies developing or marketing competing products enjoy several competitive advantages, including: ● significantly greater name recognition; **36** ● established relations with healthcare professionals, customers and third- party payers; ● established

distribution networks; ● additional lines of products, and the ability to offer rebates or bundle products to offer higher discounts or other incentives to gain a competitive advantage; ● greater history in conducting research and development, manufacturing, marketing and obtaining regulatory approval for homecare devices; and ● greater financial and human resources for product development, sales and marketing, patient litigation and customer financing. Our competitors may develop and patent processes or products earlier than us, obtain regulatory clearance or approvals for competing devices more rapidly than us or develop more effective or less expensive products or technologies that render our technology or products obsolete or less competitive. We also face fierce competition in recruiting and retaining qualified sales, scientific, reimbursement and management personnel, particularly those with direct- to- patient and- provider experience. If our competitors are more successful than us in these matters, our business may be harmed. Our long- term growth depends on our ability to develop and commercialize additional products. The medical device industry is highly competitive and subject to rapid change and technological advancements. Therefore, it is important to our business that we continue to enhance our product offerings and introduce new products. Developing products is expensive and time- consuming and could divert management' s attention away from our business. We may not be successful in developing new products or enhancements to existing products. Further, we may expend financial, management and operational resources on products that we are not able to successfully commercialize. Our ability to develop and commercialize additional products or enhancements to existing products will depend on several factors, including our ability to: ● properly identify and anticipate physician and patient needs; ● develop and introduce new products or product enhancements in a timely manner; ● avoid infringing upon the intellectual property rights of third parties; ● demonstrate the safety and efficacy of new products with data from clinical studies; ● obtain the necessary regulatory clearances or approvals for new products or product enhancements; ~~36 ~~● be fully FDA- compliant with the development, manufacturing and marketing of new devices or modified products; ● provide adequate training to potential users of our products; ● secure adequate coverage and reimbursement for our products; and ● develop and maintain an effective and dedicated sales and marketing team, as well as relationships with distributors. If we are unsuccessful in developing and commercializing new products, our ability to increase our revenue may be impaired. ~~It~~ **37It** is difficult to forecast future performance and our financial results may vary from forecasts and may fluctuate from quarter to quarter. A number of factors over which we have limited control, such as seasonal variations in revenue, may contribute to fluctuations in our financial results. In the first quarter of each year, when most patients have started a new insurance year and have not yet met their annual out- of- pocket payment obligations, we experience substantially reduced demand for our products. We typically experience higher revenue in the third and fourth quarters when more patients have met their annual insurance deductibles, thereby reducing their out- of- pocket costs for our products, and because patients desire to exhaust their flexible spending accounts at year end. This seasonality applies only to purchases and rentals of our products by patients covered by commercial insurance and is not relevant to Medicare, Medicaid or the Veterans Administration, as those payers either do not have plans that have declining deductibles over the course of the plan year and / or do not have plans that include patient deductibles for purchases or rentals of our products. To the extent that the prevalence of high deductible insurance plans and higher copay and coinsurance plans continue to grow in the private payer market, the seasonal variations in our revenue could become even more pronounced. Other factors that may cause fluctuation in our quarterly results or variations from our forecasts include: ● physician adoption of our products; ● timing of new product offerings, acquisitions, licenses or other significant events by us or our competitors; ● unanticipated pricing pressure; ● the hiring, retention and continued productivity of our sales representatives; ● our ability to expand the geographic reach of our distribution, sales and marketing efforts; ● our ability to obtain regulatory clearance or approval for our products in development or for our current products outside the United States; ● the impact of results from clinical research and trials on our existing products and products in development; ● delays in receipt of anticipated purchase orders; ● delays in, or failure of, component deliveries from our suppliers; and ● positive or negative coverage in the media or clinical publications of our products or products of our competitors or our industry. ~~37In~~ **In** the event our actual revenue and operating results do not meet our forecasts or the forecasts or estimates of the research analysts that cover us for a particular period, the market price of our common stock may decline substantially. If physicians fail to properly document medical records for patients using our products, our business could be adversely impacted. We bill Medicare Part B **, Medicaid, the Veterans Administration** and other insurers directly for sales and rentals of lymphedema products. As a result, we must comply with all laws, rules and regulations associated with filing claims with the Medicare program, including the Social Security Act, Medicare regulations, the Federal False Claims Act and the Civil Monetary Penalties Law, as well as a variety of additional federal and state laws. During an audit, insurers typically expect to find explicit documentation in the medical record to support a claim. Physicians and other clinicians, who are responsible for prescribing our products for patients, are expected to create and maintain the medical records that form the basis for the claims we submit to ~~Medicare~~ **38Medicare** and other insurers. Any failure to properly document the medical records for patients using our products could invalidate claims, impair our ability to collect submitted claims and subject us to overpayment liabilities, False Claims Act liabilities and other penalties including exclusion from the Medicare, Medicaid or private insurance programs. Our reimbursement operations group is responsible for verifying and managing patient claims for our lymphedema products. This group works with physicians and other clinicians to educate physicians and other clinicians on their record keeping responsibilities. From time to time our reimbursement operations group identifies situations where the documentation is missing, incomplete or could be questioned by Medicare or other insurers, and revises its procedures to strengthen our controls, audits and oversight compliance systems based on our experience with Medicare contractors, Medicaid, insurers, physicians and other clinicians. If our procedures are not sufficient to detect deficiencies in the medical records of patients or such procedures are not updated in a timely manner before claims are submitted to Medicare or other insurers, or if the Medicare program or other insurer disagrees with the way the medical necessity support for prescribing our products has been documented, we could face potential liabilities for submitting claims based on inadequate records. The size of the market for our products is an estimate, and may be smaller than we believe. Our estimate of the total addressable market for our products is based on a

number of internal and third- party estimates. In addition, our internal estimates are based in large part on current trends in diagnosing lymphedema, chronic venous insufficiency and chronic respiratory conditions. While we believe these factors have historically provided and may continue to provide us with effective tools in estimating the total market for lymphedema, chronic venous insufficiency, chronic respiratory conditions and our products, these estimates may not be correct and the conditions supporting our estimates may change at any time, thereby reducing the predictive accuracy of these underlying factors. As a result, our estimates of the total addressable market for our products may prove to be incorrect. **In addition, changes in underlying causes or risk factors for diseases that our products treat, such as the impact of GLP- 1 drugs on obesity, could impact our estimates of the total addressable market.** If the actual number of patients who would benefit from our products and the total addressable market for our products is smaller than we have estimated, our future growth could be adversely impacted. We may be unable to manage our growth effectively. Our past growth has provided, and our future growth may create, challenges to our organization. We intend to continue to grow and may experience periods of rapid growth and expansion. Future growth will impose significant added responsibilities on management, including the need to identify, recruit, train, integrate, retain and motivate additional employees. In addition, rapid and significant growth will place a strain on our administrative personnel, information technology systems and other operational infrastructure. Any failure by us to manage our growth effectively could have an adverse effect on our ability to achieve our development and commercialization goals. Successful growth is also dependent upon our ability to implement appropriate financial and management controls, systems and procedures. In order to manage our operations and growth, we will need to continue to improve our operational and management controls, reporting and information technology systems and financial internal control procedures. If we are unable to manage our growth effectively, it may be difficult for us to execute our business strategy and there could be an adverse impact on our business. ~~38Our~~ -- **Our** ability to maintain our competitive position depends on our ability to attract, integrate and retain key executives and highly qualified personnel. We believe that our continued success depends to a significant extent upon the efforts and abilities of our executive officers and other key personnel. Our executive officers and other key personnel are critical to the strategic direction and overall management of our company as well as our research and development process. Our future success also depends on our ability to continue to attract and retain additional executive officers and other key employees. We invest significant time and expense in training our employees, which increases their value to competitors who may seek to recruit them. Many of our competitors have greater ~~resources~~ **39resources** than we have that allows them to offer more competitive remuneration, which could adversely impact our ability to attract and retain experienced executives and other key employees. We carry a" key person" insurance policy only on our Chief Executive Officer. The replacement of any of our key personnel likely would involve significant time and costs and may significantly delay or prevent the achievement of our business objectives and would harm our business. Our productivity may be adversely affected if we do not integrate and train our new employees quickly and effectively. Changes in reimbursement coding could impair our ability to receive reimbursement for our products. HCPCS is a standardized system used by all U. S. insurance payers to provide descriptions of healthcare equipment, supplies and services. HCPCS codes are used by payers to identify what services are being billed and to assign payment rates to those specific services. HCPCS codes for durable medical equipment are assigned and managed by CMS and a Medicare contractor responsible for Pricing, Data Analysis and Coding, or PDAC. New products and product revisions must go through a coding verification process to confirm the products meet the requested HCPCS definitions. CMS or its contractor can review and revise coding assignments if they believe a product no longer meets the assigned HCPCS definition. If the PDAC contractor determines one of our products does not meet the current HCPCS definition, it could remove all coding or assign a different HCPCS code with a lesser payment rate. This could have an adverse impact on our reimbursement rates, results of operations and cash flows. If the quality of our products does not meet the expectations of physicians or patients, then our brand and reputation could suffer and our business could be adversely impacted. In the course of conducting our business, we must adequately address quality issues that may arise with our products, as well as defects in third- party components included in our products. There can be no assurance that our internal procedures to minimize risks that may arise from quality issues will be able to eliminate or mitigate occurrences of these issues and associated liabilities. If the quality of our products does not meet the expectations of physicians or patients, then our brand and reputation could suffer and our business could be adversely impacted. If our facilities are damaged or become inoperable, we will be unable to continue to research, develop, manufacture and commercialize our products and, as a result, there will be an adverse impact on our business until we are able to secure a new facility. We do not have redundant facilities. We perform substantially all of our research and development, assembly and back office activity and maintain all our finished goods inventory at one location in Minneapolis, Minnesota. Our facilities and equipment would be costly to replace and could require substantial lead time to repair or replace. The facilities may be harmed or rendered inoperable by natural or man- made disasters (such as tornadoes, flooding, fire and power outages), vulnerabilities in our technology or cyber- attacks against our information systems (such as ransomware), which may render it difficult or impossible for us to perform our research, development, manufacturing and commercialization activities for some period of time. The inability to perform those activities, combined with our limited inventory of reserve raw materials and finished product, may result in the inability to continue manufacturing our products during such periods and the loss of customers or harm to our reputation. Our insurance for damage to our property and the disruption of our business may not be sufficient to cover all of our potential losses, and this insurance may not continue to be available to us on acceptable terms, or at all. ~~39We~~ **We** may be adversely affected by natural disasters and other catastrophic events, and by man- made problems such as terrorism or violence, that could disrupt our business operations. Natural disasters or other catastrophic events may also cause damage or disruption to our operations, including causing delays in completing sales, continuing production or performing other critical functions of our business, which could have an adverse effect on our business, operating results and financial condition. Our business operations are subject to interruption by natural disasters, fire, power shortages, pandemics and other events beyond our control. In addition, acts of terrorism, violence and other geo- political unrest could cause disruptions in our business or the

businesses of our partners or the economy as a whole. In the event of a natural disaster, including a major earthquake, blizzard or hurricane, or a catastrophic event such as a fire, ~~power~~ **40power** loss, or telecommunications failure, we may be unable to continue our operations for a period of time in the affected area, which could have an adverse effect on our future operating results. Acquisition activity involves substantial risks, and we may not be able to successfully integrate newly acquired companies or businesses. We have acquired, and may in the future acquire, companies, businesses, products, services and technologies. Acquisitions involve significant risks and uncertainties, including: ● incurring significantly higher than anticipated capital expenditures and operating expenses; ● failing to assimilate the operations, customers and personnel of the acquired company or business; ● disrupting our ongoing business; ● dissipating our management resources; ● dilution to existing stockholders from the issuance of equity securities; ● liabilities or other problems associated with the acquired business; ● failing to achieve the anticipated benefits of the acquisition; ● incurring debt on terms unfavorable to us or that we are unable to repay; ● becoming subject to adverse tax consequences, substantial depreciation or deferred compensation charges; ● improper compliance with laws and regulations; ● failing to maintain uniform standards, controls and policies; and ● impairing relationships with employees and business partners as a result of changes in management. Fully integrating an acquired company or business into our operations may take a significant amount of time. We cannot assure you that we will be successful in overcoming these risks or any other problems encountered with acquisitions. To the extent we do not successfully avoid or overcome the risks or problems related to any acquisitions, our results of operations and financial condition could be adversely affected. Future acquisitions also could impact our financial position and capital needs, and could cause substantial fluctuations in our quarterly and yearly results of operations. Acquisitions could include significant goodwill and intangible assets, which may result in future impairment charges that would reduce our stated earnings. ~~40If~~ **If** we commercialize any products outside of the United States, a variety of risks associated with international operations could impact our strategy and adversely affect our future growth. If we expand internationally, we would be subject to additional risks related to entering into international markets, including: ● difficulty obtaining approvals under foreign regulatory requirements, such as more stringent requirements for regulatory clearance of products; ● difficulty successfully training patients and physicians on using our products; ● difficulty hiring a qualified direct- sales force or finding and entering into commercially acceptable agreements with suitable third- parties to market our products; **41** ● reduced protection for intellectual property rights; ● increased or different tariffs, trade barriers and regulatory requirements; ● economic weakness, including inflation, or political instability in particular foreign economies and markets; ● compliance with tax, employment, immigration and labor laws for employees living or traveling abroad; ● foreign taxes, including withholding of payroll taxes; ● foreign currency fluctuations, which could result in increased operating expenses and reduced revenue, and other obligations incident to doing business in another country; ● workforce uncertainty in countries where labor unrest is more common than in the United States; ● complex data privacy requirements; ● international regulators and third- party payers may require additional clinical studies prior to approving or allowing reimbursement for our products; ● disadvantages of competing against companies from countries that are not subject to U. S. laws and regulations, including the U. S. Foreign Corrupt Practices Act, regulations of the U. S. Office of Foreign Assets Controls and U. S. anti- money laundering regulations, as well as exposure of our foreign operations to liability under these regulatory regimes; and ● business interruptions resulting from geopolitical actions, including war and terrorism, or natural disasters including earthquakes, typhoons, floods and fires. Government Regulation, Compliance and Legal Risks We are subject to extensive federal and state regulation, and if we fail to comply with applicable regulations, we could be required to repay amounts previously received, and could suffer severe criminal or civil sanctions or be required to make significant changes to our operations that could adversely affect our business, financial condition and operating results. The federal government and all states in which we currently operate regulate various aspects of our business. Our operations also are subject to state laws governing, among other things, distribution of medical equipment and certain types of home health activities, and we are required to obtain and maintain licenses in many states to act as a durable medical equipment supplier. ~~41As~~ **As** a healthcare provider participating in governmental healthcare programs, we are subject to complex laws and regulations directed at preventing fraud and abuse, which subject our marketing, billing, documentation and other practices to government scrutiny. To ensure compliance with Medicare, Medicaid and other regulations, government agencies or their contractors often conduct routine audits and request customer records and other documents to support ~~our~~ claims submitted for payment of services rendered. Medicare has engaged a variety of contractors to audit claims submitted to the government, including Medicare Administrative Contractors, Recovery Audit Contractors, Supplemental Medical Review Contractors and Unified Program Integrity Contractors. Recovery Audit Contractors are compensated based on a percentage of overpayments ~~recovered from providers~~ **they find or collect** . Unified Program Integrity Contractors focus on potential fraud and frequently make referrals to the Office of Inspector General or the Department of Justice to pursue criminal or civil action against providers. The increased number of Medicare contractors, with their focus on recovering overpayments and identifying fraud, creates increased risk to providers like us that submit claims to federal government programs. The Office of Inspector General and the Department of Justice also initiate their own investigations into possible violations of applicable laws and regulations. ~~Violations~~ **42Violations** of federal and state regulations can result in severe criminal, civil and administrative penalties and sanctions, including debarment, suspension or exclusion from Medicare, Medicaid and other government reimbursement programs, any of which would have a material adverse effect on our business. Changes in healthcare laws and regulations and new interpretations of existing laws and regulations may affect permissible activities, the relative costs associated with doing business, and reimbursement amounts paid by federal, state and other third- party payers. There have been and will continue to be regulatory initiatives affecting our business and we cannot predict the extent to which future legislation and regulatory changes could have a material adverse effect on our business, financial condition and results of operations. We are subject to significant regulation by numerous government agencies, including the FDA. We cannot market or commercially distribute our products without obtaining and maintaining necessary regulatory clearances or approvals. Our products are medical devices subject to extensive

regulation in the United States. The FDA and other U. S. and foreign governmental agencies regulate, among other things, with respect to medical devices: ● design, development and manufacturing; ● establishment registration and product listing; ● testing, labeling, content and language of instructions for use ~~and ,~~ storage **and servicing** ; ● clinical trials; ● product safety; ● marketing, sales and distribution; ● unique device identifiers; ● premarket clearance and approval; ● record keeping procedures; ● advertising and promotion; ● recalls and field safety corrective actions; ● post- market surveillance, including reporting of deaths or serious injuries and malfunctions that, if they were to recur, could lead to death or serious injury; ~~42~~ ● post- market approval studies; and ● product import and export. Unless an exemption applies, each medical device we seek to distribute commercially in the United States requires marketing authorization from the FDA prior to distribution. The two primary types of FDA marketing ~~authorization~~ **authorizations** applicable to a **medical** device are premarket notification, also called **a** 510 (k) clearance, and premarket approval. The type of marketing authorization is generally linked to the classification of the device. When a 510 (k) clearance is required, we must submit a premarket notification to the FDA demonstrating that our proposed device is" substantially equivalent" to a legally marketed device previously found substantially equivalent through a 510 (k) premarket notification, a legally marketed device which has been reclassified from high to low or moderate risk or a legally marketed device in commercial distribution before May 28, 1976 for which the FDA does not require the submission of a premarket approval application. Such a device is commonly known as a ‘ ‘ predicate device.’’ In 2019, the FDA released an optional Safety and ~~Performance~~ **43Performance** Based Pathway for 510 (k) clearance, which allows a submitter to demonstrate that an eligible new device of a well- understood type meets FDA- identified performance criteria to demonstrate that the device is as safe and effective as a legally marketed device. The FDA may require further information, including clinical data, to make a determination regarding substantial equivalence. A medical device may be found not to be equivalent if it has different intended uses from the predicate device or possesses different technological characteristics from the predicate device which raise new questions of safety and effectiveness. A premarket approval application must be submitted to the FDA if the device cannot be cleared through the 510 (k) process. The premarket approval application process is much more demanding **and in- depth** than the 510 (k) premarket notification process and requires the payment of significant user fees. A premarket approval application must be supported by valid scientific evidence, which typically requires extensive data to demonstrate the reasonable assurance of safety and effectiveness of the device. The approval process involves FDA review of information, including but not limited to, technical, pre- clinical (bench and / or animal), clinical trials, manufacturing and labeling. The FDA clearance and approval processes frequently take longer than anticipated due to increasing FDA demands for clarification of data or new data requirements. If there is no predicate device that would permit the device to be cleared through the 510 (k) path **and the device is not 510 (k)- exempt** , then the FDA will automatically classify the device as a Class III high risk **product which requires** premarket approval ~~device~~ . In the event of this possibility, the sponsor can request a risk- based classification determination for the device in accordance with the ~~de~~ **FDA’ s De** ~~novo~~ **Novo classification request** process, which is a route to market for novel medical devices that are low to moderate risk and are not substantially equivalent to a predicate device. A company files a ~~de~~ **De** ~~novo~~ **Novo** request when it does not have a predicate to which it can claim substantial equivalence. The FDA reviews the request for a ~~de~~ **De** ~~novo~~ **Novo** decision and grants or denies the request. If the request is granted, the FDA issues an order indicating that the device may legally be marketed and the device is classified as a Class I or II device, depending on risk. Once a device is classified through the ~~de~~ **De** ~~novo~~ **Novo** process, future devices from the company or a competitor may use that device as a 510 (k) predicate. The advantage of the ~~de~~ **De** ~~novo~~ **Novo** process is that it generally requires less data than a premarket approval. The disadvantage is that it may require more data than a 510 (k) and most often will include human clinical data. The FDA **may move** ~~is increasingly moving~~ devices with slightly different proposed indication statements or different technological features off the 510 (k) path and on to the ~~de~~ **De** ~~novo~~ **Novo** path resulting in more time and expense for the company. Both the 510 (k) and premarket approval processes can be expensive and lengthy and require the payment of significant fees, unless an exemption applies **and no FDA approval is required** . The FDA' s 510 (k) clearance process usually takes from approximately three to 12 months, but may take longer. The process of obtaining a premarket approval is much more costly and uncertain than the 510 (k) clearance process and generally takes from approximately one to five years, or longer, from the time the application is submitted to the FDA until an approval is obtained. The process of obtaining regulatory clearances or approvals to market a medical device can be costly and time consuming, and we may not be able to obtain these clearances or approvals on a timely basis, if at all. In the United States, our currently commercialized products are marketed pursuant to **510 (k)** premarket ~~clearance~~ **clearances** under Section 510 (k) of the Federal Food, Drug and Cosmetic Act, or FDCA. If the FDA requires us to go through a lengthier, more rigorous examination for future products or modifications to existing products than we had expected ~~,~~ our product introductions or modifications could be delayed or canceled, which could cause our sales to decline. In addition, the FDA may determine that future products will require the more costly, ~~43lengthy~~ -- **lengthy** and uncertain premarket approval process. Although we do not currently market any devices under a premarket approval ~~,~~ the FDA may demand that we obtain a premarket approval prior to marketing certain of our future products. In addition, if the FDA disagrees with our determination that a product we currently market is subject to an exemption from premarket review, the FDA may require us to submit a 510 (k) or premarket approval application in order to continue marketing the product. Further, even with respect to those future products where a premarket approval is not required, we cannot assure you that we will be able to obtain the 510 (k) clearances required with respect to those products. The FDA can delay, limit or deny clearance or approval of a device for many reasons, including: ● for non- premarket approval devices, failure of the applicant to demonstrate to the FDA' s satisfaction that its products meet the definition of" substantial equivalence" or meet the standard for the FDA to grant a petition for ~~de~~ **De** ~~novo~~ **Novo** classification; **44** ● failure of the applicant to demonstrate that there is reasonable assurance that the medical device is safe or effective under the conditions of use prescribed, recommended or suggested in the proposed labeling; ● insufficient data from the pre- clinical studies and clinical trials; **and /** or ● the manufacturing processes, methods, controls or facilities used for the manufacture, processing, packing or installation of

the device do not meet applicable requirements. Any delay in, or failure to receive or maintain, clearances or approvals for our products could prevent us from generating revenue from these products or achieving profitability. Additionally, the FDA and other governmental authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could lead governmental authorities or a court to take action against us, including, but not limited to: ● issuing untitled (notice of violation) letters or public warning letters to us; ● imposing fines and penalties on us; ● obtaining an injunction or administrative detention preventing us from manufacturing or selling our products; ● seizing products to prevent sale or transport or export; ● bringing civil or criminal charges against us; ● recalling our products or mandating a product correction; ● detaining our products at U. S. Customs; ● delaying the introduction of our products into the market; ● delaying pending requests for clearance or approval of new uses or modifications to our existing products; and ● withdrawing or denying approvals or clearances for our products. If we fail to obtain and maintain regulatory clearances or approvals ~~,~~ our ability to sell our products and generate revenue will be materially harmed. In addition, the FDA may change its clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our ~~44products~~ **products** under development or impact our ability to modify our currently approved or cleared products on a timely basis. For example, in response to industry and healthcare provider concerns regarding the predictability, consistency and rigor of the 510 (k) regulatory pathway, the FDA published new guidance on the 510 (k) regulatory pathway in 2014, **and again in 2023 through draft guidance,** which altered **and clarified** the manner in which the 510 (k) regulatory pathway is administered and interpreted. The FDA intends these reform actions to improve the efficiency and transparency of the clearance process, as well as bolster patient safety. ~~This~~ **Any** new guidance could impose additional regulatory requirements upon us which could delay our ability to obtain new 510 (k) clearances, increase the costs of compliance or restrict our ability to maintain our current clearances. In addition, as part of the Food and Drug Administration Safety and Innovation Act, Congress reauthorized the Medical Device User Fee Amendments with various FDA performance goal commitments and enacted several" Medical Device Regulatory Improvements" and miscellaneous reforms which are further intended to clarify and improve medical device regulation both pre- and post- market. ~~Medical~~ **45Medical** devices may only be promoted and sold for the indications for which they are approved or cleared **unless an exemption applies** . In addition, even if the FDA has approved or cleared a product, it can take action affecting such product approvals or clearances if serious safety or other problems develop in the marketplace. Delays in obtaining clearances or approvals could adversely affect our ability to introduce new products or modifications to our existing products in a timely manner, which would delay or prevent commercial sales of our products. Additionally, the FDA and other regulatory authorities have broad enforcement powers. Regulatory enforcement or inquiries, or other increased scrutiny on us, could affect the perceived safety and efficacy of our products and dissuade patients and clinicians from using our products. If clinical studies of our future products do not produce results necessary to support regulatory clearance or approval in the United States or, with respect to our current or future products, elsewhere, we will be unable to expand the indications for or commercialize these products. We will likely need to conduct additional clinical studies in the future to support new indications for our products or for clearances **or approvals** of new product lines, or for the approval of the use of our products in some foreign countries. Clinical testing can take many years, can be expensive and carries uncertain outcomes. The initiation and completion of any of these studies may be prevented, delayed, or halted for numerous reasons. Clinical failure can occur at any stage of testing. Our clinical studies may produce negative, unanticipated or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and non- clinical testing in addition to those we have planned. Our failure to adequately demonstrate the safety and efficacy of any of our devices would prevent receipt of regulatory clearance or approval and, ultimately, the commercialization of that device or indication for use. Even if our products are cleared in the United States, commercialization of our products in foreign countries would require approval by regulatory authorities in those countries. Approval procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional pre- clinical studies or clinical trials. Any of these occurrences could have an adverse impact on our business. If the third parties on which we rely to conduct our clinical trials and to assist us with pre- clinical development do not perform as contractually required or expected, we may not be able to obtain regulatory clearance or approval for or commercialize our products. We often must rely on third parties, such as contract research organizations, medical institutions, clinical investigators and contract laboratories, to conduct our clinical trials and to assist us with pre- clinical development. If these third parties do not successfully carry out their contractual duties or regulatory obligations, have difficulty recruiting sufficient subjects for clinical studies or fail to meet expected deadlines, if these third parties need to be replaced, or if the quality or accuracy of the data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our pre- clinical development activities or clinical trials may be extended, delayed, suspended or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, our products on a timely basis, if at all, and our business, operating results and prospects may be adversely affected. Furthermore, our third- party clinical trial investigators may be delayed in conducting our clinical trials for reasons outside of their control. ~~45If~~ **If** we fail to comply with state and federal fraud and abuse laws, including anti- kickback, false claims and anti- inducement laws, we could face substantial penalties and our business, operations and financial condition could be adversely affected. The Federal Anti- Kickback Statute prohibits, among other things, knowingly and willfully offering, paying, soliciting or receiving remuneration, whether directly or indirectly and overtly or covertly, to induce or in return for purchasing, leasing, ordering, or arranging for the purchase, lease or order of any healthcare item or service reimbursable under Medicare, Medicaid, or other federal ~~financed~~ healthcare programs. The statutory exceptions and regulatory safe harbors protecting certain common activities from prosecution are drawn narrowly, and any remuneration to or from a prescriber or purchaser of healthcare products or services may be subject to scrutiny if they do not qualify for an exception or safe harbor. Our practices may not in all cases meet all of the criteria for safe harbor protection from anti- kickback liability. ~~Federal~~ **46Federal** false claims laws prohibit, in part, any person from knowingly presenting or causing

to be presented a false claim for payment to the federal government, or knowingly making or causing to be made a false statement to obtain payment. The majority of states also have statutes or regulations similar to the Federal Anti- Kickback Statute and Federal False Claims Act, which apply to items or services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of payer. These false claims statutes allow any person to bring suit in the name of the government alleging false and fraudulent claims presented to or paid by the government (or other violations of the statutes) and to share in any amounts paid by the entity to the government in fines or settlement. Such suits, known as qui tam actions, have increased significantly in the healthcare industry in recent years. Sanctions under these federal and state laws may include civil monetary penalties, exclusion of a manufacturer' s products from reimbursement under government programs, criminal fines and imprisonment. In addition, the ACA, among other things, amended the intent requirement of the Federal Anti- Kickback Statute and criminal healthcare fraud statutes. A person or entity does not need to have actual knowledge of this statute or specific intent to violate it. In addition, the ACA provides that the government may assert that a claim, including items or services resulting from a violation of the Federal Anti- Kickback Statute, constitutes a false or fraudulent claim for purposes of the false claims statutes. Because of the breadth of these laws and the narrowness of the safe harbors and exceptions, some of our business activities could be subject to challenge under one or more of such laws. Such a challenge, regardless of the outcome, could have a material adverse effect on our business, business relationships, reputation, financial condition and results of operations. In addition, there **are many** ~~has been a recent trend of increased~~ federal and state ~~regulation~~ **regulations** ~~of~~ **covering** payments made to physicians. The ACA imposed new reporting and disclosure requirements on device and drug manufacturers for any" transfer of value" made or distributed to ~~prescribers~~ **teaching hospitals** and other **qualified** healthcare providers. Device and drug manufacturers are also required to report and disclose any investment interests held by physicians and their immediate family members during the preceding calendar year. Failure to submit required information may result in **significant** civil monetary penalties ~~of up to an aggregate of $ 150, 000 per year (and up to an aggregate of $ 1. 0 million per year for" knowing failures to report"),~~ for all payments, transfers of value or ownership or investment interests not reported in an annual submission. Manufacturers are required to collect data and are required to submit their data reports to CMS for each calendar year by the 90th day of the subsequent calendar year. Certain states **have their own versions of the Physician Payments Sunshine Act, and may also** mandate implementation of compliance programs and / or the tracking and reporting of gifts, compensation and other remuneration to physicians or other healthcare professionals. The shifting compliance environment and the need to build and maintain robust and expandable systems to comply with different compliance and / or reporting requirements in multiple jurisdictions increase the possibility that a **manufacturer** ~~healthcare company~~ may violate one or more of the requirements. The Federal Civil Monetary Penalties Law prohibits, in part, the offering or giving of remuneration to a Medicare or Medicaid beneficiary that the person knows or should know is likely to influence the beneficiary' s selection of a particular supplier of items or services reimbursable by a Federal or state governmental program. We sometimes offer customers various discounts and other financial incentives in connection with the sales of our products. While it is our intent to comply with all applicable laws, the government may find that our marketing activities violate the Civil Monetary Penalties Law. If we are found to be in noncompliance, we could be subject ~~46to~~ **to significant** civil money penalties ~~of up to $ 20, 000~~ for each wrongful act, assessment of three times the amount claimed for each item or service and exclusion from the Federal healthcare programs. The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations **in some areas** . If our operations are found to be in violation of any of the laws described above or any other government regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment, restructuring, or restricting of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could harm our ability to operate our business and our financial results. Responding to any action or threat of action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management' s attention from operation of our business. Moreover, achieving and sustaining compliance with applicable federal and state fraud laws may prove costly. ~~Failure~~ **47Failure** to maintain the licenses and accreditations necessary to operate under our direct- to- patient and-provider model would adversely affect our business. To continue operating our business under our direct- to- patient and-provider model, we must maintain our Durable Medical Equipment certification from the Accreditation Commission for Health Care. In May 2008, we became a Durable, Medical Equipment, Prosthetics, Orthotics, and Supplies accredited supplier by the Accreditation Commission for Health Care. This accreditation status must be renewed every three years through a recredentialing process that includes an on- site review. We last renewed our accreditation with our accrediting body in May ~~2020~~ **2023** . If we are deemed out of compliance with accreditation standards, our enrollment status in the Medicare program could be jeopardized, up to and including termination. In addition to maintaining our Durable Medical Equipment certification from the Accreditation Commission for Health Care, we also must maintain certain state- required licenses. If we were found to be noncompliant, we could lose our licensure in that state. Losing ~~our~~ **any** ~~licensure~~ -- **license** could subject us to financial penalties and / or prohibit us from selling our current or future products to patients in ~~such~~ **a particular** state and our business, financial condition and results of operations could be adversely affected as a result of any such prohibition. Our products are currently made available to authorized users of the Department of Veterans Affairs Federal Supply Schedule and if we were no longer eligible to sell our products through such channel, our business may be adversely affected. Our Flexitouch **Plus** ~~and Entre systems~~ - **system** ~~are~~ **is** eligible for reimbursement by the Department of Veterans Affairs and included on the Federal Supply Schedule pricing program, established by Section 603 of the Veterans Health Care Act of 1992. To be eligible for this program, we must comply with additional laws and requirements applicable to our operations and manufacturing processes **. Our Entre Plus system is available for purchase by the Department of Veterans Affairs off contract** . If we were to lose eligibility for reimbursement by the Department of Veterans Affairs, our business, financial condition and results of operations could be adversely affected. If we modify our FDA cleared devices, we may need to seek additional clearances or approvals, which, if not

granted, would prevent us from selling our modified products. The FDA regulations require the submission and clearance of a new 510 (k) premarket notification, or possibly, premarket approval, for significant changes or modifications made in the design, components, method of manufacture or intended use of a device including changes or modifications to a 510 (k)- cleared device that could significantly affect the device' s safety or effectiveness, or would constitute a major change or modification in the device' s intended use. The FDA requires each manufacturer to make this determination, but the FDA may review any manufacturer' s decision. The FDA may not agree with our decisions regarding whether new clearances or approvals are necessary. We have modified some of our 510 (k) cleared products, and have determined based on our review of the applicable FDA guidance that in certain instances new 510 (k) clearances or premarket approval are not required. If the FDA disagrees with our determination and requires us to submit new 510 (k) notifications or premarket approval for modifications to our previously cleared products for which we have concluded that new clearances or approvals are unnecessary, we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties. ~~47Furthermore~~ -- **Furthermore** , the FDA' s ongoing review of the 510 (k) program may make it more difficult for us to make modifications to our previously cleared products, either by imposing more strict requirements on when a manufacturer must submit a new 510 (k) for a modification to a previously cleared product, or by applying more onerous review criteria to such submissions. If the FDA requires us to cease marketing a modified device until we obtain a new 510 (k) clearance or premarket approval, our business, financial condition, operating results and future growth prospects could be materially adversely affected. Further in this situation, our products could be subject to recall. Any recall or FDA requirement that we seek additional approvals or clearances could result in significant delays, fines, increased costs associated with modification of a product, loss of revenue and potential operating restrictions imposed by the FDA. ~~The~~ **48The** misuse or off- label use of our products may harm our image in the marketplace, result in injuries that lead to product liability suits or result in costly investigations, fines or sanctions by regulatory bodies if we are deemed to have engaged in the promotion of these uses, any of which could be costly to our business. The products we currently market have been cleared by the FDA for specific treatments. We train our employees and distributors in appropriate and lawful promotion of our products, within our approved indications and to be truthful and not misleading. We cannot, however, prevent a physician from using our products off- label, when in the physician' s independent professional medical judgment, he or she deems it appropriate. The FDA does not restrict or regulate a physician' s choice of treatment. There may be increased risk of injury to patients if physicians use our products off- label. Furthermore, the use of our products for indications other than those cleared by the governing regulatory body may not effectively treat such conditions, which could harm our reputation in the marketplace among physicians and patients. If the FDA determines that our promotional materials, activity, communications or training constitute promotion of or encourage off- label uses, it could request that we modify our training or promotional materials or subject us to regulatory or enforcement actions, including the issuance of untitled letters, warning letters, injunctions, seizures, civil fines or criminal penalties. It is also possible that other federal, state or foreign enforcement authorities might take action if they consider our business activities to constitute promotion of an off- label use, which could result in significant penalties, including, but not limited to, criminal, civil and administrative penalties, damages, fines, disgorgement, exclusion from participation in government healthcare programs, and the curtailment of our operations. In addition, physicians or patients may misuse our products or use improper techniques, potentially leading to injury and an increased risk of product liability. If our products are misused or used with improper technique, we may become subject to costly litigation by our clinicians or their patients. We can be subject to lawsuits, whether or not our product is proven to be defective and whether or not our employees have adequately trained the physicians. Product liability claims could divert management' s attention from our core business, be expensive to defend and result in sizeable damage awards against us that may not be covered by insurance. Our products may cause or contribute to adverse medical events that we are required to report to the FDA, and if we fail to do so, we would be subject to sanctions that would materially harm our business. Our marketed products are subject to Medical Device Reporting, or MDR, obligations, which require that we report to the FDA any incident in which our products may have caused or contributed to a death or serious injury, or in which our products malfunctioned and, if the malfunction were to recur, it could likely cause or contribute to a death or serious injury. The timing of our obligation to report under the MDR regulations is triggered by the date we become aware of the adverse event as well as the nature of the event. We may fail to report adverse events of which we become aware within the prescribed timeframe. We may also fail to recognize that we have become aware of a reportable adverse event, especially if it is not reported to us as an adverse event ~~or~~ **,** if it is an adverse event that is unexpected **, if the occurrence of the adverse event is not immediately associated with** ~~or~~ **our** ~~removed in time from the~~ **product, or if an adverse event occurs subsequent to completing** use of our ~~products~~ **product** . If we fail to comply with our reporting obligations, the FDA could take action including warning letters, untitled letters, administrative actions, criminal prosecution, imposition of civil monetary penalties, revocation of our device clearances, seizure of our products, or delay in clearance of future products. ~~48Our~~ -- **Our** products may in the future be subject to product recalls. A recall of our products, either voluntarily or at the direction of the FDA or another governmental authority, or the discovery of serious safety issues with our products, could have a significant adverse impact on us. The FDA and similar foreign governmental authorities have the authority to require the recall of commercialized products in the event of material deficiencies or defects in their design or manufacture. The FDA' s authority to require a recall must be based on a finding that there is reasonable probability that the device would cause serious, adverse health consequences or death. We may also choose to voluntarily recall a product if any material deficiency is found. A government- mandated or voluntary recall could occur as a result of an unacceptable risk to health, component failures, malfunctions, manufacturing errors, design or labeling ~~defects~~ **49defects** or other deficiencies and issues. Recalls of any of our products would divert managerial and financial resources and have an adverse effect on our reputation and business, which could impair our ability to produce our products in a cost- effective and timely manner in order to meet our patients' demands. We may also be subject to liability claims, 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. Companies are required to maintain certain records of recalls and corrections, even if ~~they~~ **the** ~~are~~ **recall or correction itself is** not reportable to the FDA. We may initiate voluntary recalls or corrections for our products in the future that we determine do not require notification of the FDA. If the FDA disagrees with our determinations, they could require us to report those actions as recalls and we may be subject to enforcement action. If we or our component manufacturers fail to comply with the FDA' s Quality System Regulation, our manufacturing operations could be interrupted, and our product sales and operating results could suffer. We and many of our component manufacturers are required to comply with the FDA' s Quality System Regulation, or QSR, which covers the procedures and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of our devices. The FDA audits compliance with the QSR through periodic announced and unannounced inspections of manufacturing **sites** and other **applicable** facilities. We and our component manufacturers have been, and anticipate in the future being, subject to such inspections. We cannot provide assurance that any future inspection will not result in adverse findings with respect to our QSR compliance. If our manufacturing facilities or those of any of our component manufacturers or suppliers are found to be in violation of applicable laws and regulations, or we or our manufacturers or suppliers fail to take satisfactory corrective action in response to an adverse inspection, the FDA could take enforcement action, including one or more of the following non- exclusive sanctions: ● untitled letters, warning letters, fines, injunctions, consent decrees and civil penalties; ● customer notifications or repair, replacement, refunds, recall, detention or seizure of our products; ● operating restrictions or partial suspension or total shutdown of production; ● refusing or delaying our requests for 510 (k) clearance or premarket approval of new products or modified products; ● withdrawing 510 (k) clearances or premarket approvals that have already been granted; ● refusal to grant export approval for our products; or ● criminal prosecution. Any of these sanctions could adversely affect our business, financial condition and results of operations. For any products that we sell outside the United States, those products and our operations would also be required to comply with standards set by foreign law, treaties and industrial standards bodies, such as the ~~49International~~ **International** Organization for Standardization, or ISO, and domestic regulatory authorities within foreign countries. Foreign regulatory bodies may evaluate our products or the testing that our products undergo against these or other standards. The specific standards, types of evaluation and scope of review differ among foreign regulatory bodies. If we fail to adequately comply with any of these standards, a foreign regulatory body may take adverse actions similar to those within the power of the FDA. Any of these actions could prevent us from marketing, distributing or selling our products and would likely harm our business. ~~Future~~ **50Future** regulatory actions may adversely affect our ability to sell our products profitably. From time to time, legislation is drafted and introduced that could significantly change the statutory provisions governing the clearance or approval, manufacture and marketing of a medical device. In addition, FDA and other **applicable** regulations and guidance are often revised or reinterpreted in ways that may significantly affect our business and our products, and new regulations or guidance documents may be promulgated. It is impossible to predict whether legislative changes will be enacted or regulations, guidance or interpretations changed or added, and what the impact of such changes or additions, if any, may be. Healthcare regulatory reform may affect our ability to sell our products profitably. In the United States, the legislative landscape, particularly as it relates to healthcare regulation and reimbursement coverage, continues to evolve. In March 2010 the ACA was passed and substantially changed healthcare financing by both governmental and private insurers. Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. The Budget Control Act of 2011 requires, among other things, mandatory across- the- board reductions in Federal spending, also known as sequestration. The American Taxpayer Relief Act of 2012 postponed sequestration for two months. As required by law, a sequestration order was issued on March 1, 2013. As a result of the sequestration order, Medicare Fee- for- Service claims with dates- of- service or dates- of- discharge on or after April 1, 2013 will continue to incur a 2 % reduction in the Medicare payment until further notice. Claims for durable medical equipment, prosthetics, orthotics and supplies, including claims under the DME Competitive Bidding Program, are reduced by 2 % based upon whether the date- of- service, or the start date for rental equipment or multi- day supplies, is on or after April 1, 2013. This 2 % reduction based on the sequestration was suspended in 2020 due to the public health emergency, and Congress extended the sequestration moratorium through March 31, ~~2021~~ **2022** . From April 1, ~~2021~~ **2022** through June 30, ~~2021~~ **2022** , the reduction went back into effect at a 1 % reduction level, and beginning July 1, ~~2021~~ **2022** , the reduction returned to a 2 % reduction level. We expect that additional state and federal healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for our products or additional pricing pressures. There have been judicial and Congressional challenges to certain aspects of the ACA. Additional state and federal health care reform measures that may be adopted in the future could have a material adverse effect on our industry generally and on our customers. Any changes in, or uncertainty with respect to future reimbursement rates, or changes in hospital admission rates could impact our customers' demand for our products and services, which in turn could impact our ability to successfully commercialize our products, or could limit or eliminate our spending on certain development projects. These changes could adversely affect our business and results of operations. There have been, and we expect there will continue to be, a number of legislative and regulatory changes to the healthcare system that could affect our future revenue and profitability and the future revenue and profitability of our customers. Federal and state lawmakers regularly propose and, at times, enact legislation that results in significant changes to the healthcare system, some of which are intended to contain or reduce the costs of medical products and services. Such uncertainty and any changes could negatively impact our ability to successfully commercialize our products or product candidates and could result in reduced demand for our products and additional pricing pressures. ~~50While~~ **While** our products are not currently subject to the competitive bidding process under Medicare, if our products were to become subject to such process in the future, it could negatively affect our business and financial condition. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 required the Secretary of Health and Human Services to establish and implement programs under which competitive acquisition areas are established throughout the United States for purposes of awarding

contracts for the furnishing of competitively priced items of durable medical equipment. ~~CMS~~ **51CMS** , the agency responsible for administering the Medicare program, conducts a competition for each competitive acquisition area under which providers submit bids to supply certain covered items of durable medical equipment. Successful bidders must meet certain program quality standards in order to be awarded a contract and only successful bidders can supply the covered items to Medicare beneficiaries in the acquisition area. There are, however, regulations in place that allow non- contracted providers to continue to provide products and services to their existing customers at the new competitive bidding payment amounts. The contracts are expected to be re- bid every three years. CMS is required to award contracts to multiple entities submitting bids in each area for an item or service, but has the authority to limit the number of contractors in a competitive acquisition area to the number it determines to be necessary to meet projected demand. Although we continue to monitor developments regarding the implementation of the competitive bidding program, we cannot predict the outcome of the competitive bidding program on our business when fully implemented, nor the Medicare payment rates that will be in effect in future years for the items subjected to competitive bidding, including our products. We expect that payment rates will continue to fluctuate, and a large negative payment adjustment could adversely affect our business, financial conditions and results of operations. We are subject to additional federal, state and foreign laws and regulations relating to our healthcare business; our failure to comply with those laws could have an adverse impact on our business. We are subject to healthcare fraud and abuse regulation and enforcement by federal and state governments, which could adversely impact our business. Healthcare fraud and abuse and health information privacy and security laws potentially applicable to our operations include: ● the federal Anti- Kickback Statute, which applies to our marketing practices, educational programs, pricing policies and **any** relationships with healthcare providers, by prohibiting, among other things, soliciting, receiving, offering or providing remuneration, whether directly or indirectly and overtly or covertly, intended to induce the referral of an individual for (i) the furnishing or the arranging for the furnishing of items or services reimbursable under a federal healthcare program, such as Medicare or Medicaid; or (ii) the purchase, lease or order of, or the arrangement or recommendation of the purchasing, leasing or ordering of, of an item or service reimbursable under a federal healthcare program. Courts have ruled that a person or entity does not need to have actual knowledge of this statute or specific intent to violate it to have committed a violation; ● federal civil and criminal false claims laws and civil monetary penalty laws, including civil whistleblower or qui tam actions that prohibit, among other things, knowingly presenting, or causing to be presented, claims for payment or approval to the federal government that are false or fraudulent, knowingly making a false statement material to an obligation to pay or transmit money or property to the federal government, knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the federal government or knowingly offering remuneration to influence a Medicare or Medicaid beneficiary' s selection of health care providers. The government may assert that a claim, including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the false claims statutes; ● HIPAA and its implementing regulations, which created federal criminal laws that prohibit, among other things, executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters; ~~51~~ ● HIPAA, as amended by HITECH, also imposes certain regulatory and contractual requirements regarding the privacy, security and transmission of individually identifiable health information; ● federal Open Payments (the Physician Payments Sunshine Act) requirements imposed by the ACA on device manufacturers regarding certain" transfers of value" made or distributed to physicians, certain other healthcare providers, and teaching hospitals. Failure to submit required information may result in **significant** civil monetary penalties ~~of up to an aggregate of $ 150, 000 per year (or up to an aggregate of $ 1. 0 million per year~~ for" knowing failures" ~~)~~, for all payments, transfers of value or ownership or investment interests that are not timely, accurately and completely reported in an ~~annual~~ **52annual** submission. Manufacturers must report detailed payment data and submit legal attestation to the accuracy of such data for each calendar year by the 90th day of the subsequent calendar year; ● federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and ● state law equivalents of each of the above federal laws, such as anti- kickback and false claims laws that may apply to items or services reimbursed by any third- party payer, including commercial insurers; state laws that require device companies to comply with the industry' s voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; 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 state laws governing the privacy and security of certain health information, many of which differ from each other in significant ways and often are not preempted by HIPAA. The risk of our being found in violation of these laws and regulations is increased by the fact that many of them have not been fully interpreted by the regulatory authorities or the courts, and their provisions are open to a variety of interpretations. We are unable to predict what additional federal or state legislation or regulatory initiatives may be enacted in the future regarding our business or the healthcare industry in general, or what effect such legislation or regulations may have on us. Federal or state governments may impose additional restrictions or adopt interpretations of existing laws that could have a material adverse effect on us. Because of the breadth of these laws and the narrowness of the statutory exceptions and safe harbors available under such laws, some of our business activities, including certain sales and marketing practices and financial arrangements, including the provision of stock options as partial compensation for consulting services, with physicians, some of whom use or purchase our products, and other customers, could be subject to challenge under one or more of such laws. Responding to any action or threat of action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management' s attention from the operation of our business. If our operations are found to be in violation of any of the laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including civil and criminal penalties, damages, fines, exclusion from governmental healthcare programs, disgorgement, contractual damages, reputational harm, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely impact our business. Failure to

comply with regulations affecting the transmission, security and privacy of health information could result in significant penalties. Numerous federal and state laws and regulations, including HIPAA and the HITECH Act, govern the collection, dissemination, security, use and confidentiality of patient- identifiable health information or more broadly personally identifiable information. HIPAA and the HITECH Act require us to comply with standards for the use and disclosure of health information within our company and with third parties. The Privacy Standards and Security Standards under HIPAA establish a set of basic national privacy and security standards for the protection of individually identifiable health information by health plans, healthcare clearinghouses and certain healthcare providers, referred to as covered entities, and the business associates with whom such covered entities contract for services. Notably, whereas HIPAA previously directly regulated only these covered entities, the HITECH Act, which was signed into law as part of the stimulus package in February 2009, makes certain ~~52of~~ **of** HIPAA' s privacy and security standards also directly applicable to covered entities' business associates. As a result, both covered entities and business associates are subject to significant civil and criminal penalties for failure to comply with Privacy Standards and Security Standards. HIPAA and the HITECH Act also include standards for common healthcare electronic transactions and code sets, such as claims information, plan eligibility, payment information and the use of electronic signatures, and privacy and electronic security of individually identifiable health information. Covered entities, such as healthcare providers, are required to conform to such transaction set standards pursuant to HIPAA. ~~HIPAA~~ **53HIPAA** requires healthcare providers like us to develop and maintain policies and procedures with respect to protected health information that is used or disclosed, including the adoption of administrative, physical and technical safeguards to protect such information. The HITECH Act expands the notification requirement for breaches of patient- identifiable health information, restricts certain disclosures and sales of patient- identifiable health information and provides a tiered system for civil monetary penalties for HIPAA violations. The HITECH Act also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons 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 attorney fees and costs associated with pursuing federal civil actions. Additionally, certain states have adopted comparable privacy and data security laws and regulations, some of which may be more stringent than HIPAA. If we do not comply with existing or new laws and regulations related to patient health information, we could be subject to criminal or civil sanctions. New health information standards, whether implemented pursuant to HIPAA, the HITECH Act, state or federal congressional action or otherwise, could have a significant effect on the manner in which we handle healthcare related data and communicate with payers, and the cost of complying with these standards could be significant. The 2013 final HITECH omnibus rule, or the HITECH Final Rule, modified the breach reporting standard in a manner that makes more data security incidents qualify as reportable breaches. Any liability from a failure to comply with the requirements of HIPAA or the HITECH Act could adversely affect our financial condition. The costs of complying with privacy and security related legal and regulatory requirements are burdensome and could have a material adverse effect on our results of operations. The HITECH Final Rule is subject to interpretation by various courts and other governmental authorities, thus creating potentially complex compliance issues for us, as well as our clients and strategic partners. In addition, we are unable to predict what changes to the HIPAA Privacy Standards and Security Standards might be made in the future or how those changes could affect our business. Any new legislation or regulation in the area of privacy and security of personal information, including personal health information, could also adversely affect our business operations. In addition, the FDA has issued guidance to which we may be subject concerning data security for medical devices. Additionally, the Federal Trade Commission has issued and several states have issued or are considering new regulations to require holders of certain types of personally identifiable information to implement formal policies and programs to prevent, detect and mitigate the risk of identity theft and other unauthorized access to or use of such information. Further, the U. S. Congress and a number of states have considered or are considering prohibitions or limitations on the disclosure of medical or other information to individuals or entities located outside of the United States. We may need to comply with applicable laws in those jurisdictions that regulate the use and disclosure of individually identifiable information. **The Federal Communications Commission maintains oversight of the Federal Telephone Consumer Privacy Act (“ TCPA ”) governing how entities engage with consumers via telephone, including text communications, typically thought of as “ telephone solicitations. ” Several states have issued or may issue similar statutes or regulations. These statutes mandate compliance with requirements such as limiting time of day for calls / outreach, restricting autodial processes, limiting or prohibiting robot- calling, and compliance with “ do not call ” registries, among other aspects. Violations can subject our company to fines, penalties and consumer actions. We may need to comply with applicable laws in these jurisdictions that regulate telephone and text messaging to consumers, including our patients, which may increase our costs of compliance.** Failure to comply with privacy and data security laws and regulations could subject us to substantial penalties and our business, operations and financial condition could be adversely affected. In addition to the HIPAA and HITECH Act regulations described above, a number of U. S. states have also enacted data privacy and data security laws and regulations that govern the collection, use, disclosure, transfer, storage, disposal, and protection of sensitive personal information, such as social security numbers, medical and financial information and other personal information. These laws and regulations may be more restrictive and not preempted by U. S. federal laws. For example, several U. S. territories and all 50 states now ~~53have~~ **54have** data breach laws that require timely notification to individual victims, and at times regulators, if a company has experienced the unauthorized access or acquisition of sensitive personal data. Other state laws contain additional disclosure obligations for businesses that collect personal information about residents and afford those individuals additional rights relating to their personal information that may affect our ability to use personal information or share it with our business partners. For example, California has laws that give California residents certain privacy rights in the collection and disclosure of their personal information and requires businesses to make certain disclosures and take certain other acts in furtherance of those rights, and has recently created a new agency, the California Privacy Protection Agency, authorized to implement and enforce California’ s privacy laws, which could

result in increased privacy and information security regulatory actions. Other U. S. states, such as Virginia, Utah, Connecticut, and Colorado, have passed consumer privacy laws that become effective in 2023. We will continue to monitor and assess the impact of these state laws, which may impose substantial penalties for violations, impose significant costs for investigations and compliance, allow private class- action litigation and carry significant potential liability for our business. We face the risk of product liability claims that could be expensive, divert management' s attention and harm our reputation and business. We may not be able to maintain adequate product liability insurance. Our business exposes us to the risk of product liability claims that are inherent in the testing, manufacturing and marketing of medical devices. This risk exists even if a device is cleared or approved for commercial sale by the FDA and manufactured in facilities licensed and regulated by the FDA or an applicable foreign regulatory authority. Our products are designed to affect, and any future products will be designed to affect, important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with our products or our products in development could result in patient injury or death. The medical device industry has historically been subject to extensive litigation over product liability claims, and we cannot offer any assurance that we will not face product liability suits. We may be subject to product liability claims if our products cause, or merely appear to have caused, patient injury or death. In addition, an injury that is caused by the activities of our suppliers, such as those who provide us with components and materials, may be the basis for a claim against us. Product liability claims may be brought against us by patients, clinicians or others selling or otherwise coming into contact with our products, among others. If we cannot successfully defend ourselves against product liability claims, we will incur substantial liabilities and reputational harm. In addition, regardless of merit or eventual outcome, product liability claims may result in: ● costs of litigation; ● distraction of management' s attention from our primary business; ● the inability to commercialize our existing or new products; ● decreased demand for our products or products in development; ● damage to our business reputation; ● product recalls or withdrawals from the market; ● withdrawal of clinical trial participants; ● substantial monetary awards to patients or other claimants; or ● loss of revenue. While we may attempt to manage our product liability exposure by proactively recalling or withdrawing from the market any defective products, any recall or market withdrawal of our products would delay the supply of those products to our distributors, clinicians and patients and may impact our reputation. We can provide no assurance that we will be successful in initiating appropriate market recall or market withdrawal efforts that may ~~54bc~~ **55be** required in the future or that these efforts will have the intended effect of preventing product malfunctions and the accompanying product liability that may result. Such recalls and withdrawals may also be used by our competitors to harm our reputation for safety or be perceived by patients as a safety risk when considering the use of our products, either of which could have an adverse impact on our business. In addition, our product liability insurance is subject to deductibles and coverage limitations. Our current product liability insurance may not continue to be available to us on acceptable terms, if at all, and, if available, coverage may not be adequate to protect us against any future product liability claims. If we are unable to obtain insurance at an acceptable cost or on acceptable terms or otherwise protect against potential product liability claims, we could be exposed to significant liabilities. A product liability claim, recall or other claim with respect to uninsured liabilities or for amounts in excess of insured liabilities could have an adverse impact on our business. Our employees, distributors, independent contractors, consultants, collaborators and suppliers may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading. We are exposed to the risk that our employees, distributors and other third parties, in spite of our compliance training and programs, may engage in fraudulent conduct or other illegal activity. Misconduct by employees, distributors and other third parties could include intentional, reckless and / or negligent conduct or disclosure of unauthorized activities ~~to us~~ that violate FDA regulations, including those laws requiring the reporting of true, complete and accurate information to the FDA, manufacturing standards, federal and state healthcare fraud and abuse laws and regulations, or laws that require the reporting of financial information or data accurately. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws intended 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, sales commission, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee and other third- party misconduct, and the steps we take to detect, prevent and remedy any such activity may not protect us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws. If any such actions are threatened or 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, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, 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. We may be unable to obtain or maintain international regulatory registrations or approvals for our current or future products and indications, which could adversely impact our business. Sales of our devices outside the United States are subject to foreign regulatory requirements that vary widely from country to country. In addition, the FDA regulates exports of medical devices from the United States **and foreign countries have varying import laws we need to comply with** . Complying with international regulatory requirements can be an expensive and time- consuming process and approval is not certain. The time required to obtain registration or approvals, if required by other countries, may be longer than that required for FDA clearance, and requirements for such registrations or approvals may significantly differ from FDA requirements. In certain countries we intend to rely upon third- party distributors to obtain all required regulatory registrations and approvals, and these distributors may be unable to obtain or maintain such registrations or approvals. Our distributors in these countries may also incur significant costs in attempting to obtain and in maintaining foreign regulatory approvals or registrations, which could increase the difficulty of attracting and retaining qualified distributors. If we are unable to obtain or maintain international registrations

or approvals, or if distributors experience delays in receiving, or fail to receive, necessary registrations or approvals to market our products outside the United States, we may be unable to market our products or enhancements in certain international markets effectively, or at all. ~~55Our~~ **56Our** operations involve the use of hazardous and toxic materials, and we must comply with environmental, health and safety laws and regulations, which can be expensive, and could have an adverse impact on our business. Our operations use or generate small volumes of hazardous or toxic materials. We are therefore subject to a variety of federal, state and local regulations relating to the use, handling, storage, disposal and human exposure to hazardous and toxic materials. Liability under environmental laws can be joint and several and without regard to comparative fault, and environmental laws could become more stringent over time, imposing greater compliance costs and increasing risks and penalties associated with violations, which could have an adverse impact on our business. There can be no assurance that violations of environmental, health and safety laws will not occur in the future as a result of human error, accident, equipment failure or other causes. The failure to comply with past, present or future laws could result in the imposition of fines, third- party property damage and personal injury claims, investigation and remediation costs, the suspension of production or a cessation of operations. We also expect that our operations will be affected by other new environmental and health and safety laws and regulations on an ongoing basis. Although we cannot predict the ultimate impact of any such new laws and regulations, they will likely result in additional costs, and may require us to change how we manufacture our products, which could have an adverse impact on our business. Financial Condition, Credit and Tax Risks If we fail to maintain proper and effective internal control over financial reporting, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, investors' views of us and, as a result, the value of our common stock. Pursuant to Section 404 of the Sarbanes- Oxley Act, our management is required to report upon the effectiveness of our internal control over financial reporting, and our independent registered public accounting firm is required to attest to the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for our management and our independent registered public accounting firm to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. In connection with our and our independent registered public accounting firm' s evaluations of our internal control over financial reporting, we may need to upgrade our systems, including information technology; implement additional financial and management controls, reporting systems and procedures; and hire additional accounting and finance staff. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us or our independent registered public accounting firm conducted in connection with Section 404 of the Sarbanes- Oxley Act may reveal deficiencies in our internal control over financial reporting that are deemed to be material weaknesses or that may require prospective or retroactive changes to our financial statements or identify other areas for further attention or improvement. Inferior internal controls could also cause investors to lose confidence in our reported financial information, which could have a negative effect on the trading price of our common stock. Internal control deficiencies could also result in a restatement of our financial results in the future. We could become subject to stockholder or other third- party litigation, as well as investigations by the SEC, the stock exchange on which our securities are listed, or other regulatory authorities, which could require additional financial and management resources and could result in fines, trading suspensions, payment of damages or other remedies. The level of our indebtedness under our credit facility may adversely impact us ~~, and the phase- out, replacement or unavailability of LIBOR and / or other interest rate benchmarks could adversely affect our indebtedness~~ . Our level of debt under our credit facility could, among other things: ● require us to dedicate a large portion of our cash flow from operations to the servicing and repayment of our debt, thereby reducing funds available for working capital, capital expenditures, research and development expenditures and other general corporate requirements; ~~56~~ ● limit our ability to obtain additional financing to fund future working capital, capital expenditures, research and development expenditures and other general corporate requirements; **57** ● limit our flexibility in planning for, or reacting to, changes in our business and the industry in which we operate; ● restrict our ability to make strategic acquisitions or dispositions or to exploit business opportunities; ● place us at a competitive disadvantage compared to our competitors that have less debt; and ● adversely affect the market price of our common stock. Further, our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. ~~In addition, our financial condition, results of operations and cash flows could be affected by changes in interest rates and actions taken by the Federal Reserve or changes in the London Interbank Offered Rate (" LIBOR") or its replacement. Future increases in market interest rates would increase our interest expense. Alternative, successor, or replacement rates following the planned phase- out of LIBOR in June 2023 may not be similar to, or produce the same value or economic equivalence of, or have the same volume or liquidity as did, LIBOR (the current benchmark rate under our Credit Agreement), which may increase our overall interest expense. In addition, the credit spread adjustments on any benchmark replacement to LIBOR under our credit facility may not produce substantially the same rate as current LIBOR based loans. The potential effect of the phase- out or replacement of LIBOR on our cost of capital cannot yet be determined and any increase in the interest we pay and a corresponding increase in our costs of capital or otherwise could have a material adverse impact on our financial condition, results of operations or cash flows.~~ Our credit facility contains covenants that restrict our business and financing activities, and the property that secures our obligations under the credit facility may be subject to foreclosure. Our credit facility contains a number of restrictions and covenants, which, among other things, restrict our ability to acquire or merge with another entity, dispose of our assets, make investments, loans or guarantees, incur additional indebtedness, create liens or other encumbrances, or pay dividends or make other distributions. The credit facility also requires us to maintain compliance with a maximum leverage ratio, a minimum fixed charge coverage ratio ~~,~~ **and** a minimum EBITDA ~~covenant and a minimum liquidity~~ covenant. These provisions impose significant operating and financial restrictions on us and may limit our ability to compete effectively, take advantage of new business opportunities or take other actions that may be in our best interests. Our ability to obtain additional or other financing or to dispose of certain assets could also be

negatively impacted because we have pledged substantially all of our assets as collateral in connection with the credit facility. Our ability to comply with the provisions under the Credit Agreement may be affected by events beyond our control and our inability to comply with any of these provisions could result in a default under the Credit Agreement. If such a default occurs, the lenders may elect to declare all borrowings outstanding, together with accrued interest and other fees, to be immediately due and payable, and they would have the right to terminate any commitments they have to provide further borrowings. If we are unable to repay outstanding borrowings when due, the lenders under the Credit Agreement also have the right to proceed against the collateral, including substantially all of our assets, granted to them to secure the indebtedness under the facility. If our indebtedness under the Credit Agreement were to be accelerated, we cannot assure you that our assets would be sufficient to repay in full that indebtedness. The occurrence of any of these events could have a material adverse effect on our business, financial condition, results of operations and liquidity. We may need substantial additional funding and may be unable to raise capital when needed, which could force us to delay or reduce our commercialization efforts or product development programs. We believe our cash, cash equivalents and cash flows from operations will be sufficient to meet our working capital, capital expenditure and debt repayment and related interest payment requirements for at least the next twelve months. However, we have based these estimates on assumptions that may prove to be ~~57incorrect~~ **incorrect** , and we could spend our available financial resources much faster than we currently expect. Any future funding requirements will depend on many factors, including: ● market acceptance of our products; ● the scope, rate of progress and cost of our clinical studies; ● the cost of our research and development activities; ● the cost of filing and prosecuting patent applications and defending and enforcing our patent or other intellectual property rights; ● the cost of defending, in litigation or otherwise, any claims that we infringe third-party patents or other intellectual property rights; **58** ● the cost and timing of additional regulatory clearances or approvals; ● the cost and timing of establishing additional sales, marketing and distribution capabilities; ● costs associated with any product recall that may occur; ● the effect of competing technological and market developments; ● the extent to which we acquire or invest in products, technologies and businesses; and ● the costs of operating as a public company. If we raise additional funds by issuing equity securities, our stockholders may experience dilution. Any future debt financing into which we enter may impose upon us covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, repurchase our common stock, make certain investments and engage in certain merger, consolidation or asset sale transactions. Any debt financing or additional equity that we raise may contain terms that are not favorable to us or our stockholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish some rights to our technologies or our products, or grant licenses on terms that are not favorable to us. Furthermore, we cannot be certain that additional funding will be available on acceptable terms, if at all. If we do not have, or are not able to obtain, sufficient funds, we may have to delay development or commercialization of our products or license to third parties the rights to commercialize products or technologies that we would otherwise seek to commercialize. We also may have to reduce marketing, customer support or other resources devoted to our products or cease operations. Any of these factors could harm our operating results. ~~A reclassification of our independent contractor trainers could require us to pay retroactive taxes and penalties, which could have a material adverse effect on our business, financial condition and operating results. Prior to the inactivation of our independent contractor home trainers in May 2020, we contracted with over 560 licensed healthcare practitioners as home trainers, who educate our patients on the proper use of our solutions. We have since reactivated a small number of healthcare practitioners in the same capacity as previously noted. Because we consider these licensed practitioners to be independent contractors, as opposed to employees, under federal and applicable state laws, we do not withhold federal or state income or other employment related taxes or make federal or state unemployment tax or Federal Insurance Contributions Act payments. Our contracts with these independent contractors obligate them to pay these taxes. The classification of healthcare practitioners as independent contractors depends on the facts and circumstances of the relationship. Recently, there has been increased focus on the tests and standards related to classifying 58individuals as employees or independent contractors, including through judicial decisions, legislative proposals and private lawsuits in certain jurisdictions. For example, California enacted a law (AB 5), which took effect January 1, 2020. AB 5 significantly limits the types of workers who may be able to be classified as independent contractors under California law, including requiring the worker to perform work that is outside the usual course of the hiring company' s business in order to be classified as an independent contractor. In addition, in October 2022, the U. S. Department of Labor published a Notice of Proposed Rulemaking that would rescind the current federal independent contractor rule (adopted by the Trump administration in 2021) and would apply a non- exhaustive six- factor totality- of- the- circumstances analysis, and could, if enacted in its current form, result in the need to reclassify certain types of workers. Other state legislatures and Congress are considering, and may enact, laws or regulations narrowing the scope of workers who may be classified as independent contractors. As a result, there is significant uncertainty regarding what the state and federal worker classification regulatory landscape may look like in coming years. In the event federal or state taxing or other regulatory authorities, or a court, were to determine that the healthcare practitioners with whom we contract should be classified as employees, we might be liable for unpaid past taxes and other costs and subject to penalties. We also could, among other things, be required to withhold income taxes, to withhold and pay Social Security, Medicare and similar taxes, to pay unemployment and other related payroll taxes and to provide certain employee benefits, including workers' compensation coverage and group medical benefits, or be forced to change our business model as it relates to the trainers to avoid various types of liability exposure associated with worker misclassification claims pursued by governmental agencies or through private legal action. As a result, any determination that the trainers are our employees could have a material adverse effect on our business, financial condition and results of operations.~~ We may be subject to liabilities related to state income, sales and use taxes, which could adversely affect our financial condition and results of operations and could decrease demand for our products. State income tax and sales and use tax laws, statutes, rules and regulations vary greatly by jurisdiction and are complex and subject to uncertainty. If it is determined that certain of these tax rules apply to us, we could be required to pay substantial tax amounts, and significant

penalties and interest for past amounts that may have been due, in addition to taxes going forward. These tax assessments, penalties and interest, and future requirements, may adversely affect our financial condition and results of operations. In addition, the imposition of sales and use taxes on our products going forward would effectively increase the cost of our products to our customers and may adversely affect demand for our productsWe may be unable to collect all of our Medicare accounts receivable. At December 31, ~~2022~~ **2023**, we had approximately $ ~~33~~ **17**. ~~2~~ **1** million of accounts receivable for sales of our Flexitouch **Plus** system to patients covered by Medicare. A portion of the related claims to Medicare are initially denied and enter the appeals process, where many are ultimately reviewed by an Administrative Law Judge. The appeal process can be lengthy, lasting several years in most cases. At December 31, ~~2022~~ **2023**, we classified $ ~~23~~ **10**. ~~1~~ **9** million of our Medicare accounts receivable related to Flexitouch **Plus** system sales as long- term assets on our balance sheet due to the estimated amount of receivables that will be paid more than one year from December 31, ~~2022~~ **2023**, as a result of delays with the Administrative Law Judge appeal process. A significant increase in Medicare denial of submitted claims or an increase in the proportion of Medicare denials that are upheld by an Administrative Law Judge could adversely affect our results of operations or cause us to reduce the carrying value of our Medicare accounts receivable related to Flexitouch **Plus** system sales. ~~Risks~~ **59Risks** Related to Our Intellectual Property We may not be able to protect our intellectual property rights throughout the world. Filing, prosecuting and defending patents on products in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States may be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. For example, many foreign countries have compulsory licensing laws, under which a patent owner must grant licenses to third ~~59parties~~ -- **parties**. Consequently, we may not be able to prevent third parties from practicing our inventions in all countries outside the United States, or from selling or importing products made using our inventions in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products, and further, competitors may export otherwise infringing products to territories where we have patent protection but enforcement rights are not as strong as those in the United States. These products may compete with our products in jurisdictions where we do not have any issued patents, and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing. Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries do not favor the enforcement of patents and other intellectual property protection, which could make it difficult for us to stop the infringement of our patents generally. Proceedings to enforce our patent rights in 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 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 around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license. The patent protection for our products may expire before we are able to maximize their commercial value, which may subject us to increased competition and reduce or eliminate our opportunity to generate product revenue. The patents related to our products have varying expiration dates and, when these patents expire, we may be subject to increased competition and we may not be able to recover our development costs or market any of our approved products profitably. For instance, many U. S. patents covering various aspects of our Flexitouch system expired in 2017. Upon expiration of our patents, we may be subject to increased competition and our opportunity to establish or maintain product revenue could be substantially reduced or eliminated. Further, we may not have sufficient time to recover our development costs prior to the expiration of our U. S. and foreign patents. We may not identify relevant patents or may incorrectly interpret the relevance, scope or expiration of a patent, which may adversely affect our ability to develop and market our products. We cannot guarantee that any of our patent searches or analyses, including but not limited to the identification of relevant patents, the scope of patent claims or the expiration of relevant patents, are complete or thorough, nor can we be certain that we have identified each and every patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of our products in any jurisdiction. The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent family' s prosecution history. Our interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact our ability to market our products. We may incorrectly determine that our products are not covered by a third- party patent. Many patents may cover a marketed product, including but not limited to patents covering the product or portions thereof, methods of use or methods relating to the product, and production processes of or for the ~~product~~ **60product**. The identification of all patents and their expiration dates relevant to the production and sale of a therapeutic product is extraordinarily complex and requires sophisticated legal knowledge in the relevant jurisdiction. It may be impossible to identify all patents in all jurisdictions relevant to a marketed product. Our determination of the expiration date of any patent in the United States or abroad that we consider relevant may be incorrect, which may negatively impact our ability to develop and market our products. ~~60Obtaining~~ -- **Obtaining** and maintaining our patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non- compliance with these requirements. The United States Patent and Trademark Office, or USPTO, and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent prosecution process. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on any issued patent and / or pending patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of a patent or patent application. We have systems in place to remind us to pay these fees, and we employ an outside firm and rely on our outside counsel to pay these fees. While an inadvertent lapse may sometimes be cured by payment of a late fee or by other means in accordance with

the applicable rules, there are many situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If we fail to maintain the patents and patent applications directed to our products, our competitors might be able to enter the market earlier than should otherwise have been the case, which may have a material adverse effect on our business. We may become involved in lawsuits to protect our patents or other intellectual property rights, which could be expensive, time- consuming and ultimately unsuccessful. Competitors may infringe our patents or other intellectual property rights. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our patent applications at risk of not issuing. Various proceedings brought before the USPTO may be necessary to determine the priority of inventions with respect to our patents and patent applications or those of our current or future collaborators. An unfavorable outcome could require us to cease using the technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if a prevailing party does not offer us a license on terms that are acceptable to us. Litigation or other proceedings may fail and, even if successful, may result in substantial costs and distraction of our management and other employees. We may not be able to prevent misappropriation of our proprietary rights, particularly in countries where the laws may not protect those rights as fully as in the United States. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential and proprietary information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock. Third- party claims of intellectual property infringement or misappropriation may adversely affect our business and could prevent us from developing or commercializing our products. Our commercial success depends in part on us not infringing the patents and proprietary rights of third parties. There is a substantial amount of litigation, both within and outside the United States, involving patent and other intellectual property rights in the medical device industry, including patent infringement lawsuits, interferences, oppositions, ex- parte review and inter partes reexamination and post- grant review proceedings before the USPTO and corresponding foreign patent offices. Numerous U. S. and foreign issued patents and ~~pending~~ **61pending** patent applications owned by third parties exist in the fields in which we are developing and may develop our products. As the medical device industry expands and more patents are issued, the risk increases ~~61that~~ -- **that** our products may be subject to claims of infringement of the patent rights of third parties. If a third- party claims that we infringe on their intellectual property or technology, we could face a number of issues, including: ● infringement and other intellectual property claims which, with or without merit, can be expensive and time- consuming to litigate and can divert management' s attention from our core business; ● substantial damages for past infringement, which we may have to pay if a court decides that our product infringes on a competitor' s patent; ● a court prohibiting us from selling or licensing our product, unless the patent holder licenses the patent to us; ● if a license is available from a patent holder, we may have to pay substantial royalties or grant cross licenses to our patents; and ● redesigning our products and processes so they do not infringe, which may not be possible or could require substantial funds and time. Third parties may assert that we are employing their proprietary technology without authorization. There may be third- party patents or patent applications with claims to products, materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our products, that we failed to identify. For example, applications filed before November 29, 2000 and certain applications filed after that date that will not be filed outside the United States may remain confidential until issued as patents. Except for the preceding exceptions, patent applications in the United States and elsewhere are generally published only after a waiting period of approximately 18 months after the earliest filing. Therefore, patent applications covering our technology or our products could have been filed by others without our knowledge. Additionally, pending patent applications that have been published can, subject to certain limitations, be later amended in a manner that could cover our technologies, our products or the use or manufacture of our products. We may also face a claim of misappropriation, if a third party believes that we inappropriately obtained and used trade secrets of such third parties. If we are found to have misappropriated a third party' s trade secrets, we may be prevented from further using such trade secrets, limiting our ability to develop our products, and we may be required to pay damages. If any third- party patents were held by a court of competent jurisdiction to cover aspects of our products, materials, formulations, methods of manufacture or methods for treatment, the holders of any such patents would be able to block our ability to develop and commercialize the applicable product candidate until such patent expired or unless we obtain a license. These licenses may not be available on acceptable terms, if at all. Even if we were able to obtain a license, the rights may be nonexclusive, which could result in our competitors gaining access to the same intellectual property. Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms. In addition, during the course of any patent or other intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our products, programs, or intellectual property could be diminished. Accordingly, the market price of our common stock may decline. Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our products. Defending against claims of patent infringement or misappropriation of trade secrets could be costly and time- consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs. In addition, litigation or threatened litigation could result in significant demands on the time and attention of our management team, distracting them from the

pursuit of other company business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, ~~redesign~~ **62redesign** our infringing products and processes or obtain one or more licenses from third parties, which may be impossible or require substantial time and monetary expenditure. In addition, the uncertainties associated with ~~62litigation~~ -- **litigation** could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into development collaborations that would help us bring our products to market. Changes in U. S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our products. As is the case with other medical device companies, our success is heavily dependent on intellectual property, particularly on obtaining and enforcing patents. Obtaining and enforcing patents in the medical device industry involves both technological and legal complexity, and therefore is costly, time- consuming and inherently uncertain. In addition, the United States has enacted ~~and is currently implementing wide- ranging~~ patent reform legislation **and generally has patent related legislation in process** . Further, several judicial rulings have either narrowed the scope of patent protection available in certain circumstances or weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents, once obtained. Depending on decisions by the U. S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future. Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties. We have become aware from time to time that third parties may be infringing on our patents or other intellectual property rights. Because of the expense and uncertainty of litigation, we have concluded in the past and may conclude in the future that even if a third party is infringing our patents or other intellectual property rights, the risk- adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of our company or our stockholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non- litigious action or solution. Intellectual property rights do not address all potential threats to our competitive advantage. The degree of future protection afforded by our intellectual property rights is uncertain, because intellectual property rights have limitations and may not adequately protect our business or permit us to maintain our competitive advantage. The following examples are illustrative: ● others may be able to make products that are similar to our products but that are not covered by the claims of the patents that we own or license from others; ● others may independently develop similar or alternative technologies or otherwise circumvent any of our technologies without infringing our intellectual property rights; ● we might not have been the first to conceive and reduce to practice the inventions covered by the patents or patent applications that we own, license or will own or license; ● we might not have been the first to file patent applications covering certain subject matter of the patents or patent applications that we own or for which we have obtained a license, or will own or for which we will obtain a license; ● it is possible that our pending patent applications will not result in issued patents; ● issued patents that we own may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors; **63** ● our competitors might conduct research and development activities in countries where we do not have patent rights, or in countries where research and development safe harbor laws exist, and then use ~~63the~~ -- **the** information learned from such activities to develop competitive products for sale in our major commercial markets; ● ownership of our patents or patent applications may be challenged by third parties; and ● the patents of third parties or pending or future applications of third parties, if issued, may have an adverse effect on our business. Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and protect other proprietary information. We consider proprietary trade secrets and / or confidential know- how to be important to our business. We may rely on trade secrets and / or confidential know- how to protect our technology, especially where patent protection is believed by us to be of limited value. However, trade secrets and / or confidential know- how can be difficult to maintain as confidential. To protect this type of information against disclosure or appropriation by competitors, our policy is to require our employees, consultants, contractors and advisors to enter into confidentiality agreements with us. However, current or former employees, consultants, contractors and advisors may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Enforcing a claim that a third party obtained illegally and is using trade secrets and / or confidential know- how is expensive, time consuming and unpredictable. The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction. Failure to obtain or maintain trade secrets and / or confidential know- how trade protection could adversely affect our competitive position. Moreover, our competitors may independently develop substantially equivalent proprietary information and may even apply for patent protection in respect of the same. If successful in obtaining such patent protection, our competitors could limit our use of our trade secrets and / or confidential know- how. We may need to license certain intellectual property from third parties, and such licenses may not be available or may not be available on commercially reasonable terms. A third party may hold intellectual property, including patent rights that are important or necessary to the development or commercialization of any future products. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our products, in which case we would be required to obtain a license from these third parties. Such a license may not be available on commercially reasonable terms or at all, which could materially harm our business. We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties. We have received, and may receive in the future, confidential and proprietary information from third parties. In addition, we employ, and may employ in the future, individuals who were previously employed at other medical device companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise improperly used or disclosed confidential information of these third parties or our employees' former employers. Further, we may be subject to ownership disputes in the future, arising, for

example, from conflicting obligations of consultants or others who are involved in developing our products. We may also be subject to claims that former employees, consultants, independent contractors, collaborators or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging our right to and use of confidential and proprietary information. If we fail in defending any such claims, in addition to paying monetary damages, we may lose our rights therein. Such an outcome could have a material adverse effect on our ~~business~~ **64business** . Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees. ~~64We~~ **We** may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property. We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents or other intellectual property. We may be subject to ownership disputes in the future, arising, for example, from conflicting obligations of consultants or others who are involved in developing our products. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees. Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed. Because we rely on third parties to assist with research and development and to manufacture our products, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third- party contractors and consultants, prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose our confidential information, including our trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by our competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that our proprietary position is based, in part, on our know- how and trade secrets, a competitor' s discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business. In addition, these agreements typically restrict the ability of our advisors, employees, third- party contractors and consultants to publish data potentially relating to our trade secrets, although our agreements may contain certain limited publication rights. For example, any academic institution that we may collaborate with in the future will usually expect to be granted rights to publish data arising out of such collaboration, provided that we are notified in advance and given the opportunity to delay publication for a limited time period in order for us to secure patent protection of intellectual property rights arising from the collaboration, in addition to the opportunity to remove confidential or trade secret information from any such publication. In the future, we may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development or similar agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development or publication of information by any of our third- party collaborators. A competitor' s discovery of our trade secrets would impair our competitive position and have an adverse impact on our business. If our trademarks and trade names are not adequately protected, then we may not be able to build and maintain name recognition in our markets of interest and our business may be adversely affected. If our trademarks and trade names are not adequately protected, then we may not be able to build and maintain name recognition in our markets of interest, and our business may be adversely affected. We currently have registered and unregistered trademarks in the United States. Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential collaborators or customers in our markets of interest. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. Further, there could be potential trade name or trademark infringement claims brought by ~~owners~~ **65owners** of other trademarks or trade names that incorporate variations of our trademarks or trade names. In addition, we have not registered our trademarks internationally, and the laws of certain foreign countries may not protect proprietary rights to the same extent as do the laws of the United States. Over the long term, if we ~~65are --~~ **are** unable to successfully register our trademarks and trade names and / or establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations. Risks Related to Ownership of Our Common Stock The trading price of the shares of our common stock has been and could continue to be highly volatile, and purchasers of our common stock may not be able to resell their shares of our common stock at or above the price at which they purchased their shares and could incur substantial losses. Our stock price has been and is likely to continue to be volatile. The stock market in general has experienced extreme volatility that has often been unrelated to the operating performance of particular companies. As a result of this volatility, investors may not be able to sell their shares of our common stock at or above the price at which they purchased their shares. The market price for our common stock may be influenced by many factors, including: ● the passage of legislation or other regulatory developments in the United States or foreign countries; ● actual or anticipated variations in our financial results or those of companies that are perceived to be similar to us; ● changes in the structure of healthcare payment systems, especially in light of current or proposed reforms to the U. S. healthcare system; ● our ability to develop and commercialize additional products; ● announcements by us or our competitors of significant acquisitions, strategic collaborations, joint ventures or capital commitments; ● market conditions in medical device

sectors and issuance of securities analysts' research reports or recommendations; ● sales of our stock by us, our insiders and our other stockholders; ● the trading volume of our common stock; ● speculation in the press or investment community; ● **perceived impacts on our business, patient population and / or addressable market due to effect of changes to the causes or risk factors for diseases that our products treat, such as the impact of GLP- 1 drugs on obesity; ●** general economic, industry and market conditions, or other events or factors, many of which are beyond our control; ● additions or departures of key personnel; and ● intellectual property, product liability or other litigation against us. In addition, the stock market has recently experienced significant volatility with respect to medical device and other life sciences company stocks. The volatility of medical device and other medical technology ~~company~~ **66company** stocks often does not relate to the operating performance of the companies represented by the stock. As we operate in a single industry, we are especially vulnerable to these factors to the extent that they affect our industry or our products, or to a lesser extent our markets. Following periods of volatility in the market price of a company' s securities, securities class action litigation has often been instituted against that company, as has been the case with us. Such litigation can result in substantial costs and diversion of management attention and resources, which could significantly harm ~~66our --~~ **our** profitability and reputation and could expose us to liability or impact negatively our business, financial condition, operating results, and prospects. Anti- takeover provisions in our charter documents and under Delaware law could make an acquisition of us, which may be beneficial to our stockholders, more difficult and may prevent attempts by our stockholders to replace or remove our current management. Provisions in our amended and restated certificate of incorporation and amended and restated bylaws, as well as provisions of Delaware law, may delay or prevent an acquisition of us or a change in our management. These provisions include: ● authorizing the issuance of" blank check" preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval; ● limiting the removal of directors by the stockholders; ● prohibiting cumulative voting in the election of directors, which would otherwise allow for less than a majority of stockholders to elect director candidates; ● prohibiting stockholder action by written consent, thereby requiring all stockholder actions to be taken at a meeting of our stockholders; ● eliminating the ability of stockholders to call a special meeting of stockholders; and ● establishing advance notice and compliance requirements for nominations for election to the board of directors, for soliciting proxies in support of nominations or for proposing matters that can be acted upon at stockholder meetings. 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, who are responsible for appointing the members of our management. In addition, because we are incorporated in Delaware, we are governed by the provisions of Section 203 of the Delaware General Corporation Law, which limits the ability of stockholders owning in excess of 15 % of our outstanding voting stock to merge or combine with us. These provisions would apply even if an offer rejected by our board were considered beneficial by some stockholders. Any provision of our amended and restated certificate of incorporation or our amended and restated bylaws or Delaware law that has the effect of delaying or deterring a change of control could limit the opportunity for our stockholders to receive a premium for their shares of our common stock, and could also affect the price that some investors are willing to pay for our common stock. If securities or industry analysts do not publish research, or publish inaccurate or unfavorable research, about our business, the price of our common stock and our trading volume could decline. The trading market for our common stock depends in part on the research and reports that securities or industry analysts publish about us or our business. If too few securities or industry analysts commence or maintain coverage of our company, the trading price for our common stock would likely be negatively affected. If one or more of the analysts who cover us downgrade our common stock or publish inaccurate or unfavorable research about our business, the price of our common stock would likely decline. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, demand for our common stock could decrease, which might cause the price of our shares and trading volume to decline. ~~Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third- party claims against us and may reduce the amount of money available to us. Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.~~ 67